



Llywodraeth Cymru
Welsh Government

PUBLIC HEALTH (WALES) BILL

Explanatory Memorandum Incorporating the Regulatory Impact Assessment and Explanatory Notes

June 2015

PUBLIC HEALTH (WALES) BILL

Explanatory Memorandum to the Public Health (Wales) Bill

This Explanatory Memorandum has been prepared by the Department for Health and Social Services of the Welsh Government and is laid before the National Assembly for Wales.

Member's Declaration

In my view, the provisions of the Public Health (Wales) Bill introduced by me on 8 June 2015, would be within the legislative competence of the National Assembly for Wales.

Mark Drakeford AM

Minister for Health and Social Services
Assembly Member in charge of the Bill

8 June 2015

CONTENTS

List of abbreviations

PART 1 – Explanatory Memorandum

1. Description
2. Legislative background
3. Purpose and intended effect of the legislation
4. Consultation
5. Power to make subordinate legislation
6. Regulatory Impact Assessment

PART 2 – Regulatory Impact Assessment

7. Options, costs and benefits
8. Competition assessment and specific impacts
9. Post implementation review

Annex A – Explanatory Notes

Annex B – Summary Costs tables

Annex C – Table of derivations

Annex D – Summary table of existing and planned tobacco / e-cigarette control measures

List of Abbreviations

ACAS - Advisory, Conciliation and Arbitration Service

BCAP – Broadcast Committee of Advertising Practice

BMA – British Medical Association

BTA – British Toilet Association

CAP – Committee of Advertising Practice

CIEH – Chartered Institute of Environmental Health

CPD – Continuing Professional Development

DfT – Department for Transport

ECHR – European Convention on Human Rights

ECITA - Electronic Cigarette Industry Trade Association

EHO – Environmental Health Officer

ENDS – Electronic Nicotine Delivery Systems

ENNDs - Electronic Non-nicotine Delivery Systems

FCTC – Framework Convention on Tobacco Control

FPN – Fixed Penalty Notice

FTE – Full Time Equivalent

GOWA – Government of Wales Act 2006

LHB – Local Health Board

MHRA – Medicines and Healthcare Products Regulators Agency

MUP – Minimum Unit Pricing for alcohol

NICE – National Institute for Health and Care Excellence

NIDs – Nicotine Inhaling Devices

NRT – Nicotine Replacement Therapy

OFT – Office of Fair Trading

PNA – Pharmaceutical Needs Assessment

PSSRU – Personal Social Services Research Unit

QALY – Quality Adjusted Life Years

RAN – Remedial Action Notice

RIA – Regulatory Impact Assessment

RPO – Restricted Premises Order

RSO – Restricted Sales Order

RYO – 'Roll Your Own' (tobacco)

SME – Small and Medium-sized Enterprise

UNCRC – United Nations Convention on the Rights of the Child

VOT – Value of time

WHO – World Health Organisation

WLGA – Welsh Local Government Association

WNHSS – Welsh Network of Healthy School Schemes

Part 1 – Explanatory Memorandum

1. Description

1. The Public Health (Wales) Bill ('the Bill') utilises legislation as a mechanism for improving and protecting the health and well-being of the population of Wales. It comprises a set of provisions in discrete areas of public health policy.
2. While a number of the issues addressed in the Bill are already well established, the Bill also responds to new and emerging health challenges. Taken together the provisions are intended to have a cumulative positive benefit for the population of Wales and seek to put in place conditions which are conducive to good health, in which harms to health can be prevented.
3. In summary the Bill proposes to introduce changes that:-
 - Place restrictions on the use of tobacco and nicotine inhaling devices (NIDs) such as electronic cigarettes in enclosed and substantially enclosed public and work places, and give the Welsh Ministers a regulation-making power to extend the restrictions to certain open spaces;
 - Provide for the creation of a national register of retailers of tobacco and nicotine products;
 - Provide the Welsh Ministers a regulation-making power to add to the offences which contribute to a Restricted Premises Order (RPO) in Wales;
 - Prohibit the handing over of tobacco and/or nicotine products to a person under the age of 18;
 - Provide for the creation of a mandatory licensing scheme for practitioners and businesses carrying out 'special procedures', namely acupuncture, body piercing, electrolysis and tattooing;
 - Introduce a prohibition on the intimate piercing of persons under the age of 16 years;
 - Change the arrangements for determining applications for entry onto the pharmaceutical list of Local Health Boards (LHBs), to a system based on the pharmaceutical needs of local communities; and
 - Require local authorities to prepare a local strategy to plan how they will meet the needs of their communities for accessing toilet facilities for public use.
4. The issues covered in the Bill are relevant both to physical and mental health and well-being, and as such, references to public health throughout the Bill and Explanatory Memorandum should be considered as encompassing both of these aspects.

2. Legislative Background

5. Section 107 of the Government of Wales Act 2006 ('GOWA 2006') provides legislative competence for the National Assembly for Wales ('the Assembly') to make laws for Wales known as Acts of the Assembly.
6. Section 108 of GOWA 2006 provides that a provision of an Act of the Assembly is within the Assembly's legislative competence if it relates to one or more of the subjects listed under any of the headings in Part 1 of Schedule 1 of that Act and does not fall within any of the exceptions specified in that Part of the Schedule (whether or not under that heading or under any of those headings), and it neither applies otherwise than in relation to Wales nor confers, imposes, modifies or removes (or gives power to confer, impose, modify or remove) functions exercisable otherwise than in relation to Wales.
7. The provisions of the Bill relate to the following subjects:

Subject 9 'Health and Health Services':

"Promotion of health. Prevention, treatment and alleviation of disease, illness, injury, disability and mental disorder. Control of disease. Family planning. Provision of health services, including medical, dental, ophthalmic, pharmaceutical and ancillary services and facilities. Clinical governance and standards of health care. Organisation and funding of national health service."

Subject 12 'Local Government':

"...Powers and duties of local authorities and their members and officers..."

Subject 15 'Social Welfare':

"...Protection and well-being of children (including adoption and fostering) and of young adults..."

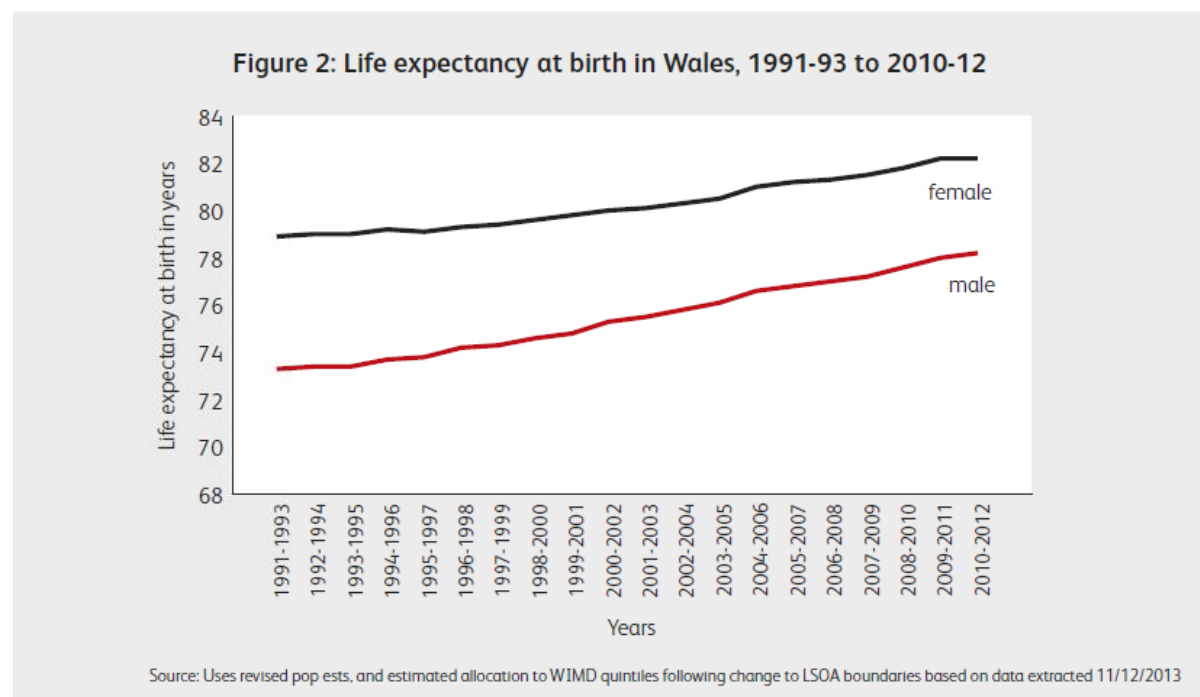
8. The above subjects provide the National Assembly with the competence to make the provisions contained in the Bill. Part 2 of the Bill contains provisions which remove pre-commencement functions of a Minister of the Crown. Those provisions will be within the Assembly's legislative competence if the Secretary of State consents to the provisions under Part 3 of Schedule 7 to GOWA 2006. Discussions with the UK Government are ongoing with a view to obtaining that consent. The Welsh Government anticipates that discussions on consent issues will be concluded during Stage 1.

3. Purpose and intended effect of the legislation

Context

9. The health of the population of Wales is continuing to improve. In general, people are living longer and enjoy better health than ever before, and more can be done to deal with health problems. Life expectancy continues to improve and the gap between males and females is decreasing, although the gap between the most and least deprived areas remains a concern.

Figure 1¹



10. Whilst health is improving, it is also clear that Wales faces a number of specific and significant health challenges. These range from overarching demographic challenges such as an ageing population, high levels of chronic disease and persisting inequalities in health, to more discrete challenges posed by lifestyle choices and contemporary developments within society.
11. The Welsh Government's priorities for public health are clear and have been set out in key policy documents including *Our Healthy Future*², the national public health framework, and the *Fairer Health Outcomes For All*³

¹ Chief Medical Officer for Wales Annual Report 2013-14: Healthier, Happier, Fairer - <http://gov.wales/topics/health/cmo/publications/annual/2014-report/?lang=en>

² Our Healthy Future – Technical Working Paper (2009) – Welsh Government

³ Fairer Health Outcomes For All (2011) – Welsh Government. <http://gov.wales/topics/health/publications/health/reports/fairer/?lang=en>

strategic action plan for reducing inequalities in health. The Welsh Government has ambitions to accelerate the pace of improvement in the health and well-being of people in Wales, and for improvements to be shared more equally across the population. In realising these ambitions the Welsh Government has signalled its ongoing commitment to taking action in a range of ways, including through legislation, to help further improve and protect health for everyone.

12. The quickly developing nature of society means that it is ever more important for the Welsh Government to keep pace with emerging public health priorities. In particular it is increasingly crucial that preventative approaches drive actions, including legislative action, in order to place sustainability at the heart of the public health agenda.
13. Legislation has historically played an important role in tackling public health issues. It has proven to be one of the most powerful tools available to governments in responding to health challenges, both old and new. Legislation in areas as varied as the ban on smoking in enclosed public places and the use of seat-belts has made significant positive contributions to public health. The Bill seeks to build on this strong tradition.
14. In bringing forward this Bill, the focus of the Welsh Government is on shaping social conditions that are conducive to good health, and where possible, preventing avoidable health harms. As part of this approach, it is also recognised that individuals have a responsibility to look after their own health, and to act in ways which promote their own physical and mental well-being.
15. The Bill adopts a preventative approach across its provisions and is therefore consistent with principles of prudent health care. It does this by seeking to intervene at points with significant potential for long-term benefits, both for the health of individuals and in avoiding the longer term burdens caused by avoidable ill health. In doing so the Bill also focuses on protecting the future health and well-being of children and young people in Wales.
16. Whilst a single piece of legislation cannot fully address all the issues affecting public health, the Bill seeks to make a positive contribution by bringing together a series of practical actions in specific areas, in order to have a positive cumulative impact on health and well-being. It is intended to make an important contribution to a broader suite of actions for improving health, alongside other legislative action, public health services, programmes and campaigns.
17. The approach taken in the Bill also sits alongside and complements the overarching approach to legislation taken forward by the Welsh Government's Well-being of Future Generations (Wales) Act. This means taking account of the importance of involving communities and reflecting the diversity of the population; public bodies acting in collaboration;

prevention; and early intervention. Such principles are intrinsic to public health.

The Public Health (Wales) Bill

18. The Bill is structured into the following Parts:-

- Part 2: Tobacco and nicotine products, which covers:-
 - Restrictions on the use of tobacco and NIDs (such as electronic cigarettes) in enclosed and substantially enclosed public and work places, and a regulation-making power to extend the restrictions to certain open spaces;
 - Register of retailers of tobacco and nicotine products;
 - A regulation-making power to add offences to the RPO regime; and
 - Handing over tobacco etc to persons under 18;
- Part 3: Special procedures;
- Part 4: Intimate piercing;
- Part 5: Pharmaceutical services;
- Part 6: Provision of toilets; and
- Part 7: General provisions.

19. The following pages describe the purpose and effect of each of the component parts. Each section includes the broad background to the proposals, the current position, the purpose of the legislation and its intended effect. No separate section is provided for Part 2, Chapter 3 of the Bill, which deals with the general operation of RPOs. This is covered in detail in relevant sections of the document which are dealing with the register of retailers of tobacco and nicotine products.

Tobacco and nicotine products

20. Tobacco smoking causes serious harm to the health of smokers and to non-smokers who are exposed to second-hand smoke. It continues to be the largest single preventable cause of ill health and death in Wales, causing around 5,450 deaths each year⁴.

21. The significant burden of illness due to smoking has major economic costs for Wales. Research shows that treating smoking related diseases costs NHS Wales an estimated £302 million per year, with the estimated cost to the Welsh economy in sickness absence and smoking breaks

⁴ Public Health Wales Observatory (2012) – ‘Tobacco and health in Wales, 2012’
<http://www.wales.nhs.uk/sitesplus/922/page/59800>

amounting to just over £90 million per year. Smoking is also a main cause of health inequalities, having been identified as a leading cause for the gap in mortality rates between the most and least deprived areas⁵.

22. Smoking experimentation and uptake can begin as early as the primary school years, or can occur later in a young person's life. Two thirds of smokers started before the age of 18, and almost 40% started smoking regularly before the age of 16⁶.
23. It is clear that young people can quickly develop a dependence on nicotine and may be unable to reduce their risks of dependence due to addiction. A London study showed that smoking a single cigarette is a risk factor for children to become regular smokers up to three years later⁷. In addition, early uptake of smoking is associated with subsequent heavier smoking, higher levels of dependency, a lower chance of quitting, and higher mortality⁸. Interventions to reduce the uptake of smoking amongst young people are therefore crucial to meet the overall aim of reducing smoking prevalence rates.
24. Good progress has been made in Wales in reducing smoking among young people,⁹ and rates of smoking amongst adults have dropped from 23% in 2010 to 21% in 2013¹⁰. However, more still needs to be done to increase the number of adults successfully quitting smoking, whilst continuing to prevent young people from starting to smoke. Smoking addiction is something which many smokers are unhappy with. The 2013 Welsh Health Survey reported that 72% of smokers would like to give up, and 41% had tried to give up in the last year¹¹.
25. In 2012, the Welsh Government published its Tobacco Control Action Plan for Wales¹² which sets out a comprehensive strategy on tobacco control, with the aim of protecting children and young people from the health harms of tobacco and reducing inequalities in health. The Tobacco Control Action Plan sets out a vision of a smoke-free society for Wales

⁵ ASH Wales and BHF Cymru (2013). The economic cost of smoking to Wales: a review of existing evidence.

⁶ Office for National Statistics. General Lifestyle Survey Overview: A report on the 2011 General Lifestyle Survey. 2013. <http://www.ons.gov.uk/ons/rel/ghs/general-lifestyle-survey/2011/rpt-chapter-1.html>

⁷ Fidler, JA et al. (2006) Vulnerability to smoking after trying a single can lie dormant for three years or more. Tobacco Control

⁸ Royal College of Physicians (2010) Passive smoking and children. London: Royal College of Physicians.

⁹ Currie C et al. eds. *Social determinants of health and well-being among young people. Health Behaviour in School-aged Children (HBSC) study: international report from the 2009/2010 survey*. Copenhagen, WHO Regional Office for Europe, 2012 (Health Policy for Children and Adolescents, No. 6).

¹⁰ Welsh Health Survey <http://wales.gov.uk/topics/statistics/theme/health/health-survey/results/?lang=en>

¹¹ <http://wales.gov.uk/statistics-and-research/welsh-health-survey/?lang=en>

¹² Welsh Government (2012) Tobacco Control Action Plan for Wales. Cardiff. Welsh Government.

with a challenging target of reducing adult smoking prevalence levels to 16% by 2020.

26. Evidence suggests that the most effective approach to tobacco control is a comprehensive strategy combining high taxation of tobacco products, regulation of tobacco advertising and sales, restrictions on smoking in public places, a tailored range of initiatives to help smokers to give up, and public awareness and education initiatives¹³.
27. While many smokers quit without recourse to smoking cessation services and products, it is recognised that nicotine products can play an important role in helping smokers to quit altogether, or to reduce their consumption of tobacco products. Nicotine products include traditional forms of licensed nicotine replacement therapy (NRT), such as nicotine patches, gums and lozenges. There is strong evidence available for long-term safety of NRT with concurrent smoking, suggesting that long-term use of NRT is not associated with an increased incidence of harm, including cardiovascular events or cancer, with the latest analysis of outcome at 12.5 years from study outset.¹⁴
28. Electronic nicotine delivery systems, commonly known as electronic cigarettes (hereafter 'e-cigarette') are a new form nicotine product, and some manufacturers have submitted products for licensing by the Medicine and Healthcare Products Regulatory Agency ('MHRA'). As the term 'e-cigarette' is widely recognised, it is used throughout this Explanatory Memorandum. Over the past five to ten years, the market for e-cigarettes has developed rapidly. This has raised concerns about the normalisation of smoking behaviours and their use by children and young people, which could lead to a nicotine addiction, and potentially a tobacco addiction if e-cigarettes are used as a gateway into tobacco smoking. In addition, concerns have been raised about their impact on indoor air quality and enforcement of current smoke-free policies. At present, the health effects of long-term e-cigarette use have not been established¹⁵.
29. In order to address these concerns, the Bill contains a number of components which make a cumulative contribution. Detailed information about the intended purpose and effects of each component is provided in the following paragraphs. The Bill's provisions will also work alongside an extensive suite of existing and planned measures at Wales, UK and European levels. These are summarised in the table at Annex D.
30. Over time the proposed measures are expected to impact on people's awareness of the health factors associated with tobacco and nicotine products, which in turn will lead to a change in behaviour. Fewer young

¹³ Gilbert A., Cornuz J. (2003) Which are the most effective and cost-effective interventions for tobacco control? Copenhagen, WHO Regional Office for Europe (Health Evidence Network report); <http://www.euro.who.int/document/e82993.pdf>

¹⁴ <https://www.nice.org.uk/guidance/PH45/chapter/9-The-evidence>

¹⁵ Pisinger Charlotta, Døssing Martin, A systematic review of health effects of electronic cigarettes, *Preventive Medicine* (2014), doi:10.1016/j.ypmed.2014.10.009

people will start smoking and some adults will successfully quit smoking. This is expected to lead to a reduction of smoking consumption/prevalence.

The Tobacco Products Directive

31. A recent important development is Directive 2014/40/EU (the 'Tobacco Products Directive'), which replaces and enhances the existing tobacco control measures set out in Directive 2001/37/EC. The revised Directive sets out harmonised rules concerning the composition and labelling of tobacco products.
32. Much of the 2001 Tobacco Products Directive remains, but the revised Directive is extended in scope, and includes new provisions to:
- Introduce a minimum pack size of 20 cigarettes and minimum weight of 30g for roll-your-own ('RYO') tobacco;
 - Continue, and enhance in some areas, the reporting of ingredients and emissions of tobacco products;
 - Increase the size of combined health warnings consisting of a text and photograph warning, to cover 65% of front and back of pack (previously 30% on front of pack and 40% on back of pack);
 - Ban certain misleading descriptors, such as 'natural' or 'organic';
 - Ban cigarettes and RYO tobacco containing characterising flavours such as menthol;
 - Introduce a traceability system and security features to 'track and trace' tobacco products, to strengthen the fight against illicit trade;
 - Regulate e-cigarettes and associated refill cartridges;
 - Regulate herbal cigarettes; and
 - Introduce a notification (or authorisation) scheme for novel tobacco products.
33. The Tobacco Products Directive 2014/40/EU must be transposed into domestic UK legislation by 20 May 2016.

Restrictions on the use of tobacco and e-cigarettes in enclosed public places

Background


34. Legislation to ban smoking in enclosed public places was introduced in Wales in 2007¹⁶ to protect the public from the harms associated with second-hand smoke. The smoking ban has been a public health success. Research commissioned by the Welsh Government shows air quality in enclosed public places has improved significantly since the smoking ban

¹⁶ The Health Act 2006 and The Smoke-free Premises etc. (Wales) Regulations 2007 (S.I. No.2007/787 (W.68)) came in to force on 2 April 2007.

was introduced¹⁷. The number of adults being exposed to second-hand smoke has also reduced.

35. Since the introduction of that ban, electronic nicotine delivery systems ('ENDS') have emerged. The function of these devices is to vaporise and deliver a chemical mixture to the user, typically composed of nicotine, propylene glycol and other chemicals. E-cigarettes are the most common form of ENDS and are normally battery operated devices that heat a liquid into an inhalable form for the user. E-cigarettes are offered in a variety of nicotine levels and some 7,000 flavours, including tobacco, menthol, fruit, chocolate and bubble-gum, some of which may appeal to children and young people¹⁸. It is known that flavoured (conventional) tobacco products are used disproportionately by young people.¹⁹
36. There are various styles of e-cigarettes in circulation. First generation devices are designed to look like their conventional (tobacco containing) counterparts, such as cigarettes, cigars, pipes and shishas. Second generation devices have an appearance often described as looking similar to pens. Third generation devices are larger versions with tanks which have a more distinct appearance that can be customised. The majority of e-cigarettes currently on the market emit a vapour and simulate the traditional hand to mouth action of regular smoking. Figure 2 below shows examples of different e-cigarette products currently available, though there are many more than these on the market and they are continually evolving.

Figure 2²⁰




Product	Description
Disposable e-cigarette 	Cigarette-shaped device consisting of a battery and a cartridge containing an atomizer to heat a solution (with or without nicotine). Not rechargeable or refillable and is intended to be discarded after product stops producing aerosol. Sometimes called an e-hookah.
Rechargeable e-cigarette	Cigarette-shaped device consisting of a

¹⁷ <http://gov.wales/topics/health/improvement/smoking/legislation/ban/?lang=en>

¹⁸ Hardcastle, K, Hughes, K, Worsley, J, Bennett, A, Ireland, R and Sweeney, S . (2014). *"Most people I know have got one": Young people's perceptions and experiences of electronic cigarettes*. Centre for Public Health at Liverpool John Moores University, Liverpool.

¹⁹ E-Cigarettes A Scientific Review. Rachel Grana, PhD, MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD
http://circ.ahajournals.org/content/129/19/1972.full?ijkey=d28c5d971050a38249828b4dc44736615120eb97&keytype2=tf_ipsecsha

²⁰ Background paper on E-cigarettes (Electronic Nicotine Delivery Systems), Rachel Grana, PhD MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD. Center for Tobacco Control Research and Education, University of California, San Francisco WHO Collaborating Center on Tobacco Control. Prepared for World Health Organization Tobacco Free Initiative December 2013.

	<p>battery that connects to an atomiser used to heat a solution typically containing nicotine. Often contains an element that regulates puff duration and/or how many puffs may be taken consecutively.</p>
<p>Pen-style, medium sized rechargeable e-cigarette</p> 	<p>Larger than a cigarette, often with a higher capacity battery, may contain a prefilled cartridge or a refillable cartridge (often called a clearomizer). These devices often come with a manual switch allowing the user to regulate length and frequency of puffs.</p>
<p>Tank-style, large-sized rechargeable e-cigarette</p> 	<p>Much larger than a cigarette with a higher capacity battery and typically contains a large, refillable cartridge. Often contains manual switches and a battery casing for customising battery capacity. Can be easily modified.</p>

37. E-cigarettes have experienced a significant rise in public awareness in recent years. There have been a number of high profile advertising campaigns and sponsorships, as well as increased attention from the media that has helped increase the popularity of the devices. Since November 2014, e-cigarettes can be advertised on terrestrial television²¹. ASH England²² estimate the number of e-cigarette users in Great Britain increased threefold over the two years from 2012, from 700,000 to 2.1 million.

38. In November 2013, a Cancer Research UK²³ commissioned report found that 121 product trademark applications relating to e-cigarette products were made in the UK between May 2012 and June 2013. It also found that sponsorship, celebrity endorsement, social networking, television advertising and product innovation were all being deployed.

39. The rationale for using e-cigarettes varies from person to person. Evidence from a variety of sources suggests that much e-cigarette use is to support stop smoking attempts or for partial replacement to reduce harm associated with regular tobacco smoking²⁴. Those who use e-

²¹ <http://www.cap.org.uk/News-reports/Media-Centre/2014/New-ecig-ad-rules.aspx>

²² ASH Fact Sheet on the use of electronic cigarettes in Great Britain. April 2014.

²³ The marketing of electronic cigarettes in the UK. A report by Marisa de Andrade, Gerard Hastings, Kathryn Angus, Diane Dixon and Richard Purves. Commissioned by Cancer Research UK. November 2013.


²⁴ MHRA website.

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice%E2%80%9393M%E2%80%9393T/NicotineContainingProducts/index.htm>

cigarettes for a partial replacement to smoking are known as 'dual users'. This may be as part of a harm reduction approach as recommended by NICE²⁵ for smokers who are unable or unwilling to quit tobacco smoking. However, even low levels of cigarette smoking confer nearly the same risk of cardiovascular disease as heavy smoking, and duration of smoking (as well as intensity) determines the risk of lung cancer²⁶.

40. Figure 3 below shows patterns of use in regular users of e-cigarettes in 2013. This shows that the majority of long term users were using the pen-style medium sized rechargeable e-cigarettes, also known as the 'second generation' devices.

Figure 3²⁷

Patterns of use in regular users		Average duration: 10 months	
	Product type		%
	'Cigarette-like'		18
	'Second generation'		72
	'Mods'		9
	Strengths used		%
	18mg/ml		49
	11mg/ml		33
	Combine strengths		21
	0mg/ml only		1
	Preferred flavour		%
	Tobacco		53
	Fruit		33
	Mint/menthol		28

41. The National Institute for Health Research has recently commissioned a large randomised controlled trial to examine the efficacy of e-cigarettes compared with nicotine replacement therapy when used within the UK's stop smoking services. The project is due to end in 2018.

Current position

42. Smoking prevalence amongst adults in Wales dropped to 21% in 2013²⁸. The percentage of non-smokers regularly exposed to second hand

²⁵ <https://www.nice.org.uk/guidance/ph45>

²⁶ Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems). Rachel Grana, PhD MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD. Center for Tobacco Control Research and Education University of California, San Francisco WHO Collaborating Center on Tobacco Control. Prepared for World Health Organization Tobacco Free Initiative December 2013.

²⁷ Vaping profiles and preferences: an online survey of electronic cigarette users. Lynne Dawkins et al. Addiction Volume 108, Issue 6, Pages 1115-1125, June 2013.

²⁸ Welsh Health Survey <http://gov.wales/statistics-and-research/welsh-health-survey/?lang=en>

smoke dropped significantly from 66% in 2005-06 to 42% in 2007, and since 2008 has remained fairly constant²⁹.

43. E-cigarettes are a relatively new product and as such the long term effects of their use are currently not known, with studies into their health impacts continually being published. There are a number of studies that provide contrasting views around the safety and health benefits for both the user and other nearby people.
44. Currently there are some regulations on the advertising of e-cigarettes, through the Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP)³⁰. These seek to ensure that advertisements do not make any claims on their use as a cessation tool or for medicinal purposes, and provide that TV advertisements must be shown after the watershed.
45. The growing market for e-cigarettes and differing levels of regulation across Europe has prompted the European Union to include e-cigarettes in the scope of the revised Tobacco Products Directive³¹ ('TPD'). The revised TPD introduces mandatory safety and quality requirements on e-cigarettes that are not covered by the Medicines Directive³². This includes provisions on nicotine content, ingredients and devices as well as refill mechanisms. It also makes one of two health warnings mandatory (*'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'* or *'This product contains nicotine which is a highly addictive substance'*); and introduces a requirement for information leaflets in unit packets of e-cigarettes and refill containers. It also introduces a notification requirement for manufacturers and importers of e-cigarettes, stricter rules on advertising and monitoring of market developments. The revised TPD does not, however, introduce restrictions on smoke-free environments or the age of sale for e-cigarettes, although Member States are free to regulate on such matters in their own domain.
46. There have been three legal challenges to the revised TPD referred to the European Courts. The Polish challenge relates to menthol cigarettes; Totally Wicked, an e-cigarette company, has challenged the e-cigarette provisions; and Philip Morris International and British American Tobacco have challenged the whole Directive. Court dates have yet to be set.
47. The Medicines and Healthcare Products Regulatory Agency ('MHRA') announced in June 2013³³ its decision to licence e-cigarettes as medicines. This was in line with the original proposal from the European

²⁹ Tobacco and Health in Wales 2012 – <http://www.wales.nhs.uk/sitesplus/922/page/50314>

³⁰ <http://www.cap.org.uk/Advice-Training-on-the-rules/Advice-Online-Database/Electronic-cigarettes.aspx>

³¹ http://ec.europa.eu/health/tobacco/products/revision/index_en.htm

³² <http://ec.europa.eu/health/documents/eudralex/vol-1/index.htm>

³³ <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Productspecificinformationandadvice%E2%80%9393M%E2%80%9393T/NicotineContainingProducts/index.htm>

Commission for the revised TPD³⁴, which required all nicotine products to be treated as medicines. Despite the European Parliament ultimately rejecting this proposal, the MHRA has maintained its position and is already accepting applications for medicinal licences for nicotine products. The Welsh Government understands a number of applications have been made. A nicotine inhaler was granted a medicinal licence in September 2014³⁵. Manufacturers of e-cigarettes who seek medicinal licences will be able to make health claims about their product, whereas e-cigarettes being sold as consumer products will not be able to make such claims.

48. The UK Government has announced its intention to introduce an age of sale restriction for all nicotine products, including e-cigarettes. This was introduced through the Children and Families Act 2014³⁶, which provides the Secretary of State for Health with powers to make regulations that will make it an offence to sell nicotine products to persons aged under 18 years old, and make it an offence to proxy purchase nicotine products for minors. On 2 February 2014 the National Assembly for Wales agreed, through a legislative consent motion³⁷, for the Secretary of State for Health to take powers in the Children and Families Act 2014 in respect of nicotine products that extend to both England and Wales. Regulations³⁸ were made on 25 March 2015.

Purpose of the provisions

49. The purpose of the Bill provisions is to bring the use of e-cigarettes into line with existing provisions on smoking. As a result, the use of e-cigarettes will be prohibited in enclosed public and work places in Wales unless an exemption has been provided. This approach is in line with recent advice from the World Health Organisation.³⁹
50. The Bill will achieve this change through a re-statement of Chapter 1, Part 1 of the Health Act 2006⁴⁰ in relation to Wales, and extending the scope of these provisions so that the smoke-free requirements will apply to the use of e-cigarettes in addition to tobacco products. This means that the re-stated smoke-free requirements will include new offences of using a nicotine inhaling device in a smoke-free place, and failing to prevent the use of a nicotine inhaling device in a smoke-free place. In addition, as is the case under the Health Act 2006, the Bill provides the Welsh Ministers with powers to:

³⁴ <http://ec.europa.eu/health/tobacco/products/revision/>

³⁵ <http://www.kindconsumer.com/products/voke-inhaler-technology>

³⁶ <http://www.legislation.gov.uk/ukpga/2014/6/part/5/crossheading/tobacco-nicotine-products-and-smoking>

³⁷ <http://www.senedd.assemblywales.org/ieDecisionDetails.aspx?Id=1498>

³⁸ S.I 2015/895 - The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015

³⁹ Electronic Nicotine Delivery System. Report by WHO. WHO Framework Convention on Tobacco Control. FCTC/COP/6/10. 21 July 2014.

⁴⁰ Health Act 2006 c.28 <http://www.legislation.gov.uk/ukpga/2006/28/contents>

- Make provisions for smoke-free vehicles, which may specify the types of vehicles that are to be smoke-free, the circumstances in which they are smoke-free, that vehicles are to be smoke-free when they are located in specific areas, and for exemptions to any of these requirements. The Welsh Ministers may only do so where they are satisfied that doing so is likely to contribute towards the promotion of the health of the people of Wales;
 - Designate additional premises, including non-enclosed spaces, as smoke-free in relation to smoking and the use of nicotine inhaling devices. The Welsh Ministers may only do so where they are satisfied that doing so is likely to contribute towards the promotion of the health of the people of Wales;
 - Exempt premises (or parts of premises) from the restated smoke-free requirements; and,
 - Specify requirements for signage to be used.
51. In the restatement, e-cigarettes are referred to as 'nicotine inhaling devices'. This is in line with the definition in the age of sale regulations. As noted above the term 'e-cigarette' is used throughout this Explanatory Memorandum due to it being a widely recognised term.
52. The purpose of the provisions is not to ban the use of e-cigarettes, nor to affect their potential use in smoking cessation attempts. A Cochrane Review⁴¹ of 13 completed studies on smoking cessation, published in December 2014, found that while recognition of the potential health benefits from smokers switching to e-cigarettes can be found in expert opinion, the quality of the evidence overall is low.
53. The aim of the Bill provisions, therefore, is to balance the potential benefits to smokers wishing to quit with any potential dis-benefits related to the use of e-cigarettes.
54. One of the potential dis-benefits is that e-cigarette use may re-normalise smoking behaviours in places where the public have become unaccustomed to smoking as a result of the smoke-free requirements. E-cigarettes have not been on the market long enough for definitive evidence to be available about whether normalisation is occurring. However, the de-normalisation of smoking through smoking bans across the world is well documented. As well as physically reducing the places where smoking may occur, reducing opportunities to smoke and making it more difficult to

⁴¹ Electronic cigarettes for smoking cessation and reduction (Review). 2014. The Cochrane Collaboration. Published by John Wiley & Sons, Ltd. Available at: <http://www.cochrane.org/features/new-cochrane-evidence-shows-electronic-cigarettes-facilitate-smoking-cessation>

smoke helps to challenge perceptions that smoking is normal behaviour⁴² and reduce the social acceptability of smoking⁴³. In a review of e-cigarette marketing⁴⁴, researchers found that many e-cigarette products replicate cigarettes so closely, both in appearance and how they are consumed, that their use looks just like – and hence models – smoking. They state that this suggests the potential for e-cigarettes to inadvertently promote smoking. Others have also expressed concerns that the use of e-cigarettes in enclosed public and work places could undermine the success of tobacco control measures, by re-normalising smoking.^{45,46}

55. E-cigarettes are used by teenagers, including those who have never smoked, but currently few of those who try them become regular users.⁴⁷ Based on data from the USA it is plausible that use among young people will increase, even among non-smokers^{48,49}. The CHETS Wales 2 report⁵⁰ found that there is some suggestion that e-cigarette use may be associated with weaker anti-smoking intentions, specifically that:

- Among non-smoking children who reported having used an e-cigarette, 14% reported they might start smoking within the next two years (compared to 2% of those who had not used an e-cigarette); and
- While few children said that they will smoke within two years, children who had used an e-cigarette were substantially less likely to say they definitely will not smoke, and more likely to say that they might.

Consideration of these data raises concerns that, in addition to re-normalising smoking, e-cigarette use may also act as a gateway to nicotine addiction and tobacco smoking.

56. The Health Act 2006 resulted in positive changes to the air quality in enclosed and substantially enclosed public and work places in Wales.

⁴² Alesci N, Forster J and Blaine T. Smoking visibility, perceived acceptability, and frequency in various locations among youths and adults. *Preventive Medicine* 2003;36(3):272-81. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12634018>

⁴³ Song A and Glantz S. Pushing secondhand smoke and the tobacco industry outside the social norm to reduce adolescent smoking. *Journal of Adolescent Health* 2008;43(4):315–17. Available from: [http://www.jahonline.org/article/S1054-139X\(08\)00235-8/fulltext](http://www.jahonline.org/article/S1054-139X(08)00235-8/fulltext)

⁴⁴ Promotion of electronic cigarettes: tobacco marketing reinvented? Marisa de Andrade, Gerard Hastings and Kathryn Angus. *BMJ* 2013;347:f7473

⁴⁵ Friends of the Board of Science bulletin; BMA Board of Science. Issue 9, October 2013. <http://www.adph.org.uk/category/stc/>

⁴⁷ 'Electronic-cigarette use among young people in Wales: evidence from two cross-sectional surveys.' Dr Graham Moore et al. Published 15 April 2015. <http://bmjopen.bmj.com/content/5/4/e007072>

⁴⁸ Electronic cigarette use and conventional cigarette use among US adolescents: a cross-sectional study. Dutra and Glantz. *JAMA Pediatr*.doi:10.1001/pediatricsrics.2013.5488. Published online 6 March 2014.

⁴⁹ Intentions to smoke cigarettes among never-smoking U.S. middle and high school electronic cigarette users, National Youth Tobacco Survey, 2011-2013. Bunnell et al. *Nicotine Tob Res* (2015) 17 (2): 228-235. doi: 10.1093/ntr/ntu166 First published online: August 20, 2014 <http://ntr.oxfordjournals.org/content/17/2/228>

⁵⁰ <http://wales.gov.uk/statistics-and-research/exposure-secondhand-smoke-cars-ecigarette-use-among-children/?lang=en>

Since the 2006 Act's enactment e-cigarettes have become much more prevalent in society. It is known that e-cigarettes contain various chemicals that are vaporised and emitted into the air, and studies have suggested that e-cigarette aerosol can contain some of the toxicants present in tobacco smoke, albeit at levels which are much lower⁵¹.

57. The safety of e-cigarettes for bystanders is currently uncertain; but the possibility of adverse health effects for third parties exposed to e-cigarettes cannot be excluded.⁵² Allowing the use of e-cigarettes in places where smoking is banned arguably creates an environment that undermines the safer one established by the Health Act 2006.
58. It is also a concern that e-cigarette use is undermining enforcement of the smoking ban. Several prosecutions under the Health Act 2006 have failed where the defendant has claimed to have been using an e-cigarette at the relevant time, rather than smoking. Respondents to the Welsh Government's Public Health White Paper consultation suggested that the vapour emitted from e-cigarettes, as well as the hand to mouth action, can make it difficult from a distance for managers of premises required to be smoke-free to differentiate between regular cigarettes and e-cigarettes.⁵³ It is also time consuming for staff working in premises where smoking is banned to investigate potential breaches of the smoke-free requirement.
59. Surveys have indicated public support for this measure. A survey in June 2014⁵⁴ reported that 52% of those questioned were in favour of the ban on smoking in enclosed public places being extended to include e-cigarettes, with 37% against and 11% answering 'don't know.' A similar UK survey in October 2014⁵⁵ reported that around 60% of those polled would like to see e-cigarettes banned indoors in public and work places. In contrast, 27% were against prohibiting their use, and 13% did not know.

Intended effect of the provisions

60. These provisions will work with other legislation to contribute to the continuing decline in the uptake of smoking by children and young people. They will work to ensure the de-normalisation of smoking is maintained. They will also work with the Age of Sale and Proxy Purchase regulations to help to protect them from the risk of nicotine addiction and the impact that nicotine can have on the developing brain; and protect children and

⁵¹ Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Hajek et al. 2014. *Addiction*, 109, 1801-1810 doi:10.1111/add.12659

⁵² German Cancer Research Centre (Ed) *Electronic Cigarettes – An Overview*. Heidelberg 2013

⁵³ <http://gov.wales/consultations/healthsocialcare/white-paper/?lang=en>

⁵⁴ YouGov for ITV Wales. <http://www.itv.com/news/wales/story/2014-07-25/wales-this-week-smoke-without-fire/>

⁵⁵ YouGov for The Sunday Times. <http://rt.com/uk/197912-uk-ecig-ban-support/>

young people from any potential gateway effect into smoking tobacco that may come from the use of e-cigarettes⁵⁶.

61. As a consequence of the legislation, the air quality enjoyed in enclosed and substantially enclosed public and work places in Wales as a result of the current smoke-free environment will be maintained.
62. The provisions are also intended to ensure that the enforcement of the Health Act 2006 is not undermined. These provisions will aid managers of premises required to be smoke-free in their enforcement of the current regime, by bringing e-cigarette use in public and work places into line with regular tobacco products. This will provide clarity and consistency for businesses and workplaces and for users of e-cigarettes when in enclosed and substantially enclosed public and workplaces in Wales. Recent surveys of e-cigarette policies in workplaces⁵⁷ and schools⁵⁸ in Wales have indicated that such clarity is required.
63. The provisions are not intended to interfere with the use of e-cigarettes in any smoking quit attempt, or in reducing the harm from smoking. E-cigarette users will still be able to use their devices in all places where smoking is permitted.
64. Provisions on smoke-free vehicles and any additional smoke-free premises, including non-enclosed spaces, will be set out in regulations. When bringing forward such legislation the Welsh Ministers will need to consider in each circumstance whether e-cigarettes should be included in such measures.

Register of retailers of tobacco and nicotine products

Background

65. Protecting young people from purchasing tobacco and nicotine products is essential as they may have inadequate information about the health consequences and, in particular, their risk of developing an addiction. Even where they have information, adolescents may not accurately judge the risks of smoking relative to other environmental

⁵⁶ <https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

⁵⁷ Welsh Government. E-cigarette policies: a survey of workplaces in Wales. 2014. <http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

⁵⁸ Welsh Government. E-cigarette policies: a survey of schools in Wales. 2014. <http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

exposures.⁵⁹ In addition, the younger a person starts smoking, the greater the risk of smoking related disease⁶⁰.

66. It has long been established that nicotine is highly addictive. Nicotine is a potent and powerfully addictive drug, which is five to ten times more potent than cocaine or morphine in producing behavioural and psychological effects associated with addiction potential in humans⁶¹. Young people can rapidly develop nicotine dependence. With regard to nicotine from smoking tobacco, symptoms can develop soon after a young person's first puff on a cigarette. Novice users often do not recognise the symptoms they experience as being related to nicotine dependence⁶². Research shows that the brain continues to develop during adolescence and that it is different from the adult brain. One of the differences is that adolescents are more sensitive to the rewarding effects of nicotine, which may be a reason that many people start to smoke during their teens⁶³. Evidence also shows young people who develop a dependence to nicotine may be unable to reduce their risks due to addiction⁶⁴.
67. The Welsh Government's Tobacco Control Action Plan for Wales⁶⁵ acknowledges the possibility that further management of the tobacco retail environment may be required to combat underage sales, and states, '*The Welsh Government will explore the possibility of introducing a tobacco retail register in Wales.*' (Action 1.6).

Current position

68. A range of legislation has been introduced in Wales to reduce the risk of young people accessing tobacco products. Measures have ranged from prohibiting the sale of tobacco products to under 18s to banning the sale of tobacco products from vending machines.
69. Currently there is no method of tracking retailers who sell tobacco or nicotine products, unlike alcohol where premises must have a licence prior to selling. Local authorities have to rely on local intelligence to enforce tobacco legislation.

⁵⁹ Tobacco control in developing countries. Oxford University Press. (2000).

⁶⁰ British Medical Association (2007). Breaking the cycle of children's exposure to tobacco smoke. British Medical Association.

⁶¹ Harm Reduction in Nicotine Addiction: Helping People who can't quit. Royal College of Physicians. (2007)

⁶² Milestones in the natural course of onset of cigarette use among adolescents. Gervais, A., et al. (2006)

⁶³ Development of the motivational system during adolescence, and its sensitivity to disruption by nicotine. Counotte, D. et al. (2011)

⁶⁴ Di Franza J et al (2007). Symptoms of tobacco dependence after brief intermittent use: the development and assessment of nicotine dependence in youth, Archives of Paediatrics and Adolescent Medicine 162 (7): 704-710

⁶⁵ <http://wales.gov.uk/topics/health/improvement/index/tobacco/?lang=en>

70. Local authorities currently provide a wide range of advice and guidance to retailers on a number of issues. However, there are challenges in ensuring that tobacco retailers are provided with the latest advice and support around tobacco and nicotine issues, due to there not being a comprehensive list available of businesses who sell these products. This means that local authorities may not be able to identify all of the businesses that may require training or guidance, and could lead to some retailers not receiving crucial information such as changes in the law.
71. Data are available on underage sales of tobacco products in Wales. Trading standards departments conducted a total of 332 test purchase attempts at retail premises, using young volunteers, across Wales during 2012/13. Of these, 51 resulted in a sale, giving a failure rate of 15%. Data from previous years, shown in the table below, indicate that this is a continuing problem.

Table 3.1

Financial Year	Number of attempts to purchase cigarettes by young volunteers	Number of times young volunteers were served	Failure rate
2007-08	148	22	15%
2008-09	720	130	18%
2009-10	884	136	15%
2010-11	518	74	14%
2011-12	536	57	11%
2012-13	332	51	15%

72. Evidence from the North East of England in 2013⁶⁶ showed that young smokers (14-15 year olds) are significantly more comfortable than their adult counterparts in purchasing illegal tobacco. 30% of 14-15 year olds were buyers of illegal tobacco, making them twice as likely as adult smokers in having purchased illegal tobacco. In addition, research published by ASH Wales⁶⁷ indicates that approximately 19% of all illegal tobacco was purchased from a shop (based on the survey conducted for this research in 2014), and the average price of a pack of 20 illegal cigarettes was £4, compared to an average price just short of £8 for legally purchased cigarettes (post-2014 budget).
73. A tobacco retail register was introduced in Scotland in 2011 as part of the Tobacco and Primary Medical Services (Scotland) Act 2010⁶⁸. In October 2014 the Scottish Government published a consultation on electronic cigarettes and strengthening tobacco control in Scotland⁶⁹, which closed in January 2015. One of the options the Scottish

⁶⁶ NEMS Market Research (2013). North East Illicit Tobacco Survey. NEMS Market Research

⁶⁷ ASH Wales (2014). Illegal Tobacco: The Problem in Wales. ASH Wales

⁶⁸ <http://www.legislation.gov.uk/asp/2010/3/contents>

⁶⁹ Scottish Government (2015). A Consultation on Electronic Cigarettes and Strengthening Tobacco Control in Scotland. Scottish Government

Government was seeking views on was to establish a statutory requirement for e-cigarette retailers to register on the Scottish Tobacco Retailers Register. In Northern Ireland, the Tobacco Retailers Act (Northern Ireland) 2014⁷⁰ includes provisions on creating a tobacco retail register for Northern Ireland. This provision has not yet been commenced.

74. In England and Wales, section 143 of the Criminal Justice and Immigration Act 2008 amended the Children and Young Persons Act 1933 to enable a magistrates' court to impose a Restricted Premises Order (RPO) or a Restricted Sales Order (RSO) on those who have persistently sold tobacco to under 18s (at least three separate occasions within a two year period). A RPO prohibits all sales of tobacco products (including cigarette papers) from the premises for a period up to, but not exceeding one year. A RSO prohibits a person from selling any tobacco products (including cigarette papers) or having any management functions in respect of any premises in relation to the sale on the premises of tobacco products (including cigarette papers) to any person. A RSO can be for any period of time up to, but not exceeding, one year. The Children and Young Persons Act 2014 extends the RPO and RSO regime to nicotine products.
75. In Northern Ireland, a court can issue a RPO if the offender has committed three tobacco offences within the last five years. These offences must have resulted in either a Fixed Penalty Notice or a conviction, however this is not restricted to sales of tobacco to under 18s. In Scotland, the Sheriff can issue a Tobacco Banning Order if the person has been subject of three or more relevant enforcement actions within the last two years in respect of each premise specified in the Order. A person is the subject of a relevant enforcement action if they have been issued with a Fixed Penalty Notice or convicted of an offence within Chapter 1 (Display, Sale and Purchase of tobacco products) or Chapter 2 (Register of tobacco retailers) of the Tobacco and Primary Medical Devices (Scotland) Act 2010.
76. In relation to nicotine products, sections 92 and 93 of the Children and Families Act 2014 provide the Secretary of State with the power to make regulations to prohibit the sale of nicotine products to persons under the age of 18. This is intended to protect children and young people from the risk of nicotine addiction and possible tobacco use. The UK Government ran a six week consultation on behalf of England and Wales on the draft regulations, which closed on 28 January 2015. The regulations were then made on 25 March 2015.⁷¹
77. Results from a report⁷² published in July 2014 by Public Health England and Trading Standards Institute of a test-purchasing study

⁷⁰ <http://www.legislation.gov.uk/nia/2014/4/crossheading/register-of-tobacco-retailers/enacted>

⁷¹ S.I. 2015/895 – The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015

⁷² Trading Standards Institute (2014). Youth access to E cigarettes and associated products. Trading Standards Institute

involving young people under the age of 18 attempting to purchase e-cigarettes from a variety of retailers, showed that 40% of young people were able to purchase e-cigarettes.

Purpose of the provisions

78. In order further to strengthen the current tobacco control legal framework, the Bill includes provisions to establish a national register of retailers of tobacco and nicotine products. The primary purpose is to reinforce the importance of protecting under 18s from tobacco and nicotine products, as well as reducing the risk of under 18s accessing these products.
79. All retailers who sell either tobacco products or nicotine products in Wales will have to register in order to be permitted to sell these products (as will be defined in regulations). One application form will be submitted to cover all of the premises where these products are sold. A proportionate payment will need to accompany the application form, which will contribute to the overall administration costs of the register.
80. The creation of a national register of retailers of tobacco and nicotine products will provide local authorities with a definitive list of retailers within their authority who sell either tobacco or nicotine products. Local authorities will therefore be able to utilise the register to aid enforcement of tobacco and nicotine legislation, for example relating to age of sale and the display of tobacco products. This will be a significant change to the current position of fragmented intelligence.
81. The register will also be an invaluable tool in disseminating information and guidance to retailers around the sale of tobacco and nicotine products. This could include, for example, information on changes to legislation which retailers need to be aware of, or guidance which provides advice or support for retailers. Having a register of retailers of these products is intended to reduce the risk of retailers not being aware of important changes in the way that these products are sold, for example the introduction of the ban on selling tobacco products in vending machines.
82. A Registration Authority will be named to manage the national register for the whole of Wales, which may be a local authority or other body (such as a voluntary sector or private organisation). This role will include processing applications for premises to be included on the register. The Registration Authority may not grant an application if it relates to premises which are currently under a RPO, or to an individual who is currently the subject of a RSO. If an application is received with multiple premises, only the premises currently subject to a RPO would not be added to the register.
83. The Bill provides that it will be an offence for a premise (including mobile units) to sell tobacco or nicotine products in Wales if they are not

on the national register. It also places a duty on retailers to notify the Registration Authority of certain changes (such as if a retailer is no longer selling tobacco or nicotine products, or a change of ownership). This is to ensure that the register contains the most up to date information possible on retailers of tobacco and nicotine products.

84. Local authorities will enforce offences relating to the register. In order effectively to enforce these offences, it may be necessary to gain entry to a non-registered premises from which it is believed that tobacco products and/or nicotine products are being sold. The Bill therefore provides a power of entry to local authority officers, along with an associated offence of obstructing an officer from exercising this power.
85. In addition to creating a register, the Bill will also provide the Welsh Ministers with powers to include other tobacco offences that may be counted towards the application for a RPO. In order to include new offences, the offence must be at least a Level 4 penalty and be an offence that relates to the supply, sale, transport, display, offer for sale, advertising or possession of tobacco or nicotine products.
86. Adding other tobacco and/or nicotine offences to the current RPO regime will reinforce the importance of selling these products responsibly. Evidence indicates the most effective incentive for legislative compliance is the real threat of a loss of licence, rather than the possibility of a prosecution and a fine.⁷³
87. Having an enhanced RPO regime is intended to provide Wales with a more effective negative licensing model. A negative licensing system is one in which no licence or permit is required prior to trading, but a business committing serious breaches may be barred from selling products. For tobacco and nicotine products, this means that a retailer would not need to obtain a licence prior to selling these products, but if they commit three relevant tobacco or nicotine offences within a three year period they may be issued with a RPO, which will prohibit that premises from selling these products for a period up to one year. The length of time a retailer will be prohibited from selling tobacco products or nicotine products will be determined by a magistrates' court. If a premise is subject to a RPO, it may not be included on the retail register until such time as the Order expires.

Intended effect of the provisions

88. The intended effect of the legislation is to protect children and young people under the age of 18 from the harms associated with tobacco and nicotine use. This will be achieved by providing local authorities with a definitive list of retailers who sell tobacco and/or nicotine products within their authority area. This will assist trading standards officers within these

⁷³ Licensing of Tobacco Retailers and Wholesales. The Allen Consulting Group. 2002

areas in enforcing existing tobacco legislation, and provide retailers with guidance and information on their responsibilities linked to tobacco and nicotine products legislation.

89. In addition, it is anticipated that combining a strengthened RPO regime with a national register will add benefit by enhancing existing levers available to local authorities for enforcement of tobacco and nicotine offences. These provisions will also support the policy aim of reducing access to tobacco and nicotine products by under 18s.

Handing over tobacco etc to persons under 18

Background

90. Most smokers start smoking during adolescence and, currently in Wales, among school Year 11 pupils (i.e. aged 15-16), 9% of boys and 14% of girls are regular (weekly) smokers⁷⁴. Two thirds of adults who have ever smoked in the UK say that they started smoking before the age of 18 and two fifths had started smoking regularly before the age of 16⁷⁵. Those under the age of 18 are particularly vulnerable consumers, as previously outlined.
91. Controlling access is an established strategy for reducing consumption of substances harmful to health, in particular tobacco. Restricting young people's access to tobacco and nicotine products can therefore help protect them from developing an addiction to nicotine⁷⁶. Article 16 of the WHO Framework Convention on Tobacco Control states, "*Each Party shall adopt and implement effective legislation, executive, administrative or other measures at the appropriate government level to prohibit the sales of tobacco products to persons under the age set by domestic law, national law or eighteen*"⁷⁷. Restricting access to tobacco and nicotine products for children and young people through legislation can therefore support a wider programme of protecting children and young people from health harms.
92. Remote sales are purchases of tobacco products or nicotine products through the internet or phone sales, which are then delivered. Alternatively, they can involve paying for them at the point of order and arranging to collect the products at a later point.

⁷⁴ Welsh Government (2011). Health Behaviour in School-aged Children: initial findings from the 2009/10 survey in Wales. Social Research No. 09/2011. Cardiff: Welsh Government.

⁷⁵ Office for National Statistics. General Lifestyle Survey 2011. Office for National Statistics (2013)

⁷⁶ Stead L.F, Lancaster T. Interventions for preventing sales to minors (review). The Cochrane Collaboration 2008.

⁷⁷ World Health Organisation. WHO Framework Convention on Tobacco Control. World Health Organisation 2003.

93. Whilst there are no specific UK or Welsh studies on the number of under 18s currently attempting to purchase tobacco remotely, there is evidence of a problem with the delivery of online sales of other age restricted products, such as alcohol. A survey conducted by South Wales Police in March 2013 using 15 year old volunteers to attempt to purchase alcohol from major supermarket websites, found that in 44% of the cases alcohol was delivered to the volunteer with no proof of age requested⁷⁸. Alcohol Concern Cymru conducted a survey of 1,000 14-17 year olds in 2013 and found that 21% of 14-15 year olds had successfully purchased alcohol online and 15% of all 14-17 year old respondents had successfully purchased alcohol online⁷⁹. It is considered reasonable to assume similar issues could become apparent for similar age-restricted goods, such as tobacco products and nicotine products.
94. There is already some evidence from the USA that there may be an issue with young people being able to access tobacco products via the internet. Kurt, et al. showed that in the majority of cases 11 to 15 year olds were able to purchase tobacco products via the internet. Out of 83 purchase attempts, 93.6% of purchases attempted by credit card and 88.9% of purchases attempted by money order were successful⁸⁰. A recent study in North Carolina has also shown that minors were easily able to purchase e-cigarettes from the internet.⁸¹

Current position

95. The current legal position on underage sales of tobacco (including cigarette papers) is set out in the Children and Young Persons Act 1933, Children and Young Persons (Protection from Tobacco) Act 1991 and the Children and Young Persons (Sale of Tobacco) Order 2007. In summary, it is illegal to sell cigarettes or other forms of tobacco products, including cigarette papers, to a person under 18 years of age. Additional legislation has been introduced to prevent under 18s from gaining easy access to tobacco products, such as prohibiting the sale of tobacco from vending machines⁸², and the Children and Families Act 2014 introduced an offence for someone over the age of 18 to purchase, or attempt to purchase, tobacco products for a person or persons under the age of 18⁸³.
96. In relation to nicotine products, sections 92 and 93 of the Children and Families Act 2014 provide the Secretary of State within the UK Government with the power to make regulations to prohibit the sale of

⁷⁸ Alcohol Concern Cymru. On Your Doorstep. Alcohol Concern Cymru 2013

⁷⁹ Same as previous reference

⁸⁰ Kurt M. Ribisl, PhD; Rebecca S. Williams MHS; Annice E. Kim, MPH. JAMA 2003

⁸¹ Williams RS, Derrick J, Ribisl KM. Electronic Cigarette Sales to Minors via the Internet. *JAMA Pediatr.* 2015 Mar 2; 169(3): e1563. Doi:10.1001/jamapediatrics.2015.63

⁸² The Protection from Tobacco (Sales from Vending Machines) (Wales) Regulations 2011

⁸³ Children and Families Act 2014

nicotine products to persons under the age of 18 in England and Wales. Regulations were made on 25 March 2015.⁸⁴

97. There is no current legislation which prevents tobacco products or nicotine products which have been purchased remotely from being handed over to a person or persons under the age of 18. As other opportunities to access tobacco products or nicotine products are reduced, remote sales could provide children and young people under the age of 18 with access to these products.
98. Currently every major supermarket chain in Wales that makes home deliveries which include tobacco products has voluntary policies in place to govern their deliveries. These policies provide that their drivers are not permitted to hand over the tobacco products to any customer who appears to be under the age of 18, if they cannot provide proof of age to confirm they are 18 or over. It is likely that some retailers will extend their policies to cover nicotine products in future in response to regulations introducing an age of sale for nicotine products in England and Wales.
99. While there are a number of retailers who currently have policies, this voluntary practice is not universal across all retailers who sell tobacco products remotely, and there is currently no legal requirement for retailers to ensure tobacco and/or nicotine products are only being handed over to persons aged 18 or over.
100. According to data published by the Office of National Statistics⁸⁵ internet sales have increased in recent years. In March 2012 internet sales contributed 8.9% of all retail sales, increasing to 11.6% in January 2015. For food stores this has increased from 2.9% in March 2012 to 4% in January 2015. This indicates that using the internet as a method for shopping is continuing to increase, and it is likely that this trend will continue. It has been assumed that this upward trend is likely to be reflected across the spectrum of goods available for remote purchasing, including tobacco and nicotine products.

Purpose of the provisions

101. In recognition of the potential for persons under the age of 18 to access tobacco products and nicotine products via remote sales, and the voluntary nature of the policies currently in place, the Bill creates a new offence of knowingly handing over these products to a person under the legal age of sale in Wales. The primary purpose of the offence is to reduce the risk of young people under the age of 18 from accessing tobacco products and/or nicotine products which form part of the delivery.

⁸⁴ S.I. 2015/895 – The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015

⁸⁵ Retail Sales, January 2015. Office of the National Statistics

102. The offence would only occur in situations where the delivery driver is aware that they are handing over either tobacco products and/or nicotine products to someone who is under the age of 18. As such, postal services such as Royal Mail, or courier services where the courier is delivering a fully enclosed and addressed package would not be covered by the offence.
103. It will be the responsibility of the person handing the tobacco product or nicotine product over to the customer to ensure they have followed the appropriate age verification checks. A person who commits an offence of knowingly handing over a tobacco product or nicotine product to an unsupervised person under the age of 18 will be liable, on summary conviction, to a fine not exceeding level 4 on the standard scale. Local authorities will be responsible for enforcing the provisions.
104. For the purposes of the offence, a person will be viewed as being “unaccompanied” unless the handing over takes place in the presence of another person who is aged 18 or over.

Intended effect of the provisions

105. The intended effect of the provisions is to reduce the risk of young people under the age of 18 of accessing tobacco products and /or nicotine products. This will be achieved by requiring delivery agents to visually assess if the person they are handing the tobacco products and/or nicotine products is aged 18 or over, and verify age where appropriate. This will be similar to the process if purchasing these products in a shop.
106. The provisions will also further enhance the overall legislative framework aimed at children and young people from the harms associated with tobacco and nicotine, such as age of sale legislation and the ban on selling tobacco products from vending machines.

Special procedures

Background

107. A number of cosmetic and therapeutic procedures have become increasingly popular over the last decade, both in Wales and further afield. These include acupuncture, body piercing, electrolysis and tattooing.
108. There are known and well reported health risks connected to these procedures - defined within the Bill as ‘special procedures’ - if they are carried out in an unhygienic fashion. It is therefore important that practitioners employ safe working practices, and particularly that good infection control practices are followed at all times, so that both clients and practitioners are adequately protected.

109. Improper and unhygienic practices may result in localised skin infections at the site of the procedure, or even lead to the spread of infectious diseases that can affect the health of clients, as well as jeopardise the health of the practitioner themselves. Although uncommon, unsafe or unhygienic practices can lead to the transmission of diseases such as blood-borne viruses.⁸⁶
110. Complications that can arise include swelling, infection, bleeding, allergic or toxic reactions to the substances used, as well as tears or other physical injury. Nerve damage and scarring may also occur if procedures are poorly performed. In relation to cosmetic piercing, a survey carried out in England found that over a quarter of people who had a cosmetic piercing procedure (other than of the earlobes) experienced complications, and around half of those who experienced complications considered them serious enough to seek further help.⁸⁷ The prevalence was higher amongst those aged 16-24, with health problems occurring with around a third of piercings. Although most problems associated with a cosmetic piercing are usually minor and self limiting, some complications are serious enough to require medical attention or admission to hospital, and there are individual cases of significant damage to health.⁸⁸ Poorly performed oral piercings can damage the tongue and teeth, cause airway obstruction through swelling, and affect speech.⁸⁹ Complications can be particularly serious for those with underlying health conditions, and cases of individuals who have died following a cosmetic piercing have been recorded.^{90,91}
111. The risks associated with special procedures can be minimised by taking a number of steps. These include:
- Good cleanliness of the premises where the procedure is taking place, and of the fixtures and fittings;
 - Hygienic practices by practitioners; and
 - Having correct processes in place for cleaning, sterilization or disposal of instruments, materials and equipment.

Current position

⁸⁶ Hayes, MO. Harkness, GA. (2001) Body piercing as a risk factor for viral hepatitis: an integrated research review. *American Journal of Infection Control*. 29, 271-274.

⁸⁷ Bone, A. Ncube, F. Nichols, T and Noah, ND. (2008) Body piercing in England: a survey of piercing at sites other than earlobe. *BMJ*, 336, 1426.

⁸⁸ BBC News online (2007) Belly stud 'almost killed teen' Available at: http://news.bbc.co.uk/1/hi/wales/south_east/7020936.stm

⁸⁹ Whittle, JG and Lamden, KH. (2004) Lip and tongue piercing: Experiences and views of general dental practitioners in South Lancashire. *Primary Dental Care*, 11(3), 92-96.

⁹⁰ BBC News online (2005) Lip piercing death 'misadventure'. Available at:

http://news.bbc.co.uk/1/hi/england/south_yorkshire/4429298.stm

⁹¹ BBC News online (2010) Caerphilly woman's infection death after tongue pierce. Available at: <http://www.bbc.co.uk/news/uk-wales-11543757>

112. Existing legislative controls in relation to special procedures aim to ensure that infection control arrangements are adequate and effectively carried out. The primary means of enforcing these arrangements is by use of the current registration requirements under the Local Government (Miscellaneous Provisions) Act 1982 ('the 1982 Act'). In addition, there are other regulatory controls that contain provisions for the immediate prohibition of activities, or for the control of premises or things where a risk of significant harm to public health can be demonstrated.
113. The creation of a registration scheme under the 1982 Act is not mandatory. In addition, where local authorities have adopted the provisions, enforcement is often inconsistent across Wales. Many local authorities have not yet adopted the most recent Welsh Government model byelaws⁹² relating to the cleanliness and hygiene of premises, practitioners and equipment.
114. Local authorities are however unable to refuse registration under the 1982 Act. Enforcement of the registration requirement also relies on a local authority being able to prove that a person is 'carrying on a business'. This can be difficult as, for example, tattooists may work from home.
115. Registration under the 1982 Act is also not subject to a 'competency test' to require that proprietors and those they employ can demonstrate a level of hygiene and infection control knowledge that is appropriate to the procedure they perform. Neither is there any requirement for consent forms, pre- and post-procedure consultation, aftercare advice or record keeping. It is considered, therefore, that the current registration system does not address the public health concerns and protect the public effectively, and there have been examples of unregistered practitioners being prosecuted.⁹³

Purpose of the provisions

116. In response to the perceived inadequacies with the current system, the Bill seeks to create a compulsory, national licensing system for practitioners of specified special procedures in Wales. The system will mean that in order to perform any of the special procedures defined within the Bill, an individual must be licensed and the premises or vehicle from which they operate approved. Individual licences and approvals will be valid for a period of three years. Temporary licences and approvals will also be available for exhibitions and events. The overall purpose is to ensure that where these special procedures are provided in Wales, they are carried out in a manner which is not potentially harmful to health.

⁹² Welsh Government website:

<http://wales.gov.uk/topics/health/protection/communicabledisease/acupuncture/?lang=en>

⁹³ <http://www.cardiffnewsroom.co.uk/index.php/archive/198-illegal-scratcher-prosecuted>

117. In order to provide for a system which comprehensively protects the public, the Bill provides that a licence will be required for an individual practitioner, and that approval is obtained for any premises/vehicle from which a special procedure is performed. This aims to better meet customer expectations and responds to the different business models within the sector. This approach is intended to ensure that individual practitioners practice to appropriate standards, as well as ensure that special procedures are only carried out in suitable environments.
118. The procedures defined as 'special procedures' for the purposes of the licensing system are:-
- Acupuncture;
 - Body piercing;
 - Electrolysis; and
 - Tattooing.
119. The Welsh Government is aware that the area of special procedures is a quickly evolving one, and is subject to a number of factors including changes in fashion trends. In order to ensure the legislation remains up to date and effective as new procedures are constantly being devised, the Bill provides the Welsh Ministers with a power to amend the list of special procedures. This will be done via secondary legislation, subject to the affirmative procedure.
120. Following the establishment of the licensing system, it will be an offence for a practitioner to conduct any special procedures without a licence or to perform them from premises or vehicles that are not approved. The Bill does provide exemptions to these requirements, for example members of specific professions (such as doctors) will not be required to have a licence to practice special procedures, unless regulations provide otherwise. A power is also available for the Welsh Ministers to exempt members of other specified professions via regulations, subject to the affirmative procedure.
121. The Welsh Ministers will, by way of regulations, set licensing criteria and mandatory licensing conditions, so that standards of practice and enforcement of special procedures are consistent throughout Wales. The licensing criteria will specify, amongst other things, an individual's eligibility for a licence. The mandatory licensing conditions will set out the requirements a licence holder must meet in order to retain their licence, including conditions relating to the standards of hygiene, the way in which special procedures are to be performed, and the information to be provided during pre and post-procedure consultations. The Bill provides that licence holders and proprietors of approved premises/vehicles will be under a duty to meet the requirements and to operate in accordance with the national conditions.
122. The Bill provides that local authorities are to be responsible for enforcing the licensing requirements, and for keeping a register of special procedures licences issued by them that have not yet expired and

premises/vehicles that they have approved. A local authority must make the information on the register open to the public. The Welsh Ministers can arrange for the duties imposed on local authorities (i.e. to keep a register) to be discharged by a single local authority. The single local authority would then keep a central register on behalf of others. The register has the purpose of ensuring that anyone seeking to have one of the defined special procedures can search for information and know that the practitioner or business they choose has met the national standards.

123. In order to support the requirements, the Bill creates a number of requirements and offences. In order to prevent the provision of special procedures without holding a licence, or a non-approved premises/vehicle being used for the provision of special procedures, a local authority can issue a stop notice. The local authority may also take action by issuing a remedial action notice if a licence holder or premises/vehicle contravenes one or more of their applicable mandatory conditions. This notice will order specific action and steps to be taken to rectify the issue within 14 days. The Bill provides local authority officers with the power to enter premises for the purpose of determining applications for licences or approvals, to carry out inspections and to enforce the requirements.

124. If a local authority is satisfied that a licence holder has failed to comply with a mandatory licensing condition, and that there is a significant risk to public health due to their practices, then the Bill provides that it may revoke a special procedure licence, either in full or in so far as it relates to the performance of a particular special procedure. Similarly, the local authority can revoke the premises/vehicles approval. Where the local authority has taken action and for example issued a stop notice, or has revoked a licence/approval or refused an application, an individual has the right to make representations to the local authority and appeal to a magistrates' court against the decision.

Intended effect of the provisions

125. The legislation will institute a system of mandatory licensing for those practitioners who provide special procedures in Wales, to which national standards will be attached and enforced by local authorities. The system aims to drive up standards in relation to the performance of special procedures, and ensure an improved and consistent approach to the regulation of these procedures across Wales.

126. In addition to the benefits associated with improving standards of practice, individuals who wish to have one of the special procedures performed will also directly benefit by having improved access to information about the procedure before it is undertaken, as well as aftercare advice. People seeking to undergo these procedures will be able to access a register of licence holders and approved premises/vehicles for special procedures within their area. This will help improve transparency

and ensure people in Wales are better informed about the practice of special procedures.

127. It is intended that the majority of licence holders who perform special procedures, and the premises/vehicles where they are performed, will gain reputational benefits from the system. By meeting the requirements, they will be able to independently demonstrate to the public that they practice to appropriate standards of hygiene and cleanliness, as well as protecting themselves from health risks by undertaking appropriate infection control procedures. Public confidence and client understanding will be further enhanced by the requirement for practitioners to provide pre- and post-procedure consultations to ensure that people are fully aware of the risks connected with the particular procedure, and how to self-administer any aftercare. This should result in a lower incidence of infection, if the aftercare advice provided is appropriately adhered to.
128. As well as improving client and practitioner safety, the Bill will also provide local authorities with consistent and effective enforcement powers with which to inspect premises/vehicles and, where necessary, prevent unsafe practice.

Intimate piercing

Background

129. As previously indicated above within the section on special procedures, complications following body piercing can include swelling, infection, bleeding, allergy and tear or physical injury. Nerve damage and scarring may also occur if a body piercing is poorly performed. Complications can be particularly serious for those with underlying health conditions, and cases of individuals who have died following a cosmetic piercing have been recorded^{94,95}. In addition, although uncommon, unsafe or unhygienic practices can lead to the transmission of infectious diseases such as blood borne viruses.⁹⁶
130. A study in England found that amongst individuals aged 16-24 complications were reported with around a third of all body piercings⁹⁷. The same study found a higher incidence of complications in connection with certain types of body piercings, including intimate piercings. Problems

⁹⁴ BBC News online (2005) Lip piercing death 'misadventure'.

http://news.bbc.co.uk/1/hi/england/south_yorkshire/4429298.stm

⁹⁵ BBC News online (2010) Caerphilly woman's infection death after tongue pierce. Available at: <http://www.bbc.co.uk/news/uk-wales-11543757>

⁹⁶ Hayes, MO. Harkness, GA. (2001) Body piercing as a risk factor for viral hepatitis: an integrated research review. American Journal of Infection Control. 29, 271-174

⁹⁷ Bone, A. Ncube, F. Nichols, T and Noah, ND. (2008) Body piercing in England: a survey of piercing at sites other than earlobe. BMJ, 336, 1426.
<http://www.bmj.com/content/336/7658/1426>

were most likely to be reported in the case of tongue piercing (50%), followed by piercings of the genitals (45%) and the nipples (38%).

131. Furthermore, as young people continue to grow during their teenage years, an intimate piercing performed at a young age could result in further complications arising as their bodies develop. Young people may also be less likely to have the experience or knowledge of how to clean or maintain an intimate piercing, leading to an increased risk of infection.
132. In addition to the risks to health, the intimate piercing of children and young people may also be considered a child protection issue. By undergoing the procedure, young people may be putting themselves in a vulnerable position by placing themselves in situations in which their 'intimate' areas are exposed to, touched and pierced by an adult who may be previously unknown to them.
133. It is therefore considered that there is a need to strengthen the legislative framework relating to the intimate piercing of children and young people. This is considered necessary to both protect them from potential health harms and threats to their emotional well-being.

Current position

134. In Wales there is currently no age restriction for any body piercing.
135. As a general principle, and where legislation does not provide to the contrary, a young person can give valid consent to a procedure if they are sufficiently capable of understanding the nature of the act to be done. In each case, the question of capacity must be determined in accordance with the *Gillick*⁹⁸ principles.
136. Due to the nature of the procedures and the intimate areas involved, criminal legislation such as the Sexual Offences Act 2003 ('the 2003 Act') may be relevant, particularly offences such as sexual assault. However, an intimate piercing is not automatically a sexual assault or criminal offence. Section 3 of the 2003 Act provides that a person commits an offence of sexual assault if:
- (A) intentionally touches another person (B);
 - the touching is sexual;
 - (B) does not consent to the touching; and,
 - (A) does not reasonably believe that (B) consents.
137. Section 7 of the 2003 Act provides for the offence of sexual assault of a child under the age of 13. Section 7 does not allow for a child to consent to the touching. This essentially means that a child under the age of 13 cannot consent to a sexual assault regardless of their mental capacity or

⁹⁸ *Gillick v West Norfolk and Wisbech Health Authority* [1986] AC 122.

comprehension. However, a person over the age of 13 can legally consent to a sexual assault.

138. In applying the section 7 test, there is no argument that a practitioner of intimate cosmetic piercing would be intentionally touching another person if they were to perform a piercing on them. The question therefore is whether that touching is classed as 'sexual'.
139. The question of whether intimate piercing is 'sexual touching' as defined within section 78 of the 2003 Act depends on how a 'reasonable person' views the activity. If it is not considered to be sexual touching, a child under the age of 13 would be able to consent to the touching; if however it is considered to be sexual touching, then only a person over the age of 13 can consent to it.
140. It is understood from discussions with people within the sector that many practitioners already choose not to perform intimate piercing on young people. However, intimate piercing is not expressly prohibited by law.

Purpose of the provisions

141. The primary purpose of these provisions in the Bill is to protect children and young people from the potential health harms which can be caused by an intimate piercing, and to avoid circumstances where children and young people are placed in a potentially vulnerable situation. The Bill seeks to achieve this by prohibiting the intimate piercing of a person who is under the age of 16 in Wales, in any setting. It will also be an offence to make arrangements to perform such a procedure on a person under the age of 16 in Wales. Intimate piercing is defined within the Bill as the piercing of an intimate body part, including breast (including nipple and areola), penis and vulva.
142. By setting the prohibition at the age of 16, the Bill provisions align with the age of consent for sexual activity. The Bill does not prevent the intimate piercing of persons aged 16 and 17 as this would be considered to be inconsistent with the types of decisions made more generally by people of these ages, such as being able to join the army or learning to drive.
143. The prohibition aims to reinforce existing good practice within the piercing industry. Many practitioners choose not to perform intimate piercings on young people, but because the law does not expressly prohibit it, it is still possible for a person under the age of 16 to undergo these procedures. The Bill will not affect the ability of practitioners who currently choose not to perform intimate piercings on people under the age of 18, from still having such policies in place – it will complement them.

144. The Bill provides that it will be an offence for a person in Wales to perform or make arrangements to perform an intimate piercing on a person who is under the age of 16. This means that a young person would not have to undergo an intimate piercing for an offence to be committed – making arrangements to carry out the piercing is sufficient for an offence to be committed.
145. The fact that a person under the age of 16 may have given their consent will not be a defence. Similarly, it will not be a defence to say that a parent or guardian of the person under the age of 16 consented to the intimate piercing on their behalf.
146. The Bill provides, however, for a ‘due diligence’ defence for a person who offers to perform or performs the intimate piercing. The defence will be that the practitioner took reasonable steps to ensure that the person requesting an intimate piercing was aged 16 or over, such as checking their age.
147. The Bill places a duty on local authorities to undertake enforcement action in relation to the provisions, including bringing forward prosecutions, investigating complaints and taking other steps. These steps may involve communicating with body piercing practitioners to prevent an offence taking place or undertaking ‘test purchasing’ inspections to assess compliance. The local authority must also consider, at least once every 12 months, the extent to which it is appropriate for them to carry out a programme of enforcement action within their area to prevent the intimate piercing of persons under 16 years. The local authority must appoint ‘authorised officers’ for these purposes. In undertaking their programme of enforcement action, the local authority must consult with the Chief Officer of Police who may assist the local authority with the enforcement of the provisions.
148. In order to allow investigations as to whether a practitioner is making arrangements to, or performing intimate piercings on individuals aged under 16, it may be necessary to gain entry to premises from which intimate piercings are carried out. The Bill provides powers of entry to local authority authorised officers and the Police, although access to premises used as a dwelling will require a warrant by a Justice of the Peace. Once the officer or the constable has gained entry, they may undertake an inspection of the premises and obtain copies of, for example, CCTV records or consent documents. The power of entry is accompanied by an associated offence of obstructing an officer from exercising their powers.

Intended effect of the provisions

149. Whilst many practitioners in Wales already choose not to perform intimate piercings on children and young people, the changes brought forward in the Bill will achieve greater clarity and consistency in the law. As such, practitioners should no longer be at risk of complaints from parents

or allegations of improper conduct in relation to this issue. At the same time, young people under the age of 16 will be protected from placing themselves in potentially vulnerable situations.

150. Imposing an age restriction of 16 for intimate piercings in Wales will contribute to the promotion of good health by helping to avoid unnecessary harm. The Bill will do this by seeking to reduce the incidence of body piercing-related complications (including infections and injuries) amongst young people whose bodies are still maturing, and who may be less adept at keeping up with aftercare requirements.

Pharmaceutical services

Background

151. Community pharmacies have an integral role to play in shaping and contributing to improvements in public health. They are located on high streets, in supermarkets and GP practices in villages, towns and city centres across Wales. Many are open six, and occasionally seven days a week. Community pharmacies are generally patients' first and often their most frequent point of contact with a healthcare professional. As such, they are uniquely well positioned to make a wide range of services easily available to local people.

152. There are three main providers of NHS pharmaceutical services in Wales:-

- Community pharmacies;
- Dispensing doctors; and
- Dispensing appliance contractors.

153. There were 714 community pharmacies providing NHS services in Wales as at 31 March 2014.⁹⁹ This compares with 703 at March 31 2004.¹⁰⁰ Evidently, the current arrangements governing NHS pharmaceutical services result in a stable market with little net change in community pharmacy numbers over time. A positive relationship exists between deprivation and pharmacy numbers¹⁰¹, with pharmacies more prevalent in more economically deprived areas, meaning that access is generally better in areas with the greatest need. In addition, NHS dispensing doctors principally serve rural populations.

⁹⁹ <http://gov.wales/statistics-and-research/community-pharmacy-services/?skip=1&lang=en>

¹⁰⁰ Statistics for Wales release (26 November 2009) <http://wales.gov.uk/statistics-and-research/community-pharmacy-services/?lang=en/statistics-and-research/community-pharmacy-services/?tab=previous&lang=en>

¹⁰¹ Hinchliffe A. 2012 Distribution of community pharmacies and deprivation in Wales. Public Health Wales.

154. Around 70 million prescriptions (71.2 million in 2013/14¹⁰²) are dispensed in community pharmacies in Wales every year. Furthermore, pharmacies are high street retailers, routinely visited by people who do not consider themselves to be ill. Each visit is an opportunity to engage with members of the public about their lifestyle and to make a contribution to improving their health.
155. Community pharmacies also provide a convenient and less formal environment for those who cannot or do not wish to visit other kinds of health services. For example, many provide emergency contraception, smoking cessation and sexual health advice, and in 2012, Wales was the first part of the UK to introduce free seasonal influenza vaccination from community pharmacies on a national basis.
156. As at 31 March 2014, 35.6% of community pharmacies were owned by 'independent' contractors¹⁰³ (i.e. those comprised of five NHS premises or fewer), with the remainder owned by larger businesses with six or more NHS premises, including multinationals and supermarkets (referred to as 'multiples'). There has been a trend towards greater market consolidation in the last decade.
157. As at March 31 2014, there were four dispensing appliance contractors in Wales¹⁰⁴ (who can only supply appliances such as incontinence aids and dressings). They are run by small to medium enterprises and often operate a distance-selling model, providing services to other parts of the UK.
158. There are a small number of pharmacies that do not provide NHS pharmaceutical services. These are not directly affected by the changes in the Bill and, as such, are not considered in this Explanatory Memorandum.

Current position

159. The Welsh Government establishes the overall structure in which community pharmacies operate by providing the legislative and policy framework. Within this the responsibility for planning and providing pharmaceutical services is vested in Local Health Boards ('LHBs'), who have responsibility for planning health services to meet the needs of their resident population. This includes determining the number and location of pharmacies in their areas.

¹⁰² Statistics for Wales release (12 November 2014) <http://wales.gov.uk/statistics-and-research/community-pharmacy-services/?lang=en#statistics-and-research/community-pharmacy-services/?lang=en>

¹⁰³ Statistics for Wales release (12 November 2014) <http://wales.gov.uk/statistics-and-research/community-pharmacy-services/?lang=en/statistics-and-research/community-pharmacy-services/?lang=en>

¹⁰⁴ Same as previous reference

160. The general duty to provide NHS pharmaceutical services, as with other aspects of NHS primary care services, is conferred directly on LHBs under the NHS (Wales) Act 2006 ('the 2006 Act'). LHBs manage local lists of approved providers, referred to as 'pharmaceutical lists', and the inclusion of pharmacy premises on pharmaceutical lists entitles the pharmacy to provide NHS pharmaceutical services at those premises. These arrangements govern the provision of NHS pharmaceutical services and not the right to open and conduct a pharmacy business in Wales. This is dealt with under separate UK wide legislation, the Medicines Act 1968.
161. The Welsh Ministers have extensive powers and duties to make regulations and to issue directions to LHBs, which govern the detail of the NHS pharmaceutical services system. This includes specifying the terms of service for NHS pharmacists and the application of the 'control of entry' test, which is the test that must be satisfied before LHBs may grant an application for entry, or amendment to an entry, on their pharmaceutical list.
162. Section 80 of the 2006 Act places a duty on LHBs to make arrangements for the provision of the pharmaceutical services that are set out in subsections 80(3)(a) to (d). These core pharmaceutical services are essentially dispensing services. There is a duty on the Welsh Ministers to make regulations governing the way in which LHBs make these arrangements. All regulations are laid before the National Assembly for Wales using the negative resolution procedure.
163. Section 81 of the 2006 Act sets out arrangements that the Welsh Ministers may make for the provision of additional pharmaceutical services. Additional pharmaceutical services are defined as services of a kind that do not fall within section 80. Section 81 gives the Welsh Ministers the power to give directions to a LHB (i) requiring it to arrange for the provision of additional pharmaceutical services, or (ii) authorising it to arrange for the provision of services if it wishes.
164. Section 83 of the 2006 Act contains the 'core' of the Welsh Ministers' regulation making powers in relation to the provision of pharmaceutical services and, amongst other things, sets out the requirement for regulations to require LHBs to prepare and publish pharmaceutical lists, and sets out the current 'control of entry' test.
165. Section 84 sets out a requirement for the Welsh Ministers to provide for rights of appeal against decisions that are made by LHBs in exercise of powers conferred upon them by regulations made under section 83.
166. The main instruments of subordinate legislation made under powers in the 2006 Act are:

- the Pharmaceutical Services (Wales) Regulations 2013 as amended¹⁰⁵;
- the NHS Pharmaceutical Services (Advanced and Enhanced Services) Directions 2005 as amended;
- the NHS Pharmaceutical Services (Charges for applications) Directions 2013; and
- the National Health Service Committees and Tribunals Regulations 1992 as amended¹⁰⁶.

167. This subordinate legislation describes in detail, amongst other things:

- the procedures by which persons wishing to provide NHS pharmaceutical services apply for inclusion in a pharmaceutical list;
- the procedures which must be followed by a LHB in determining such applications;
- the rights of appeal against the decisions of a LHB;
- the terms of a person's inclusion in the pharmaceutical list; and
- the procedures to be followed by LHBs when dealing with breaches of terms of service.

168. Since the late 1980s, applications for entry onto a pharmaceutical list (or applications to change an existing entry) have been determined by LHBs (or their predecessor health bodies) by applying what is commonly known as the 'control of entry' test. This is set out in Section 83 of the 2006 Act. Broadly speaking, an application will only succeed if a LHB considers it 'necessary or expedient' to grant it in order to secure (in the neighbourhood to which the application relates), the adequate provision of NHS pharmaceutical services. This test has been subject to considerable review by the courts, whose decisions have established various precedents and criteria as to how LHBs should apply the test when considering applications.

169. The NHS Pharmaceutical Services (Wales) Regulations 2013 set out the current 'control of entry' arrangements. In addition to setting out the conditions under which pharmacists can apply to provide NHS pharmaceutical services, and the terms and conditions under which those services will be provided, the regulations make special provision for areas that are 'rural' in character and they prescribe the circumstances in which, in those areas, doctors can apply for and be granted the right to provide pharmaceutical services to their patients. These are commonly known as 'dispensing doctors'.

170. The current regulatory regime and approach has been in place for over 25 years and does not adequately reflect the way in which the role of pharmacies has changed in that time. In the last ten years community pharmacy numbers in Wales have been largely unchanged, however

¹⁰⁵ S.I. 2013/898

¹⁰⁶ S.I. 1992/664

prescription volumes have grown by over 40% (from 54.0 million in 2004 to 76.2 million in 2013).

171. Under the current arrangements, when determining applications LHBs only consider the pharmaceutical services defined under section 80 of the 2006 Act. Broadly speaking this relates only to the dispensing of prescriptions. The onus on deciding when, and in relation to which areas applications to provide pharmaceutical services are made, rests with applicants.
172. However, community pharmacies also increasingly provide additional services. As set out above, these additional pharmaceutical services are covered under section 81 of the Act and are provided for by way of directions. They include the provision of emergency contraception, influenza vaccinations and support to stop smoking.
173. Decisions as to whether pharmacies are allowed to provide NHS pharmaceutical services are made on the basis of whether there is adequate access to pharmacies for the dispensing of prescriptions, and not on whether these additional services are offered or needed. This has the effect that pharmacies wishing to offer additional services are unable to enter the market, because the market entry test fails to recognise the additional services they wish to offer and whether those services would support addressing local health needs.
174. Finally, there are existing provisions in the 2006 Act which allow a LHB to remove a person from a pharmaceutical list where there are fitness to practice concerns. These fitness matters are set out in section 107(2),(3) and (4) of the NHS Wales Act 2006 and relate to situations where it is determined that a person is no longer fit to be included in the pharmaceutical list for reasons of fraud, unsuitability or efficiency of service provision. There are no express powers to remove a person or an entry in respect of premises from a pharmaceutical list on other grounds¹⁰⁷.

Purpose of the provisions

175. In order to maximise the public health role of community pharmacies, the Bill seeks to make a fundamental change to the way in which decisions about pharmaceutical services in Wales are made by LHBs, shifting from one driven by applications from pharmacy contractors and focused heavily on the dispensing of prescriptions, to one which is alert and responsive to the broader pharmaceutical needs of local communities.
176. The aim of the provisions is to improve the planning and delivery of pharmaceutical services in Wales. The Bill principally achieves this by amending the 2006 Act to require each LHB to prepare and publish an

¹⁰⁷ Apart from those set out in section 83(6)(d) of the 2006 Act

assessment of the need for pharmaceutical services in its area (a so called 'pharmaceutical needs assessment' or 'PNA'), to keep the PNA under review and revise it as appropriate. The Bill also amends the current 'control of entry' test set out at section 83 of the 2006 Act. It moves away from the current test which is determining applications by reference to whether or not it is 'necessary or expedient' to approve the application, to an assessment that is based on whether, having regard to its most recent PNA and to any matters that are specified in regulations, it is satisfied that to grant the application would meet a need in its area for services or some of the services specified in the application.

177. The above essentially provides for decisions about the location and extent of pharmaceutical services available in a LHB's area to be determined on the basis of those assessments. The provisions also aim to improve the quality of pharmaceutical services by encouraging existing pharmacies to adapt and expand their services in response to local needs.

178. The Bill gives the Welsh Ministers the power to set out in regulations the information that must be included in a PNA. It is intended that regulations will require a PNA to detail the current provision of pharmaceutical services, identify the pharmaceutical needs of its population and areas where pharmaceutical services do not meet needs, and where action is needed to ensure adequate provision. This could include describing the nature of pharmaceutical services required by particular areas.

179. The first PNAs will be produced in accordance with a timetable set out by the Welsh Ministers in regulations. The regulations will ensure that the timing of subsequent PNAs will be arranged so as to coincide with the frequency of wider needs assessments, in particular the local well-being assessments provided for by the Well-Being of Future Generations (Wales) Act.

180. Applications from persons wishing to provide pharmaceutical services in the LHB area will then be determined against the PNA. Therefore, pharmacies would be permitted to provide NHS pharmaceutical services if they are able to demonstrate that in doing so they will meet a particular unmet local need or service requirement identified in an LHB's PNA.

181. The Bill will also provide LHBs with a power to address gaps in pharmaceutical service provision, as identified in the LHB's PNA, by allowing the Welsh Ministers to specify in regulations the circumstances in which a LHB may invite applications for the provision of pharmaceutical services. The regulations could, for example, specify that LHBs are able to invite applications to provide pharmaceutical services in areas where there are identifiable unmet pharmaceutical needs, but the LHB is not in receipt of any applications to provide pharmaceutical services.

182. Alongside the changes to introduce a system of needs-based entry, an exit regime will also be introduced that enables graduated actions to be

taken to deal with those providers who are failing to meet their terms of service obligations – and who may therefore be receiving NHS remuneration whilst inadequately fulfilling their contractual obligations. It is intended to commence the existing provisions in section 106A of the 2006 Act, which enables the Welsh Ministers to set out in regulations a system of notices and penalties which apply where pharmacists breach their terms and conditions of service with a LHB. This will be coupled with a new power in the Bill which enables the Welsh Ministers to set out in regulations the grounds or circumstances in which a LHB may remove a pharmacist or premises from a pharmaceutical list.

183. It is intended that regulations will set out that a LHB will be able to remove a pharmacy or premises from the pharmaceutical list, in cases where local resolution has failed and where a pharmacist has failed to comply with notices issued to it by the LHB setting out action it needs to take to comply with the terms and conditions of service. The Bill provides that the Welsh Ministers must set out in regulations that a LHB is under a duty to notify a pharmacist about its intention to remove them from its list and the reasons for the intended removal, before a decision to remove is made. The pharmacist will be granted the right to make representations to the LHB before a decision is made. Regulations will also confer a right of appeal to the Welsh Ministers against a decision of a LHB to remove a pharmacist or premises from a pharmaceutical list.

Intended effect of the provisions

184. The intended effect of the legislation is to improve the planning and delivery of pharmaceutical services by ensuring that LHBs robustly consider the pharmaceutical needs of their populations and align services more closely with them. This will require LHBs to take a more integrated approach to identifying the pharmaceutical needs of populations, including considering the contribution of all pharmaceutical services providers (e.g. pharmacies and dispensing doctors). LHBs will use these assessments to identify where additional pharmacies are required, where existing providers are adequately addressing pharmaceutical needs, and where additional services are required from existing pharmacies.
185. The changes will provide pharmacy contractors with increased certainty, reducing business risk and allowing them to invest in the delivery of wider services.
186. A further intended effect of the legislation is that pharmacies will be more responsive to the needs of the populations they serve, and provide services effectively to address identified pharmaceutical needs. Where there is a lack of quality or consistent delivery, LHBs will be able to implement improvement measures. These could include taking action against particular pharmacies for persistent breaches of terms and conditions of service, or inviting additional pharmacies to apply to provide particular services. This should result in pharmacies providing services

more consistently and to a higher standard, and ensure that pharmacies provide services in locations where they are needed. These changes will also make decisions about the entry of new pharmacies more transparent.

187. Ultimately, the changes provided for in the Bill will allow for gradual improvement in the quality and consistency of NHS pharmaceutical services.

Provision of toilets

Background

188. Provision of, and access to, toilets is an issue that affects public health. Accessible, clean toilets that are well located in places such as town centres, parks, promenades, cycle trails and walking routes can help encourage the public to take exercise and stay more physically active. This has clear health and economic benefits. Conversely, toilets that are poorly designed, inadequately maintained and inadequately located can create an atmosphere of neglect that discourages public use. A lack of adequate toilet facilities can also impact on an individual's physical and mental health, as well as affecting the wider environmental health of the population.
189. Toilets for public use matter to everybody and remain a high-profile issue. They are, however, even more important to certain groups within society, including older people, disabled people, people with particular needs (including certain medical problems), women, children and young people and their families. These groups can be disproportionately affected by poor provision. For example, poor provision is understood to have particular negative impacts on older people, as some may be less likely to leave their homes without having confidence that adequate facilities will be available to them. This can contribute to increased social isolation and inactivity, as well as affecting people's ability to maintain independence and dignity in later life.
190. In 2007, Help the Aged (now Age UK) published a report entitled *Nowhere to go – Public Toilet Provision in the UK*¹⁰⁸. This summarised a survey of older people's views on public toilet provision in their areas, and showed that more than half of older people found that a lack of public toilets prevented them from going out as often as they would like.
191. The House of Commons' Communities and Local Government Committee examined the evidence on the provision of public toilets in

¹⁰⁸ http://www.ageuk.org.uk/documents/en-gb/for-professionals/communities-and-inclusion/id6256_nowhere_to_go_public_toilet_provision_in_the_uk_2007_pro.pdf

England and published its report, *The Provision of Public Toilets*, in 2008¹⁰⁹.

192. The Committee recommended that “...*the Government imposes a duty on each local authority to develop a strategy on the provision of public toilets in their areas, which should include consultation with the local community and which should be reviewed annually. The duty of compiling and reviewing a public toilet strategy is a simple requirement that will go a long way towards achieving the right of people who live in and visit this country to have accessible and clean public toilets, wherever they live, work or visit. The way in which local authorities plan and utilise their own strategic plan is a decision for them; the fact that they have a plan should be a duty placed on them by the Government.*” (recommendation 26).
193. In the same report the Committee explained that: “*our public toilet provision should not be allowed to decline at the current rate because of neglect arising from the lack of any clear strategy*”. The UK Government responded to the report in January 2009 and declined to implement the recommendation to impose a duty on local authorities to develop strategies on the provision of public toilets.
194. The National Assembly for Wales’ Health and Social Care Committee conducted a short inquiry into the public health implications of inadequate public toilet facilities in Wales in 2012. The Committee concluded in its report¹¹⁰ that there is a strong public health case for better public toilet provision, and that a set of potential practical solutions exist which could, if implemented, lead to improved local provision of public toilets. Suggested solutions included ensuring that local authorities make the most of existing resources, charging for use, making toilet facilities within public buildings available for public use, and the introduction of a strategy for Wales to ensure that public toilets are accessible to all.
195. In November 2013, a short debate took place in the National Assembly for Wales on the importance of public toilets¹¹¹. During the debate the Welsh Government acknowledged the importance of public toilets, and indicated that provision should remain a priority and that all possible efforts should be made to sustain it.
196. The Welsh Government has previously sought to find creative solutions to help improve the provision of local toilets. The Public Facilities Grant Scheme was initially established in 2009/10 for three years to increase the provision of free public access to toilet facilities in Wales. This sought to improve the quality and accessibility of facilities by encouraging local

¹⁰⁹ The House of Commons, Communities and Local Government Committee Twelfth Report of Session 2007–08 ‘The Provision of Public Toilets’ printed 6 October 2008. Available at: <http://www.publications.parliament.uk/pa/cm200708/cmselect/cmcomloc/636/63602.htm>,

¹¹⁰ <http://www.senedd.assemblywales.org/mglIssueHistoryHome.aspx?IId=2572>

¹¹¹ National Assembly for Wales Short debate: A public inconvenience – why public toilets are important. 13 November 2013. Available at: http://www.assemblywales.org/docs/rop_xml/131113_plenary_english.xml

authorities to work in partnership with local businesses to allow public access to their facilities. The scheme was extended annually from April 2012 before the funding (£200,000) was transferred into the Revenue Support Grant from 2014/15. It is now for each local authority to decide how this funding is utilised to deliver the range of services it is responsible for in order to meet the needs and priorities of its communities.

197. This issue is not unique to Wales. Major cities around the world, including Melbourne, Australia¹¹², have identified public toilet access and provision as a key issue, and have developed strategies to address it.

Current position

198. It is known that public toilet provision currently varies between local authorities. Discussions also indicate that there are pressures around the provision of facilities, leading to reductions in the number of public toilets in Wales in recent years.
199. The current legal position in relation to toilet facilities is set out in various pieces of primary and subordinate legislation. The provision and maintenance of toilets in public places is at the discretion of local authorities, including community councils, who have the power, under section 87 of the Public Health Act 1936, to provide public conveniences, but no duty to do so. Section 87 also allows local authorities to charge for the use of the toilets that they provide.
200. A local authority has power under section 20 of the Local Government (Miscellaneous Provisions) Act 1976 to require toilets to be provided and maintained in any place providing entertainment, exhibitions, sporting events, and places serving food and drink for consumption on the premises. A local authority may also use powers under section 106 of the Town and Country Planning Act 1990 to make an agreement with a developer for the provision of toilets as part of the approved development.
201. Where a local authority is a highway authority for a particular highway, section 114 of the Highways Act 1980 provides that it may provide public sanitary conveniences (including lavatories) in proper and convenient situations, and may manage such conveniences.
202. Whilst the current legislative framework enables local authorities to make provision for toilets, there are no legislative requirements on them to do so. It is for individual local authorities to decide whether or not to provide public toilets and, if so, how many. In doing this, each local authority must balance competing local demands for a broad range of

¹¹² City of Melbourne, Public Toilets Plan. Available at:
<http://www.melbourne.vic.gov.uk/AboutCouncil/PlansandPublications/strategies/Pages/PublicToiletPlan.aspx>

public services against the need to avoid excessive burdens on local taxpayers.

203. The current system governing provision and access to public toilets poses a number of significant challenges. These can be summarised as follows:-

- The provision and maintenance of public toilets in Wales is at the discretion of local authorities, meaning provision in Wales varies according to local authority;
- There is poor planning around making the best use of toilets already accessible to the public within public buildings, for example those in public libraries, community and town halls, sports centres and museums;
- The provision and maintenance of public toilets in Wales is a considerable cost to local authorities and, as a consequence, provision is declining and toilets are under threat of closure across Wales;
- Public toilets that are poorly designed, inadequately maintained and poorly located can create an atmosphere which attracts vandalism, graffiti, criminal damage and anti-social behaviour (which increase costs even further for local authorities); and
- The previous Public Facilities Grant Scheme was limited in that it focused purely on improving public access to toilets within private establishments.

Purpose of the provisions

204. The aim of the provisions is to improve planning of provision of toilets available for use by the public by ensuring each local authority in Wales assesses the needs of its community in relation to toilets, and then takes a strategic and transparent approach to best meet that need. This is intended to address the current challenges regarding the provision of these facilities within communities.

205. To achieve this, the Bill places a duty on each local authority in Wales to prepare and publish a local toilets strategy for its area. The Bill provides that this strategy must include an assessment of the community's need for toilets, including changing facilities for babies and changing places facilities for disabled persons, as well as details of how the local authority proposes to meet that need. There is no requirement for the strategies to be presented to the Welsh Government for approval, as instead there is an expectation that the strategies will be subject to local authorities' existing scrutiny structures.

206. The duty to prepare a local toilets strategy will not in itself require local authorities directly to provide and maintain public toilets, but will require them to take a strategic view across their area on how these facilities can be provided and accessed by their local population. In doing so it is envisaged that local authorities will consider a full range of options for making facilities available to the public. An illustration of this process is if a public toilet is not available at a park but a local authority identifies a need for one, then the local authority should consider different ways of ensuring that the need is met. This could be by the local authority directly providing the facility, but equally could be met in other ways, such as the local authority working with a private business within or near to the park to make their facilities available to the public.
207. The Bill's provisions on local toilets strategies are ultimately intended to benefit local communities across Wales. Accordingly, the provisions seek to ensure that appropriate engagement with communities takes place as part of the development of the strategies, and that the process takes place in a manner which is both transparent and supports local accountability.
208. Local authorities will therefore be required to consult with interested parties on their draft strategies and to publish their final strategies so that they are available to be viewed. Whilst the Bill does not prescribe the format of the consultation process, it is expected that local authorities will take an inclusive approach in order to ensure appropriate engagement across their communities.
209. The Bill provides a clear framework to govern the timescales for the production of the new local toilet strategies. In order further to support local accountability, this is closely aligned to the cycle for local government elections. The Bill also provides the framework for how and when the local strategies should be reviewed, and contains detail about what should be included as part of any review.
210. In order to provide local authorities with the flexibility to respond to changing circumstances, they will be able to review the strategies at any time. The Bill also provides for a mandatory review period, which is again intended to align with the cycle for local government elections and local plans provided for in other legislation, in order to both reduce unnecessary bureaucracy and ensure a coherent approach to planning at community level. The importance of ongoing engagement with local communities is upheld within these provisions, through a requirement for any revised strategy to be published.
211. As it is recognised that there will be numerous considerations relevant to local authorities in developing their strategies, the Bill provides that the Welsh Ministers will be able to issue guidance on this matter. Local authorities will then be required to have regard to any guidance produced. It is currently envisaged that topics which could be covered by guidance may include further detail around expectations for local consultation and engagement, publicising the toilets that are available in the local

authority's area for use by the public, as well as guidance about the broader range of options which a local authority should consider for providing access to toilets for the public, in addition to traditional stand-alone 'public toilets'. This will include, for example, facilities in settings which are already in receipt of public funding, such as sports centres, libraries and other similar amenities.

212. In recognition of the importance of ensuring that the needs of different groups of people across communities are considered through local toilet strategies, the Bill explicitly provides that the term 'toilets' includes changing facilities for babies and changing places facilities for disabled persons.

213. For clarity the Bill also repeals and restates existing local authority powers to provide public toilets.

Intended effect of the provisions

214. The legislation aims to result in improved planning of toilets that are available to the public, which better meets the needs of local communities. The process of preparing the local toilets strategies will enable a broader consideration of options available for providing toilets for use by the public, ranging from traditional stand-alone 'public toilets' through to new and creative solutions. The Bill will also increase local engagement and transparency in relation to this issue.

215. The intended effect of the legislation is not to prevent local authorities from taking decisions which they need to take during the course of their activities, which may include decisions to close certain facilities when appropriate to do so. Instead, the intended effect is to improve the planning of provision so that any such decisions are taken within the overall context of meeting the community needs which they have identified. This will also mitigate the impacts of changes to provision.

4. Consultation

216. The foundations for the preparation and development of this Bill were set in 2012. Following the commitment to consult on the need for public health legislation, a Green Paper was published by the then Minister for Health and Social Services,¹¹³ which explored whether legislation could help efforts to further improve overall health and well-being in Wales. The Green Paper referenced a number of broad challenges facing public health in Wales, including the need to do more to prevent ill health occurring in the first place, and asked whether legislation would provide an effective way of making further progress in key areas.
217. A total of 371 responses were received to the Green Paper and a summary of the responses was published in May 2013.¹¹⁴ A clear majority of respondents supported the idea that legislation could make a positive contribution to further improve and protect health. The responses indicated support for two distinct approaches to public health legislation: one for an overarching approach requiring organisations to consider health across their functions, and the other for a targeted approach aimed at addressing specific public health challenges.
218. The response to the Green Paper informed the development of an approach to public health legislation which responded to both of these messages. Firstly, it was recognised that the Well-being of Future Generations (Wales) Bill¹¹⁵ provided opportunities to ensure health considerations form a central part of the overall legislative framework for the public service in Wales. This Bill as approved by the National Assembly for Wales provides seven well-being goals which public bodies in Wales will need to align themselves to. They include the specific goals of 'a healthier Wales' and 'a more equal Wales', with the other goals also playing an important role in furthering the public health agenda.
219. Secondly, developmental work took place to arrive at a series of legislative proposals for addressing specific public health concerns. These were developed and consulted upon in a Public Health White Paper, and now form the basis of the Public Health (Wales) Bill.

Public Health White Paper

220. The Public Health White Paper entitled *Listening to you: Your health matters*¹¹⁶ was published in April 2014. This brought together a series of distinct yet related proposals for addressing priority public health issues through preventative approaches. The proposals were presented under

¹¹³ <http://wales.gov.uk/consultations/healthsocialcare/publichealth/?lang=en>

¹¹⁴ <http://wales.gov.uk/consultations/healthsocialcare/publichealth/?lang=en>

¹¹⁵ <http://wales.gov.uk/topics/sustainabledevelopment/future-generations-bill/?lang=en>

¹¹⁶ <http://wales.gov.uk/consultations/healthsocialcare/white-paper/?lang=en>

three broad themes of improving health across the life course; building community assets for health; and regulation for health.

221. The proposals related to:

- establishing a national tobacco retailers' register requiring businesses to inform enforcement authorities if they sell tobacco;
- restricting the use of electronic cigarettes in enclosed public places;
- considering the creation of an offence of delivering tobacco products to a person aged under 18;
- strengthening the role of LHBs in planning and delivering the number, location and type of pharmaceutical services required to meet the needs of their communities;
- requiring local authorities in Wales to develop a strategy to address the provision of and access to toilets for public use; and
- introducing a National Special Procedures Register, to cover acupuncture, body piercing electrolysis and tattooing.

222. The White Paper also consulted on other proposals, namely the introduction of minimum unit pricing for alcohol sold and supplied in Wales ("MUP"), the introduction of nutritional standards in specified settings, and banning smoking in certain open spaces (such as hospital and school grounds).

223. The Welsh Government intends to take forward proposals on MUP separately to the Public Health (Wales) Bill, and so the consultation responses to that element of the White Paper are not summarised in this Explanatory Memorandum. The White Paper also made it clear that, if progressed, the nutritional standards proposals would be taken forward by way of secondary legislation and/or guidance. The proposals do not therefore form part of the Bill and, as such, they are not covered in this Explanatory Memorandum. Finally, while the Bill provides the Welsh Ministers with a power to make certain open spaces in Wales smoke-free in the future, it does not explicitly ban smoking in prescribed open spaces. As such, this chapter does not include a detailed overview of the responses to that element of the White Paper.

224. A total of 713 responses to the White Paper were received, and a consultation summary report was published in November 2014.¹¹⁷ Responses were drawn upon in the course of the development and refinement of the legislation. The responses were received from the following:-

Table 4.1: Responses to the Public Health White Paper, by type of respondent

Type of respondent	Number	Percentage of total response
Academic/Research bodies	8	1.2%

¹¹⁷ <http://wales.gov.uk/consultations/healthsocialcare/white-paper/?lang=en>

NHS organisations	15	2.2%
Health related organisations	22	3.3%
Local government	55	8.2%
Advisory groups	7	1.0%
Voluntary sector organisations	34	5.0%
Representative groups	48	7.1%
Private sector organisations	36	5.4%
Private individuals	434	64.6%
Specific responses to Youth Friendly version	39	5.5%
Specific responses to Easy Read version	2	0.1%
Others	13	1.9%
Total	713	100%

225. In general terms the consultation responses illustrated support for the role of legislation in improving and protecting health. They represented a full spectrum of views, ranging from arguments that the proposals should be extended and taken further, through to calls for more modest reform.

226. The nature of responses to the White Paper also varied significantly. Whilst some focused on single issues, others provided detailed comments on the full range of proposals. Differing views were offered for each of the proposals, with those relating to limiting the use of electronic cigarettes in enclosed public places attracting the most divided response.

227. Some of the most common overall themes and trends arising from the responses included:

- Levels of support for individual proposals often varied according to sector; for example health organisations and local authorities were generally supportive of most proposals, but in some cases there was opposition from bodies representing particular groups or interests;
- A number of respondents, whilst supportive of the policy intent, expressed reservations regarding implementation, including the potential implications for local government;
- A number of respondents (primarily health-related organisations) commented that the White Paper had in their view lost some of the aspiration shown in the previous Green Paper, due to its focus on practical actions in discrete policy areas; and
- Some respondents expressed disappointment that the White Paper did not include specific proposals in additional policy areas relevant to public health, such as mental health and physical activity.

228. A series of public engagement events and stakeholder meetings were held to coincide with the White Paper consultation. These are summarised in the consultation summary report, and have been supplemented by further informal engagement with key stakeholders beyond the formal consultation period.

229. A brief overview of the written responses to the White Paper for each policy proposal in the Bill is provided in the following paragraphs. These are intended to provide a flavour of the response, but should be considered in the context of the additional detail available in the consultation summary report.

Limiting the use of electronic cigarettes in enclosed public places (this relates to Part 2, Chapter 1 of the Bill - 'Smoking and use of nicotine inhaling devices')

230. 525 responses were received in respect of this proposal. This included 271 copies of an identical letter from private individuals stating general opposition on the basis that e-cigarettes are a safer alternative to smoking, are a good aid to smoking cessation, and that banning their use in public places would force users outside into the proximity of second-hand smoke.

231. All of the LHBs in Wales and Velindre NHS Trust supported the proposal, as did Public Health Wales, local authority enforcement teams and their representative organisations. Responses from voluntary sector organisations and representative groups were mixed, whilst all responses received from e-cigarette and tobacco companies opposed the proposal. Responses often referred to specific examples of research on both sides of the debate, as well as local and personal experiences.

232. Respondents' overall position either in favour or opposed to restricting the use of e-cigarettes in enclosed public places was generally reflected in their responses to the consultation questions on specific issues. The consultation questions focused primarily on whether the use of e-cigarettes in enclosed public spaces:-

- undermines the current smoking ban and makes it more difficult to enforce;
- normalises the act of smoking; and
- acts as a gateway to the use of conventional tobacco products.

233. An extensive number of arguments was provided to support views on both sides of the debate for each of these issues. Further information on the range of arguments put forward is provided in the consultation summary report.

234. The White Paper also asked for views about potential exemptions and penalties for a ban on the use of e-cigarettes in enclosed public places. The majority of respondents who provided comments suggested that exemptions should mirror those of the Smoke-Free Regulations 2007 ('the

2007 Regulations'), in order to help achieve consistency of enforcement. Responses on the issue of penalties were more mixed, with responses varying from those suggesting that penalties should mirror those of the 2007 Regulations, to those arguing that e-cigarettes are different products to conventional cigarettes and that any penalties should be considered in their own right.

235. In addition to comments directly addressing the proposal, respondents also offered broader comments relating to e-cigarettes. A high proportion of these related to the additional regulation of e-cigarettes, and the need for further research. A number of respondents on both sides of the debate expressed support for new age of sale restrictions being introduced in Wales through regulations arising from the UK Government's Children and Families Act 2014. Other comments included references to the potential impact of the proposal on e-cigarettes licensed as medicines, and concerns related to the safety of e-cigarettes.

Tobacco retailers' register (relates to the Part 2, Chapter 2 of the Bill - 'Register of retailers of tobacco and nicotine products')

236. 119 responses were received in respect of the tobacco retailers' register proposal. The majority indicated broad agreement that the introduction of a retailers' register would be helpful both in assisting in attempts to reduce under age sales of tobacco, and in assisting in the enforcement of the existing display ban. The minority of respondents who generally opposed the proposal were primarily from the private sector, including some retailers' representatives and a number of tobacco and e-cigarette companies. The principal concerns related to the registration of street traders and a view that a register could inadvertently increase the level of sales of illegal tobacco.
237. The registration fee structure proposed in the White Paper attracted a mixed response. Whilst a number of respondents agreed with the structure which was presented, others felt it would not result in a full cost recovery for the organisation tasked with managing and administering the register. Conversely, a small number of respondents commented that the proposed fee structure was too high, and that admission to the register should be either free of charge or lower than the level proposed.
238. The most commonly supported enforcement and penalty regime for the register was that of local authority trading standards officers, taking into account their ability to make applications for Restricted Sales Orders (RSOs) and Restricted Premises Orders (RPOs). A number of respondents emphasised the importance of having a method in place to ensure that retailers are required to keep the register updated with correct information, and offered specific suggestions for how this could be achieved.

239. A number of respondents suggested that a national retailers' register should also cover retailers of Electronic Nicotine Delivery Systems (ENDS) such as e-cigarettes.

Internet sales of tobacco (this relates to Part 2, Chapter 4 of the Bill - 'Handing over tobacco etc. to persons under 18')

240. 104 responses were received in respect of this proposal. Respondents commonly felt there are likely to be problems connected with persons aged under 18 receiving a delivery of tobacco products purchased online by an adult, and that legislation would therefore be appropriate. Amongst these, some specific concerns were expressed that existing age verification checks are not sufficiently robust.
241. A number of respondents stated that they were either unaware or unable to find evidence of there being a problem in this area; although it was also suggested that current mechanisms would not allow such a problem to be easily identified.
242. Amongst responses which did not favour legislation, these most commonly referred to a lack of available evidence in this area, as well as a preference for other forms of action for ensuring tobacco products are not delivered to persons aged under 18.

National Special Procedures Register (this relates to Parts 3 and 4 of the Bill – 'Special Procedures' and 'Intimate Piercing')

243. 102 responses were received in respect of this proposal. The majority felt that current information, regulation and enforcement in relation to acupuncture, tattooing, semi-permanent skin colouring, cosmetic piercing and electrolysis do not protect the public effectively. This was a consistent message across responses from local authorities and LHBs.
244. A clear majority of respondents supported the establishment of a National Special Procedures Register, as this was commonly felt to have potential for achieving consistency of approach across Wales, helping individuals to make informed choices when deciding who to go to for a particular procedure, and ensuring practitioners and premises meet certain standards. There was also general agreement that local authorities would be best placed to administer and enforce the register.
245. A number of respondents suggested that additional procedures should be considered for inclusion on the register. A wide number of procedures were referenced, including dermal fillers, chemical peels, colonic irrigation, botox, scarification, branding, implants and tongue splitting. Conversely, some respondents argued that acupuncture should not be included on the register due to the other forms of regulation in operation in that area.
246. A number of specific points of detail were addressed by the consultation questions. In response to these the majority of respondents

commented that it would be appropriate for the Welsh Government to be able periodically to amend the list of procedures covered by the register, in order to ensure it remains fit for purpose. A variety of views were offered in relation to registration fees, with a majority favouring a national approach and setting fees at a level which would not be prohibitive for small businesses and individual practitioners.

247. Amongst the other issues covered, a range of suggestions were provided for how frequently practitioners and businesses should be required to re-register, as well as suggestions for the composition of a 'fit and proper persons' test. Specific suggestions were also provided on information which could be covered by mandatory pre-and post-procedure consultation discussions.

248. The White Paper also continued previous discussions regarding the evidence of harm caused by cosmetic piercing, particularly the intimate cosmetic piercing of young people. Whilst the majority of respondents provided comments regarding health risks associated with cosmetic piercing in general, a number also strongly advocated a prohibition on the intimate cosmetic piercing of children and young people.

Better planning and delivery of public health services through community pharmacy (this relates to Part 5 of the Bill - 'Pharmaceutical Services')

249. 96 responses were received in respect of this proposal. The responses indicated broad support for the proposal, with common agreement that community pharmacies could play a stronger role in promoting and protecting health as part of a network of local health care services. A number emphasised that community pharmacies are locally based and convenient for the public to access, and also referred to the services community pharmacies currently provide which promote and protect public health.

250. A majority of respondents indicated that undertaking pharmaceutical needs assessments would result in better planning and delivery of pharmacy services. This view was apparent in responses from LHBs, Public Health Wales, pharmacy contractors, representative organisations and individual pharmacists. A number of suggestions were offered for how assessments could be carried out consistently and to best effect, as well as suggestions for what should be incorporated in a pharmaceutical needs assessment and the frequency of the assessments.

251. Specific consultation questions covered a range of points of detail in relation to the provision of pharmaceutical services within an area. For example, these covered issues such as the ability of LHBs to invite additional pharmacies to be established in order to meet locally identified pharmaceutical needs, and the availability of sanctions to LHBs to support improved quality and consistency. Such elements of the proposal attracted broad general support, although there was an emphasis on the need for any sanctions to be reasonable and proportionate.

252. Amongst the general reservations expressed in relation to the proposal, these most commonly referred to the need to avoid unnecessary complexity or onerous bureaucracy.

Local authority strategies on the provision of and access to toilets for public use (relates to Part 6 of the Bill - 'Provision of toilets')

253. 120 responses were received in respect of this proposal. The majority favoured the introduction of a duty on local authorities in this area and commonly referred to the need to safeguard provision in times of austerity.

254. Responses from health organisations, community councils, representative organisations and members of the public indicated broad support for the proposals. A number referred to the potential health impacts associated with poor public toilet provision, and responses from representative organisations referred to the particular impacts which poor provision can have on the groups they represent.

255. Whilst responses from the local government sector recognised the importance of the issue, the majority did not favour the imposition of a duty to develop a strategy on this issue, due to concerns regarding the current financial climate facing local authorities. Conversely, a number of respondents felt that a local authority strategy on this issue would not in itself be sufficient, and suggested that the proposed duty should go further by requiring the provision of adequate facilities.

256. Amongst the other issues raised, respondents commented on the need to think of creative solutions in order to secure improved provision, the importance of involving local communities in local needs assessments, and the effectiveness of the previous Public Facilities Grant Scheme.

Other consultations

Consultation on how to make cosmetic piercing safer for young people

257. Following a commitment to consult on how to make cosmetic piercing safer for young people, a consultation document was published in 2011.¹¹⁸ 228 responses were received and a summary of responses was then published.¹¹⁹

258. As a result of further policy work and consideration, elements of the previous proposal (such as that relating to a standardised consultation for all cosmetic piercing) were taken forward through the broader proposal for a National Special Procedures Register, which was consulted upon in the subsequent Public Health White paper. This was in recognition that the

¹¹⁸ <http://wales.gov.uk/consultations/healthsocialcare/cosmetic/?lang=en>

¹¹⁹ <http://wales.gov.uk/consultations/healthsocialcare/cosmetic/?lang=en>

wider issues of improved regulation, information and enforcement apply more widely than just the cosmetic piercing industry.

259. In recognition of the ongoing support for restrictions in relation to the intimate piercing of children and young people which was illustrated in responses to the Public Health White Paper, this issue has also been addressed in the Public Health (Wales) Bill.

5. Power to make subordinate legislation

260. The Bill contains provisions to make subordinate legislation. The table on the following pages sets out, in relation to each provision in the Bill:

- (i) The person upon whom, or the body upon which, the power is conferred;
- (ii) The form in which the power is to be exercised;
- (iii) The appropriateness of the delegated power; and
- (iv) The applied procedure - that is whether the regulations are subject to “affirmative”, “negative”, or “no procedure”, together with reasons why that procedure or lack of is considered appropriate.

261. The Welsh Government will consult on the content of the subordinate legislation when and where it is considered appropriate to do so.

262. Where the Bill confers powers for subordinate legislation to prescribe technical matters of detail which may change from time to time, it is considered that the negative procedure is the most appropriate. Where a power contained in the Bill confers significant powers of decision making on Welsh Ministers, a power to amend or repeal an enactment contained in primary legislation or to impose a financial burden on the public, it is considered that the affirmative procedure is the most appropriate procedure.

Section or Schedule of Bill	Power conferred on	Form	Appropriateness	Procedure	Reason for procedure
Part 2 – Tobacco and Nicotine Products					
Chapter 1 – Smoking and use of nicotine inhaling devices					
2(2)(b)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to exempt a device, or a description of device, that would otherwise fall within the definition of nicotine inhaling devices for the purposes of Chapter 1.	Negative	The subject matter is technical and entails only the exemption of devices from the definition of a nicotine inhaling device. As such, the exercise of the power would only remove obligations from persons, and does not therefore require the additional safeguard that the affirmative procedure would provide.
3(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to specify further devices enabling the inhalation of a substance, or descriptions of devices, to which Chapter 1 is to apply whether or not such devices enable nicotine to be inhaled.	Affirmative	To provide additional security for the Assembly in that the range of devices to which Chapter 1 applies will not be widened – which could potentially be regarded as placing an onerous duty on members of the public – without full consideration and the opportunity for debate. Section 3(4) also states that regulations may specify other devices to which this Chapter applies only if the Welsh Ministers

					are satisfied that doing so would contribute towards the promotion of the health of the people of Wales.
5(2)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to place a duty upon specified persons who control or are concerned in the management of premises or vehicles that are smoke-free by virtue of regulations made under sections 8 or 9 to take reasonable steps to cause a person to stop smoking/using a nicotine inhaling device in those places.	Affirmative	To provide additional security for the Assembly in that the range of persons subject to such a duty will not be widened – which could potentially be regarded as placing an onerous duty on members of the public – without full consideration and the opportunity for debate.
6(7)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to specify what “enclosed” and “substantially enclosed” mean for the purposes of designating smoke-free workplaces and public premises.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. The power is also comparable with that at section 2(5) of the Health Act 2006, to which the negative procedure applies.
8(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to designate any places in Wales, or description of place in Wales, as being smoke-free through	Affirmative	To provide additional security for the Assembly in that additional smoke-free spaces will not be added – which could potentially be regarded as placing an

			regulations. Such places or description of places may not be enclosed or substantially enclosed.		<p>onerous duty on members of the public – without full consideration and the opportunity for debate.</p> <p>Section 8(3) also states that the regulations may provide for a place or description of a place to be treated as smoke-free premises only if the Welsh Ministers are satisfied that doing so is likely to contribute towards the promotion of the health of the people of Wales.</p>
9(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to designate the circumstances in which a vehicle (excluding ships and hovercraft) should be treated as a smoke-free vehicle.	Affirmative	<p>To provide additional security for the Assembly in that the circumstances in which a vehicle must be smoke-free will not be determined – which could potentially be regarded as placing an onerous duty on members of the public – without full consideration and the opportunity for debate.</p> <p>In addition, section 9(2) states that the regulations may provide for a vehicle to be treated as smoke-free only if the Welsh Ministers are satisfied that doing so is likely to contribute towards</p>

					<p>the promotion of the health of the people of Wales.</p> <p>The power is also comparable with that at section 5 of the Health Act 2006, to which the affirmative procedure applies.</p>
10(1)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to exempt premises, or specified areas within specified premises, from the smoke-free requirements.</p> <p>The exemption may be from the smoke-free requirements in relation to smoking, or the use of nicotine inhaling devices, or both.</p>	Affirmative	<p>To provide additional security for the Assembly in that premises or parts of premises exempted from the smoke-free requirements will not be determined – which could significantly affect the operation of these provisions – without full consideration and the opportunity for debate.</p> <p>The power is also comparable with that at section 3 of the Health Act 2006, to which the affirmative procedure applies.</p>
11(1)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to prescribe for requirements for the display of signs.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.</p>
11(3)	Welsh Ministers	Regulations	Suitable for delegated powers as	Affirmative	To provide additional security for

			this enables the Welsh Ministers to impose a duty to display smoke-free signage on persons occupying or managing smoke-free vehicles and additional smoke-free places.		the Assembly in that the range of persons subject to such a duty will not be widened – which could potentially be regarded as placing an onerous duty on members of the public – without full consideration and the opportunity for debate.
12(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to specify persons, or descriptions of persons, as enforcement authorities (for the purposes of this Chapter)	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
Chapter 2 – Retailers of Tobacco and Nicotine Products					
22(2)	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to specify a Registration Authority in respect of the Retailers Register	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
23(3)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to prescribe the detail as to the form and content of applications for registration, and on the	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may

			accompanying fee.		need to be updated from time to time.
26(6)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to impose a charging fee in connection with revising the Retailers Register.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time.
28	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to modify Chapter 2 so that it applies to vehicles and other moveable structures.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
39(2)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to specify the definition of 'nicotine product' in respect of the register of retailers of tobacco and nicotine products	Affirmative	To provide additional security for the Assembly in that the definition of 'nicotine product' will not be amended – which could potentially be regarded as placing an onerous duty on business – without full consideration and the opportunity for debate.
Chapter 3 – Prohibition on sale of Tobacco and Nicotine Products					
40(2)	Welsh Ministers	Regulations	To enable the Welsh Ministers to specify the definition of a 'tobacco or nicotine offence' in respect to issuing Restricted Premises Orders in regulations.	Affirmative	To provide additional security for the Assembly in that the definition of 'tobacco or nicotine offence' will not be widened – which could potentially be regarded as placing

					<p>an onerous duty on business—without full consideration and the opportunity for debate.</p> <p>Section 40(2) also states that a ‘tobacco or nicotine offence’ may be specified in regulations only if the Welsh Ministers are satisfied that the offence is one that relates to the supply, sale, transport, display, offer for sale, advertising or possession of tobacco or nicotine products. And, in the case of an offence that is triable only summarily, it is punishable by a fine of an amount corresponding to, or greater than, level 4 on the standard scale.</p>
Chapter 4 – Handing over tobacco etc. to persons under 18					
N/A					
Part 3 – Special Procedures					
49(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to specify that a special procedures licence is required for exempted individuals (members of a profession set out in paragraphs (a) to (ga) of section	Affirmative	To provide additional security for the Assembly that specified special procedures will not be able to be performed by exempted individuals without a licence - without full consideration with the opportunity for debate.

			25(3) of the National Health Service Reform and Health Care Professions Act 2002) to undertake specified special procedures.		In addition, section 49(5) provides further detail in relation to these regulations.
49(3)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to exempt individuals who are not members of profession specified in paragraphs (a) to (ga) of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002, but who are members of a qualifying register, from the requirement to operate under the authority of a special procedures licence.	Affirmative	<p>To provide additional security for the Assembly that the list of those unregulated exempted practitioners will be fully considered with the opportunity for debate.</p> <p>In addition, sections 49(4) and 49(5) provide further detail in relation to these regulations.</p>
51(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to prescribe the licensing criteria that must be met on application for a special procedures licence in order for the application to be granted.	Affirmative	<p>To provide additional security for the Assembly that the licensing criteria – which could potentially be regarded as placing an onerous duty on those applying for a special procedures licence – will be fully considered with the opportunity for debate.</p> <p>Furthermore, section 53 states that before exercising this regulation making power, the</p>

					Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.
51(3)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to set out the requirements, before a licence is issued or renewed, for a local authority to follow in relation to the inspection of those premises or vehicles identified in a licence application.	Affirmative	<p>To provide additional security for the Assembly that the licensing criteria – which could potentially be regarded as placing an onerous duty on local authorities – will be fully considered with the opportunity for debate.</p> <p>Furthermore, section 53 states that before exercising this regulation making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.</p>
51(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make different provision for different purposes in respect of the licensing criteria. This includes providing different descriptions of premises and vehicles, different descriptions of special procedures and the different circumstances in which a	Affirmative	<p>To provide additional security for the Assembly that the licensing criteria – which could potentially be regarded as placing an onerous duty on those applying for a special procedures licence – will be fully considered with the opportunity for debate.</p> <p>Furthermore, section 53 states</p>

			special procedure is performed.		that before exercising this regulation making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.
52(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to prescribe the mandatory licensing conditions that are to apply to those holding a special procedures licence.	Affirmative	<p>To provide additional security for the Assembly that the mandatory licensing conditions – which could potentially be regarded as placing an onerous duty on those holding a special procedures licence –will be fully considered with the opportunity for debate.</p> <p>Furthermore, section 53 states that before exercising this regulation making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.</p>
52(3)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make different provision for different purposes in respect of the mandatory licensing conditions. This includes providing different descriptions of	Affirmative	To provide additional security for the Assembly that the mandatory licensing conditions – which could potentially be regarded as placing an onerous duty on those holding a special procedures licence –will be fully considered with the

			premises and vehicles, different descriptions of special procedures and the different circumstances in which a special procedure is performed.		<p>opportunity for debate.</p> <p>Furthermore, section 53 states that before exercising this regulation making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.</p>
58(6)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to exempt specified premises or vehicles from the requirement to obtain approval from the local authority and to exempt a person, premises or vehicle associated with an exhibition, entertainment or other event, from the requirement to obtain approval from the local authority.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical in nature. Also, the content of these provisions may need to be updated from time to time.
59(3)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this requires the Welsh Ministers to make regulations in relation to the approval of premises and vehicles in respect of the performance of a special procedure.</p> <p>The regulations must specify the</p>	Affirmative	To provide additional security for the Assembly that the mandatory licensing conditions – which could potentially be regarded as placing an onerous duty on those applying for or holding a premises or vehicle approval – will be fully considered with the opportunity for debate

			<p>criteria that must be met, the circumstance in which an application is to be granted, and the mandatory approval conditions to which approval is to be subject.</p> <p>They must also make provision about appeal against refusal of an application.</p>		
59(7)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to make provision about the way in which applications for approval of premises or vehicles must be made and dealt with. This includes the payment of a fee, the circumstances in which an application must not be granted, or may be granted at the discretion of the local authority and the process for renewal of approval or variation of approval.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time.</p> <p>.</p>
59(8)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to make different provisions for different purposes to do with the approval of premises and vehicles in respect of the</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.</p>

			performance of a special procedure. This includes providing different descriptions of vehicles or premises, different descriptions of special procedures and the different circumstances in which a special procedure is performed.		
76(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to amend the list of special procedures in section 46.	Affirmative	<p>To provide additional security for the Assembly that the list of special procedures will not be amended without full consideration and the opportunity for debate.</p> <p>In addition, section 76(3) states that this power is to be exercised only if the Welsh Ministers consider—</p> <p>(a) that the procedure is one that is capable of being performed for aesthetic purposes, or for purposes that the Welsh Ministers consider to be therapeutic, and</p> <p>(b) that its performance for those purposes is capable of causing harm to human health.</p>

77(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to amend the definition of “body piercing” by describing objects that may be implanted in an individual’s body. This is a technical matter that may need updating.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical in nature. Also, the content of these provisions may need to be updated from time to time.
Part 4 – Intimate piercing					
N/A					
Part 5 – Pharmaceutical services					
89 Inserts section 82A(3) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to detail when and how a Local Health Board (LHB) should publish an assessment of pharmaceutical needs.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
89 Inserts section 82A(4) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make further provisions about the preparation, publication, review and revision of assessments	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
90(3) Inserts section 83 (2A) into the	Welsh Ministers	Regulations	The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may

NHS (Wales) Act 2006			<p>power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to specify persons or descriptions of persons who are not to be included within a pharmaceutical list.</p>		<p>need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
90(3) Inserts section 83 (2C) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to make provision as to the procedure that LHBs should follow, and matters they should take into account, when determining whether to grant an application to their pharmaceutical list.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
90(4) Inserts section 83 (3A) into the NHS (Wales) Act	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to</p>

2006			Suitable for delegated powers as this enables the Welsh Ministers to prescribe circumstances in which two or more applications to an LHB's pharmaceutical list may or must be considered together.		time. This procedure is located in section 203 of the NHS (Wales) Act 2006.
90(5) Amends section 83 (4) of the NHS (Wales) Act 2006	Welsh Ministers	Regulations	The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power. Suitable for delegated powers as this enables the Welsh Ministers to make provision for LHBs to take into account prescribed matters when considering two or more applications together.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time. This procedure is located in section 203 of the NHS (Wales) Act 2006.
90(6) Inserts section 83 (4A) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power. Suitable for delegated powers as this enables the Welsh Ministers to modify the application of section 83(5).	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time. This procedure is located in section 203 of the NHS (Wales) Act 2006.
90(7)(a)	Welsh Ministers	Regulations	The regulation-making power is	Negative	The subject-matter is relatively

Inserts section 83 (6) (za) into the NHS (Wales) Act 2006			<p>located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to make provision as to the circumstances in which LHBs may invite applications for inclusion within their pharmaceutical list.</p>		<p>minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
90(7)(b) Inserts section 83 (6) (g) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to make provision for LHBs to remove a person or an entry in respect of premises from their pharmaceutical list in relation to breaches of terms of service.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
90(8) Inserts section 83 (10A) into	Welsh Ministers	Regulations	The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the

the NHS (Wales) Act 2006			power. Suitable for delegated powers as this enables the Welsh Ministers to require LHBs to give reasons for decisions made under section 83 NHS (Wales) Act 2006.		content of these provisions may need to be updated from time to time. This procedure is located in section 203 of the NHS (Wales) Act 2006.
90(10) Inserts section 84 (4) of the NHS (Wales) Act 2006	Welsh Ministers	Regulations	The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power. Suitable for delegated powers as this requires the Welsh Ministers to make provision for LHBs to give notice of their intention to remove a person or premises from their pharmaceutical list, and to provide for the right to make representations.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time. This procedure is located in section 203 of the NHS (Wales) Act 2006.
Part 6 – Provision of toilets					
N/A					
Part 7 – General					
100(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make consequential, incidental, transitional or saving	Negative or Affirmative	This power is required to allow the Welsh Ministers to make supplementary, incidental, consequential, transitional or

			provision as they consider appropriate in connection with the Bill.		<p>saving provisions if they consider it necessary or expedient for the purposes of, in consequence of or for giving full effect to any provision of the Bill.</p> <p>If the regulations amend or repeal any provision of an Act of Parliament or Measure or Act of the National Assembly for Wales then they are subject to the affirmative procedure.</p> <p>If the regulations make any other consequential, incidental, supplementary or transitional provision the regulations will be subject to the negative procedure.</p>
101(2)	Welsh Ministers	Order	The Welsh Ministers may appoint by order that other provisions (not listed in 101(1)) shall come into force on such date (or dates) as stated in the order.	No procedure applicable to commencement order	These orders will be confined to commencement and are technical in nature.
Schedule 1 – Fixed Penalty Notices					
Paragraph 5	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to prescribe the form in which	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the

			Fixed Penalty Notices for specified offences under the Bill must take. (Those offences are of smoking or using nicotine inhaling devices in a smoke free premises or vehicle; failure to prevent smoking or use of a nicotine inhaling device in smoke-free premises; and failure to notify certain changes to or provide information in relation to the register of tobacco or nicotine products.)		content of these provisions may need to be updated from time to time.
Paragraph 6	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to prescribe the amount set for Fixed Penalty Notices under the Bill.	Affirmative	To provide additional security for the Assembly in that the amount set for FPNs – which could be regarded as an onerous duty on members of the public and/or will potentially place financial obligations on members of the public – will not be determined without full consideration and the opportunity for debate.
Paragraph 9	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to prescribe the discounted amount in relation to Fixed Penalty Notices under the Bill.	Affirmative	To provide additional security for the Assembly in that the discounted amount set for FPNs – which impose a financial burden on members of the public – will not be determined without full

					consideration and the opportunity for debate.
Schedule 2 – Smoking and nicotine inhaling devices: consequential amendments					
Paragraph 17	Welsh Ministers	Regulations	Suitable for delegated powers as this retains the Welsh Ministers' current power to prescribe the form of the Fixed Penalty Notice that may be issued by a local weights and measures authority for the offence under section 91 of the Children and Families Act 2014 ('Purchase of Tobacco and Nicotine Products etc. on behalf of persons under 18')	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical.
Schedule 3 – Further provision in connection with special procedure licences					
Paragraph 4(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make provision about the way in which applications for a special procedures licence will be dealt with by the local authority. These regulations will be in addition to the details provided in Schedule 3, paragraphs 1, 2, 3 and 4.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical /administrative in nature. Also, the content of these provisions may need to be updated from time to time.
Paragraph 5(3)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make provision about the form and content of special procedures	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/administrative in nature.

			licences. These regulations will be in addition to the details provided in Schedule 3, paragraphs 5(1) and 5(2).		Also, the content of these provisions may need to be updated from time to time.
Paragraph 20(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make provision about the procedures applicable to a local authority licensing committee and its sub-committees.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
Schedule 4 – Provision of toilets: consequential amendments N/A					

Other secondary legislation

Section or Schedule of Bill	Power conferred on	Form	Power
Part 6 – Provision of toilets			
91(8)	Welsh Ministers	Guidance	The Welsh Ministers may issue guidance to local authorities about the matters which they should take into consideration when preparing or reviewing their local toilets strategy.
94(1)	County, county borough and community councils	Byelaws	County, county borough and community councils may make byelaws as to the conduct of persons using public toilets that they provide.

6. Regulatory Impact Assessment

263. A Regulatory Impact Assessment has been completed for the Bill in accordance with Standing Order 26.6(vi) and follows at section 7.
264. A competition assessment and specific impact assessments are included at section 8.
265. There are no specific provisions in the Bill which charge expenditure on the Welsh Consolidation Fund.

Part 2 – Regulatory Impact Assessment

7. Options, costs and benefits

266. This regulatory impact assessment (RIA) is structured around each policy element of the Public Health (Wales) Bill for ease of reference. It presents a series of options for each, followed by costs and benefits. Summary tables showing the additional cost associated with each preferred option are presented in Annex B.
267. The costs and benefits associated with each option have been produced using the best information available at the time. This information has been prepared through discussion with key stakeholders, including local authorities, LHBs and other agencies. The costs and benefits associated with each option have been assessed over a five year period from 2016/17, with a longer period used in some cases. Where costs are expected to extend beyond the initial five year period (i.e. recurrent costs) these are identified in the text.
268. For clarity and consistency, costs in this RIA have been rounded to the nearest £100. Throughout the document figures are annual, across Wales unless specified otherwise. RIAs will be produced for the subordinate legislation arising from the Bill at the appropriate time; therefore costs for subordinate legislation have not been covered. For example, any costs and benefits associated with making open spaces such as school, hospital and play grounds smoke-free will be assessed as part of subordinate legislation brought forward by Welsh Ministers.
269. Throughout this RIA, where there is uncertainty, a cautious approach has been taken to the assessment of costs. This is likely to mean that in a number of areas the actual costs associated with implementing the legislation may be lower. There is also likely to be further potential for savings if certain aspects of implementation are co-ordinated across different areas of the Bill, for example if training sessions are combined for a number of related policies. In addition, any future reduction in the number of local authorities in Wales could lead to further savings being made.
270. The following chapter is structured into the following areas:-
- Tobacco and nicotine products
 - Restrictions on the use of tobacco and electronic cigarettes in enclosed public places;
 - Register of retailers of tobacco and nicotine products;
 - Handing over tobacco etc to persons under 18.
 - Special procedures;
 - Intimate piercing;

- NHS pharmaceutical services; and
- Provision of toilets.

Tobacco and nicotine products (Part 2)

271. In this section of the RIA an assessment of the options, costs and benefits is only provided for those elements of the Bill which involve changes to the current position. For example, an assessment is only provided for the addition of nicotine inhaling devices to the existing smoke-free requirements. An assessment is not provided for any restatement of existing requirements, as this is not expected to have any additional costs or benefits. For ease of reference this part of the RIA is entitled 'Restrictions of the use of tobacco and e-cigarettes in enclosed and substantially enclosed public and work places' as the term 'e-cigarettes' is widely recognised to a larger audience than the term 'nicotine inhaling devices'.

272. Similarly, no separate assessment is included for Part 2, Chapter 3 of the Bill, which deals with the general operation of restricted premises orders. This is covered in detail in the relevant section of the RIA which deals with the register of retailers of tobacco and nicotine products.

Restrictions of the use of tobacco and e-cigarettes in enclosed and substantially enclosed public and work places (Part 2, Chapter 1)

Options

273. Three options have been considered:

- Option 1 – Do nothing;
- Option 2 – Issue non-statutory guidance to businesses on restricting the use of e-cigarettes in their premises; and
- Option 3 – Legislation to restrict the use of e-cigarettes in enclosed and substantially enclosed public and work places. This is the preferred option.

Option 1: Do nothing

Description

274. Under this option, the status quo would remain. Some premises in Wales have already introduced restrictions on the use of e-cigarettes in their indoor premises. Other premises may wish to do the same, while

others may not. There would be no enforcement of these voluntary e-cigarette-free policies by local authority enforcement teams, although they could provide advice on the development of a policy at the request of business owners.

Costs

Welsh Government

275. There would be no costs to the Welsh Government from this option.

Local authorities

276. Costs to local authorities for the provision of advice to businesses on e-cigarette use in their premises would continue. At present, local authorities are being approached by businesses for advice on: whether e-cigarettes are permitted to be used inside their premises under the current smoke-free requirements; enforcement issues with regard to distinguishing between e-cigarettes and conventional ones; and how they can continue to meet their requirement to prevent smoking in their premises. They are also being asked for advice on whether to extend their smoke-free policies to include e-cigarettes and how to do this, as well as receiving queries from members of the public about e-cigarette use in public and work places. These queries would potentially continue under Option 1 and may increase if the number of e-cigarette users continues to increase.

277. Local authorities do not currently record the level of such queries being received. However, a few local authorities have been able to give an indication of the time taken to deal with them. A conservative assumption has therefore been made that in 2013/14 there were approximately three queries per local authority in Wales from businesses regarding the use of e-cigarettes in their premises, and that each query took around 30 minutes to deal with. It has also been assumed that in 2013/14 there were approximately three queries from members of the public about indoor e-cigarette use per local authority, and that each query took around 10 minutes to deal with. At a cost of £26.40 per hour¹²⁰, the cost of queries made to local authority enforcement teams in 2013/14 regarding public use of e-cigarettes is estimated at approximately £1,200. Applying an assumption that the use of e-cigarettes continues to increase, it is likely the number of queries received by local authorities would also increase year on year, as these businesses recognise they need advice on whether the use of e-cigarettes is, or should be, permitted in their premises. The cost is estimated to increase from £1,200 in 2016/17 to £2,700 in 2020/21.

¹²⁰ Annual Survey of Hours and Earnings 2014 (provisional results). Office of National Statistics

Public and work places

278. There may be costs incurred in public and work places who choose to implement existing voluntary guidance on e-cigarette use in their premises. For example, ASH has produced guidance for businesses on developing an organisational approach to the use of e-cigarettes on premises¹²¹. Uptake of this guidance is not known and so these costs have not been quantified.

E-cigarette industry

279. There would be no additional costs to the e-cigarette industry from this option.

Health

280. There may be costs to health from exposure to second-hand e-cigarette vapour. Studies have suggested that e-cigarette use in indoor rooms impairs air quality, albeit to a markedly lesser extent than conventional cigarettes. In a review of e-cigarettes for the publication *Addiction*, the authors suggest that e-cigarette aerosol does not include most of the chemicals found in tobacco smoke, but users exhale nicotine and some other particles, primarily consisting of flavours, aroma transporters, glycerol and propylene glycol. The review also found that no long-term study has been conducted so far, but pollutant levels are much lower than from cigarettes and are likely to pose a much lower risk (if any) compared to cigarettes.¹²² A systematic review on the safety of e-cigarettes as a tobacco cigarette substitute by Farsalinos and Polosa came to a similar conclusion.¹²³
281. Some studies suggest that particles of e-cigarettes aerosol may be deposited deep in the lung and justify health concerns.¹²⁴ A study by environmental scientists suggests that there is a possible exposure risk to passive smokers in enclosed spaces with limited ventilation if all the emissions from e-cigarettes were exhaled.¹²⁵ These potential costs to health would continue under Option 1 in premises that permit indoor e-cigarette use. However, these costs are unable to be quantified due to the current lack of data on the long-term impact of exposure to second-hand e-cigarette vapour.

¹²² Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Hajek et al. 2014. *Addiction*, 109, 1801–1810 doi:10.1111/add.12659

¹²² Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Hajek et al. 2014. *Addiction*, 109, 1801–1810 doi:10.1111/add.12659

¹²³ Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. Farsalinos and Polosa. *Therapeutic Advances in Drug Safety*. Apr 2014; 5(2): 67–86. doi: 10.1177/2042098614524430 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/>

¹²⁴ Electronic Cigarettes – An Overview – Supplement March 2014. Volume 19. German Cancer Research Center, Heidelberg. DKFZ. Red Series Tobacco Prevention and Tobacco Control.

¹²⁵ McFiggans et al 2014 <http://www.slideshare.net/neilmclaren/1150-harrison-and-mc-figgans>

Table 7.1: Summary of Costs for Option 1

Sector	Year				
	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Local Authorities					
Providing advice*	1,200	1,500	1,900	2,300	2,700
Total costs for local authorities	1,200	1,500	1,900	2,300	2,700
Total costs	1,200	1,500	1,900	2,300	2,700

*Based on an assumption of a year-on-year accumulative increase of 1 business and 1 public enquiry per local authority per year.

Benefits

Health

282. Maintaining the status quo would allow users of e-cigarettes to continue to use them in public and work places (unless a voluntary e-cigarette-free policy exists), which may or may not assist smoking cessation attempts. Evidence on whether e-cigarettes are an effective aid to smoking cessation is, to date, limited. For example, one study has suggested e-cigarettes may be modestly effective at helping smokers to quit, with similar achievement of abstinence as with nicotine patches¹²⁶. Another study of 5,863 smokers found that people attempting to quit smoking without professional help are 60% more likely to report succeeding if they use e-cigarettes than if they use will-power alone or over-the-counter nicotine replacement therapies¹²⁷, and a Flemish study of 48 tobacco smokers unwilling to quit smoking and who had not previously used an e-cigarette found that second generation e-cigarettes were immediately and highly effective in reducing abstinence induced cigarette craving and withdrawal symptoms.¹²⁸

¹²⁶ Electronic cigarettes for smoking cessation: a randomised controlled trial. Christopher Bullen, Colin Howe, Murray Laugesen, Hayden McRobbie, Varsha Parag, Jonathan Williman, Natalie Walker. www.thelancet.com Published Online September 7, 2013
[http://dx.doi.org/10.1016/S0140-6736\(13\)61842-5](http://dx.doi.org/10.1016/S0140-6736(13)61842-5)

¹²⁷ Brown J, Beard E, Kotz D, Michie S, and West R (2014) Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. *Addiction* 109: doi: 10.1111/add.12623.
<http://www.addictionjournal.org/press-releases/e-cigarette-use-for-quitting-smoking-is-associated-with-improved-success-rates->

¹²⁸ Effectiveness of the Electronic Cigarette: An Eight-week Flemish Study with Six-month Follow-up on Smoking Reduction, Craving and Experienced Benefits and Complaints. Adriaens et al (2014). *Int. J. Environ. Res. Public Health* 2014, 11(11), 11220-11248; doi:10.3390 <http://www.mdpi.com/1660-4601/11/11/11220/htm>

283. A more overarching position is given by a Cochrane Review¹²⁹, published in December 2014, of 13 completed studies, which found that while recognition of the potential health benefits from smokers switching to e-cigarettes can be found in expert opinion, the quality of the evidence overall is low, because it is based on only a small number of studies and more studies of e-cigarettes are needed.
284. There is no evidence that these benefits would not accrue under Options 2 and 3 as well, as neither option suggests a complete ban on e-cigarettes.

Public and work places

285. People who were smoking tobacco and switch to e-cigarettes may take fewer or shorter smoking breaks if they are allowed to use their e-cigarette inside their workplace. A 2013 ASH Wales report¹³⁰ estimated the cost of smoking breaks to the Welsh economy to be £41 million per year. The potential reductions in these costs from smokers who switch to using e-cigarettes are unquantifiable due to a lack of evidence.
286. Of those workplaces that responded to the Welsh Government's survey of workplace e-cigarette policies and reported not having an e-cigarette policy, just over one in ten (14%) reported that this was because they supported e-cigarette use for smoking cessation (from a list of prompted answers).
287. However, many organisations have already adopted a policy on e-cigarettes^{131,132,133} and so any benefit from fewer or shorter breaks would be limited to organisations without an existing policy that prevents indoor e-cigarette use. In addition it is understood, anecdotally, that some e-cigarette users already voluntarily 'step outside' to use their e-cigarettes as a courtesy to others or out of habit due to the smoking ban. This may further limit the extent of this benefit.
288. Some respondents to the Welsh Government's Public Health White Paper suggested a further benefit, in that the use of e-cigarettes in public places can normalise anti-smoking behaviours, reinforce the message that it is good to stop smoking, and therefore promote smoking cessation.¹³⁴

¹²⁹ Electronic cigarettes for smoking cessation and reduction (Review). 2014. The Cochrane Collaboration. Published by John Wiley & Sons, Ltd. Available at: <http://www.cochrane.org/features/new-cochrane-evidence-shows-electronic-cigarettes-facilitate-smoking-cessation>

¹³⁰ The economic cost of smoking to Wales: a review of existing evidence. Dr Aimee Grant. ASH Wales and the British Heart Foundation. 2013.

¹³¹ Welsh Government. E-cigarette policies: a survey of workplaces in Wales. 2014. <http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

¹³² Research into E-cigarette Policies in the Independent Hospitality Sector. CIEH Wales. November 2014. Not published.

¹³³ Welsh Government. E-cigarette policies: a survey of schools in Wales. 2014. <http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

¹³⁴ <http://wales.gov.uk/consultations/healthsocialcare/white-paper/?lang=en>

However, there is no current evidence to suggest that these effects are happening.

Option 2: Issue guidance on the use of e-cigarettes in indoor areas

Description

289. This option would involve the Welsh Government issuing non-statutory guidance to businesses on restricting the use of e-cigarettes in their premises. There would be no enforcement of these voluntary e-cigarette-free policies by local authority enforcement teams, although they would be expected to provide advice on the applicability of the guidance to individual businesses.

Costs

Welsh Government

290. There would be costs to the Welsh Government associated with producing and issuing the voluntary guidance. Staffing costs to produce the guidance (based on 6,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £7,500. This is based on approximately five weeks of a FTE Higher Executive Officer (£4,600) to develop the guidance, and five weeks of a FTE Team Support for administration support (approximately £2,900).¹³⁵

291. The intention would be to provide electronic versions of the guidance, with a small number of paper versions of the guidance produced. It is anticipated that printed versions would cost approximately £900. The guidance could be made available on the Business Link website and disseminated through the Corporate Health Standard and Small Workplace Health Award, as well as through the Welsh Network of Healthy School Schemes and Healthy and Sustainable Pre-School Scheme.

292. It is anticipated that design and typesetting would require 1 week of a 0.5 FTE Executive Officer, which would cost approximately £300. It is estimated that translation and proofreading would cost approximately £600.¹³⁶ The total cost for the development, design, translation and printing of guidance would therefore be £9,300. All of these costs would be incurred in 2016/17.

293. In addition to staff costs for the development of the guidance, there would also be some staff involvement once the guidance has been published, such as ensuring the guidance remains up to date and relevant. It is anticipated that approximately a 0.1 FTE Executive Officer would be

¹³⁵ Based on Welsh Government staff planning costs

¹³⁶ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

allocated to support this work in the first year, reducing to 0.05 FTE of an Executive Officer for later years. This would equate to approximately £3,000 in 2016/17, with the cost reducing to £1,500 per year from 2017/18 onwards.

294. The guidance would be updated every three years. It is anticipated that this would require 1 week of a FTE Higher Executive Officer. This would equate to approximately £900. Design and translation costs would amount to half the original costs, a total of £500. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,400, incurred every three years. The first review would take place in 2019/20.
295. Training sessions for local authority enforcement officers would need to be held to support the guidance, and it is envisaged that these would be organised by local authority enforcement teams. The Welsh Government would cover the costs associated with hosting the training. Each session would be approximately a half day and it is envisaged that two sessions would be held, one in North Wales and one in South Wales. These sessions would cost approximately £2,000, based on room hire and refreshments for 35 people for each session (£1,200)¹³⁷, and possible costs for external trainers to run the sessions (£800). However, these costs could be reduced if the training is combined with other relevant topics. This one-off cost would be incurred in 2016/17.
296. The development, production and reviewing of the guidance could be outsourced to an external body (for example a local authority). If this work is outsourced the costs would still be met by the Welsh Government.

Local authorities

297. Local authority enforcement teams would incur some staff costs, initially focussed on helping to develop the guidance and training sessions. Once the guidance is published, enforcement teams would incur costs from engaging with premises to encourage them to implement actions from the guidance. The guidance would therefore have an impact on the workload of local authority enforcement teams. This would be essential due to the voluntary nature of the guidance, as premises would have to choose to adopt it.
298. In addition, enforcement teams may need to deal with queries and support premises in implementing the guidance. It is anticipated that this support would be higher in the first 12 months following the publication of the guidance, but would then reduce for subsequent years. It is estimated that for the initial 12 months the cost would be the equivalent of a 0.05 FTE enforcement officer post per local authority, then reducing to a 0.025

¹³⁷ Based on costs from similar training sessions organised by Welsh Government.

FTE post per local authority. This would equate to a total of approximately £50,300 in 2016/17, reducing to £25,100 per annum from 2017/18.¹³⁸

299. There would be costs to local authorities for enforcement officers to attend training sessions on the guidance. It is estimated that this would cost approximately £9,200¹³⁹ in 2016/17.

300. These costs would not be accommodated within the existing budget made available to local authorities when the Health Act 2006 came into force, because Option 2 represents an additional function to the smoke-free regime.

Public and work places

301. The guidance would be applicable to every public and work place in Wales, and so the costs to premises that choose to adopt it are included here. It is anticipated that publically owned premises, such as museums, council buildings, LHB operated hospitals and local authority maintained schools, would implement any Welsh Government guidance. There are 490 public sector organisations in Wales (excluding schools), which employ 315,000 people¹⁴⁰. Each public sector organisation would need to consider the guidance, develop a policy on e-cigarettes, discuss it at relevant committees and/or boards and with relevant unions, and communicate the policy to its staff. Based on this taking approximately four hours at a rate of £15.17 per hour^{141, 142}, the cost to the public sector for undertaking a full consideration of the guidance would be approximately £29,700.

302. However, according to the Welsh Government workplace survey on e-cigarette policies, 62% of those public sector organisations who responded already have an e-cigarette policy in place, or are in the process of developing one¹⁴³. It is considered that uptake of the guidance among organisations with an existing policy on e-cigarettes would be less time consuming. Such organisations would need to: review the guidance; make any necessary updates to their policies; discuss the revised policy at relevant committees and/or boards; discuss with relevant unions; and communicate the policy update to staff. Based on this taking approximately two hours at a rate of £15.17 per hour, the cost per public sector organisation which already has a policy on e-cigarette use in their

¹³⁸ Based on costs being duplicated in each of the 22 Welsh local authorities

¹³⁹ Based on 5 hours at an hourly rate of £26.40 (to include the half day training session and travel time) for 70 enforcement officers to attend

¹⁴⁰ Size analysis of businesses. Welsh Government. 23 October 2014.

<http://wales.gov.uk/statistics-and-research/size-analysis-welsh-business/?lang=en>

¹⁴¹ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (HR and Industrial relations officers). <http://www.ons.gov.uk/ons/publications/reference-tables.html?edition=tcm%3A77-337425>

¹⁴² Hourly rates have been increased by a factor of 30% to incorporate on costs.

¹⁴³ 294 workplaces responded to the survey out of 1507 invited. Although less than one per cent of employers in Wales are public sector organisations, 45% of the responses were from public sector workplaces.

premises would be £30.34. The cost to the public sector for implementing Welsh Government voluntary guidance is therefore estimated to be approximately £20,500 in 2016/17.¹⁴⁴

303. The Welsh Government guidance would be updated every three years. Costs associated with reviewing an update to the guidance are only additional under Option 2 among those organisations that do not already have an e-cigarette policy in place (because costs of a policy review would be incurred by those with an existing policy under Option 1). It is estimated that the cost to public sector organisations for reviewing the updated guidance, making necessary amendments and re-issuing to staff would be approximately £5,600 in 2019/20. This has been based on a review being conducted in 186 public organisations and the review taking two hours per organisation, at a rate of £15.17 per hour.
304. There are 1,333 state maintained primary and 207 state maintained secondary schools in Wales. Each school would need the relevant lead person to consider the guidance, discuss the policy at working group level, as well as with school governors, unions and school councils. It is estimated this would take on average two hours per school (less than other public settings as local Welsh Network of Healthy School Schemes (WNHSS) co-ordinators would provide support based on experience in other schools), at a rate of £29.37 per hour^{145, 146}. The cost to schools in Wales for undertaking a full consideration of the guidance would be approximately £90,400 in 2016/17.
305. However, according to the Welsh Government survey of e-cigarette policies in schools in Wales¹⁴⁷, around three-quarters of the secondary schools (74%) and a third of primary schools (34%) that responded¹⁴⁸ have an e-cigarette policy or were in the process of developing one. The National Quality Award of the WNHSS already requires schools to consider the use of e-cigarettes in their premises¹⁴⁹. The need for any Welsh Government guidance in secondary schools is therefore likely to be relatively low (around 26%), but could be higher amongst primary schools (around 66%). The cost to schools without an existing policy on e-

¹⁴⁴ Based on 62% of public sector organisations considering the guidance against their existing policies at a cost of £9,200, and 38% of public sector organisations creating a new policy based on the guidance at a cost of £11,300.

¹⁴⁵ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Teaching and educational professionals).

<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-337425>

¹⁴⁶ Hourly rates have been increased by a factor of 30% to incorporate on costs.

¹⁴⁷ Welsh Government. E-cigarette policies: a survey of schools in Wales. 2014.

<http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

¹⁴⁸ 31% of secondary schools and 13% of primary schools in Wales responded to the Welsh Government survey.

¹⁴⁹ Over 99 per cent of maintained schools are involved in the WNHSS and as at 31 March 2015 78 schools have achieved the National Quality Award, which is independently assessed after 9 years of involvement.

cigarette use for implementing Option 2 is therefore estimated at approximately £54,900¹⁵⁰ in 2016/17.

306. Similar steps would be required among schools with existing policies on e-cigarettes. It is estimated that this would take approximately 1.5 hours at a rate of £29.37 per hour, equating to a cost of £26,700 in 2016/17. The estimated total cost to schools in 2016/17 is therefore £81,600.
307. The Welsh Government guidance would be updated every three years. Costs associated with reviewing an update to the guidance are only additional under Option 2 among those schools that do not already have an e-cigarette policy in place (because costs of a policy review would be incurred by those with an existing policy under Option 1). It is estimated that the cost to schools for reviewing the updated guidance, making necessary amendments and discussing in relevant forums would be approximately £41,100 in 2019/20. This has been based on a review taking place in 880 primary and 54 secondary schools and the review taking 1.5 hours per school, at a rate of £29.37 per hour.
308. In the private sector, each enterprise would need to consider whether they should adopt the guidance. There are an estimated 231,100 private sector enterprises in Wales, employing an estimated 1.06 million people. 99.3% of the private sector in Wales consists of small or medium sized enterprises (SMEs).¹⁵¹ It is estimated that for large employers (those with 250+ employees), each enterprise would need to:- consider the guidance and assess its applicability to their premises (probably by senior management); make a decision on whether to adopt it (estimated to take two hours at a rate of £30.07 per hour^{152,153}); and develop a policy on e-cigarettes and communicate the policy to staff (estimated to take approximately two hours at a rate of £21.55 per hour^{154,155}). If all 1,618 large employers adopted the guidance, there would be a total one-off cost of approximately £167,000. For SMEs, it is estimated that the time needed to consider and implement the guidance would be two hours, at a rate of £20.49 per hour¹⁵⁶. If all 229,482 SMEs adopted the guidance, there would

¹⁵⁰ There are 1,333 primary and 207 secondary schools in Wales. Using results of the Welsh Government's survey of e-cigarette policies in primary and secondary schools, it has been estimated that the uptake rate would be approximately 66% of primary schools (880 schools) and 26% of secondary schools (54 schools). These calculations do not account for special or independent schools. Independent schools are accounted for in the private sector calculations.

¹⁵¹ Size analysis of businesses. Welsh Government. 23 October 2014.

¹⁵² ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Chief executive and senior officials). <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-337425>

¹⁵³ Hourly rates have been increased by a factor of 30% to incorporate on costs.

¹⁵⁴ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Corporate Managers). <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-337425>

¹⁵⁵ Hourly rates have been increased by a factor of 30% to incorporate on costs.

¹⁵⁶ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Managers, directors & senior officials). <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-337425>

be a total one-off cost of £9,404,200. This would amount to a total cost of £9,571,200.

309. However, it has been assumed that it is unlikely that all 231,100 private sector enterprises would need to undertake a full consideration of the guidance. Some have already taken voluntary action (89% of those large employers and 47% of those SMEs who responded to the Welsh Government workplace survey reported having or intending to have a policy prohibiting e-cigarette use on the premises¹⁵⁷). Of workplaces that responded to the Welsh Government e-cigarette policy survey and did not have a policy or were not in the process of developing one, 18% reported, from a list of prompted answers, that this was because they had not got around to developing one yet. It is therefore estimated that the maximum uptake in the private sector could be limited to this 18%, which is estimated to cost approximately £900,500¹⁵⁸ in 2016/17.
310. Private sector enterprises with an existing policy may also choose to review their policies against the guidance. It is estimated this would take approximately half the time of a full review of the guidance, and would cost large employers £74,300 and SMEs £2,210,000¹⁵⁹.
311. The total cost to the private sector for the adoption of new guidance and any review of existing guidance is therefore £3,184,000 in 2016/17.
312. The Welsh Government guidance would be updated every three years. Costs associated with reviewing an update to the guidance are only additional under Option 2 among those private enterprises that do not already have an e-cigarette policy in place (because costs of a policy review would be incurred by those with an existing policy under Option 1). The cost to the private sector of reviewing the updated guidance, making necessary amendments and discussing in relevant forums is estimated to cost around half that of a full review. The maximum cost of this review for the private sector would be approximately £450,200 in 2019/20.
313. Current available evidence on the implementation of workplace e-cigarette policies in Wales is limited and the Welsh Government survey aimed to inform this. It is acknowledged the survey carries some limitations, including its online format and the potential for self-selection bias in the data received. In the absence of other data, the results of this survey have been used throughout this RIA.
314. However, similar levels of existing policies on e-cigarettes to that reported in the Welsh Government workplace survey were reported in a

¹⁵⁷ 294 workplaces responded to the Welsh Government survey; 81 of these were large workplaces (approximately 20% of large workplaces in Wales) and 213 SMEs (less than 1% of SMEs in Wales).

¹⁵⁸ Based on the workplace survey, it has been assumed that 53% of SMEs and 11% of large employers don't have a policy. We have estimated that 18% of private enterprises without an existing policy on e-cigarettes equates to approximately 21,893 SMEs at a cost of £40.98/SME and 32 large employers at a cost of £103.24/large employer

¹⁵⁹ We estimate this equates to approximately 107,857 SMEs at a cost of £20.49/SME and 1,440 large employers at a cost of £51.62/large employer

survey of the independent hospitality sector conducted by the Chartered Institute of Environmental Health (CIEH) Wales.¹⁶⁰ The CIEH survey was conducted through a structured interview relating to policies and the use of e-cigarettes within businesses. 200 businesses within the hospitality sector in Wales were surveyed by personal interview or by telephone. The number of businesses that were interviewed within each local authority was based on the density of populations within the different geographical areas. Once a business was randomly identified and it was established that they do not participate in either the Corporate Health Standard or the Small Workplace Award, they were contacted to be part of the study. Of the 200 small independent businesses surveyed¹⁶¹, 49.5% either actively had a policy on use of e-cigarettes (26%), or had procedures in place which amounted to a policy on control of e-cigarettes (23.5%). In addition, 6% of those surveyed were in the process of developing a policy.

315. There may be costs to businesses incurred by e-cigarette breaks, but only where these are in addition to existing breaks being taken by smokers to smoke their tobacco products. These costs are explored fully under Option 3.
316. The maximum annual cost of e-cigarette breaks under Option 2 is estimated at a range between £885,200 and £1,436,600 per year. The bottom end of the range is based on the cost of additional e-cigarette breaks in public sector organisations (where uptake of the guidance would be expected in 100% of premises) calculated in Option 3 and no uptake of the guidance in the private sector. The top end of the range is based on 18% of the maximum cost of additional e-cigarette breaks in the private sector calculated in Option 3 (i.e. the maximum uptake of guidance of 18% among private enterprises which do not currently have a policy in place); which it is estimated amounts to £551,400, plus the cost to the public sector organisations. See Option 3 paragraphs 338-345 for calculations.

E-cigarette industry

317. Such voluntary restrictions are not intended to affect e-cigarette use prevalence rates, but it is acknowledged that they may have an impact on e-cigarette uptake, thereby reducing the sales of e-cigarettes in Wales. The impact on sales of e-cigarettes of restrictions on their use is explored fully under Option 3. It is estimated that the impact on the e-cigarette industry under Option 2 would be within a range of £0 to £198,500 per annum.
318. The top of the range is based on the following:

¹⁶⁰ Research into E-cigarette Policies in the Independent Hospitality Sector. CIEH Wales. November 2014. Not published.

¹⁶¹ The 200 independent premises surveyed by CIEH Wales comprised of: 42 hotels; 42 B&Bs; 42 pubs; 41 restaurants; and 33 cafes.

- The market for e-cigarettes in Wales has been attributed to the working population only as we consider they would be more regularly exposed to voluntary restrictions on e-cigarette use;
- In 2013, the working population of Wales was 1.387 million; with 331,000 working in the public sector (24% of the working population) and 1,058,000 working in the private sector (76% of the working population);
- The e-cigarette market among public sector workers is therefore estimated to be valued at £2,156,600 and among private sector workers at £6,829,400;
- The lower end of the range is based on uptake of the guidance in an additional 38% of public organisations¹⁶² and 0% of private enterprises¹⁶³;
- The top end of the range is based on uptake of the guidance in an additional 38% of public organisations and an additional 18% of private enterprises which do not already have a policy in place; and
- The estimates outlined under Option 3 in paragraphs 354-356 on the size of the e-cigarette market in Wales and the likely percentage of e-cigarette users who would exit the market following restrictions on use of e-cigarettes also apply.

Table 7.2

Reduction to the market (£8.986 million)	Range	
	Additional restrictions in 38% of public organisations and 0% of private enterprises £	Additional restrictions in 38% of public organisations and 18% of private enterprises which do not already have a policy in place £
Maximum impact: 15% of e-cigarette users exit	122,900	198,500

¹⁶² According to the Welsh Government workplace survey on e-cigarette policies, 62% of those public sector organisations who responded have already got an e-cigarette policy in place, or are in the process of developing one.

¹⁶³ Of workplaces that responded to the Welsh Government e-cigarette policy survey and did not have a policy or were not in the process of developing one, 18% reported, from a list of prompted answers, that this was because they had not got around to developing one yet.

market*		
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*See Option 3 paragraph 355 for further explanation and referencing

319. As with Option 3, it is considered that any impact on sales would not happen immediately following implementation of Welsh Government guidance by premises, but if it was to occur would be more likely to happen over a period of time. Any reduction to the market is likely to be permanent and has therefore been accounted for as an annual cost.

Health

320. There may be costs to health from exposure to second-hand e-cigarette vapour in premises that choose not to adopt the voluntary guidance. These were outlined under Option 1.

321. These potential costs to health would continue under Option 2 in premises that permit indoor e-cigarette use, but would be lower than maintaining the status quo as in Option 1. However, these potential costs are not able to be quantified due to the current lack of data on the long-term impact of exposure to second-hand e-cigarette vapour.

Table 7.3: Summary of additional costs associated with Option 2

Sector	Year				
	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government					
Staff costs for development of guidance	7,500	0	0	0	0
Design and translation	900	0	0	0	0
Printing costs	900	0	0	0	0
Staff costs for implementation and ongoing support for the guidance	3,000	1,500	1,500	1,500	1,500
Costs to review guidance	0	0	0	1,400	0
Costs to cover training	2,000	0	0	0	0
Total cost for Welsh Government	14,300	1,500	1,500	2,900	1,500
Local Authorities					
Staff costs to encourage and support premises	50,300	25,100	25,100	25,100	25,100

implementing guidance					
Attending training	9,200	0	0	0	0
Total cost for local authorities	59,500	25,100	25,100	25,100	25,100
Public and Work Places					
Implementing guidance:					
Public sector	20,500	0	0	5,600	0
Schools	81,600	0	0	41,100	0
Private sector	3,184,800	0	0	450,200	0
E-cigarette breaks	885,200 – 1,436,600	885,200 – 1,436,600	885,200 – 1,436,600	885,200 – 1,436,600	885,200 – 1,436,600
Total cost for public and work places	4,172,100-4,723,500	885,200-1,436,600	885,200-1,436,600	1,382,100-2,430,400	885,200-1,436,600
E-cigarette Industry					
Impact on sales*	0 – 198,500	0 – 198,500	0 – 198,500	0 – 198,500	0 – 198,500
Total cost for e-cigarette industry	0– 198,500	0 – 198,500	0 – 198,500	0 – 198,500	0 – 198,500
Total cost	4,245,900-4,995,800	911,800-1,691,700	911,800-1,691,700	1,410,100-2,656,900	911,800-1,691,700

*It is not anticipated that all of these costs would occur in 2016/17 but they have been attributed here for accounting purposes.

Benefits

Local authorities

322. There would be benefits to local authority enforcement teams who, under the current status quo, have to provide advice on a case-by-case basis on the use of e-cigarettes in premises. This is time consuming and the costs associated with such enquires are outlined under Option 1. Issuing Welsh Government guidance would remove the need to deal with such queries as they could direct owners of premises to the guidance. There would therefore be cost savings for local authorities.

Public and Work Places

323. Premises would be able to decide, on a case-by-case basis, whether they should apply restrictions on the use of e-cigarettes in their premises. This would allow them to reflect on their specific customer base, their

working environment and the image their business is trying to project. It is not possible to quantify this benefit, but it is considered likely that premises would only implement voluntary guidance on the basis that it is of benefit to their organisation.

Other

324. If premises adopt the voluntary guidance then many of the benefits explored in detail under Option 3 would also apply to Option 2.

Table 7.4: Summary of cost savings associated with Option 2

Sector	Year				
	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Local authorities					
Dealing with queries / cases	1,200	1,500	1,900	2,300	2,700
Total savings for local authorities	1,200	1,500	1,900	2,300	2,700
Total Savings	1,200	1,500	1,900	2,300	2,700

Option 3: Legislation to restrict the use of e-cigarettes in enclosed and substantially enclosed public and work places

Description

325. Under this option, the Welsh Government would introduce legislation to extend the current smoke-free requirements for enclosed and substantially enclosed public and work places in Wales to include restrictions on the use of e-cigarettes. The Welsh Ministers may opt to make regulations to provide for additional exemptions to the requirement to be smoke-free in relation to use of an e-cigarette, for example, to permit the demonstration of e-cigarettes licensed as medicines within pharmacy consulting rooms. They may also make regulations on smoke-free vehicles and additional smoke-free premises, which may include non-enclosed spaces. An assessment of the impact of such provisions will be carried out when making the relevant regulations. Local authorities would also be responsible for enforcing the extended smoke-free requirements. Existing WLGA guidance¹⁶⁴ for officers on the enforcement of the current smoke-free requirements would need to be updated to reflect the restrictions on use of e-cigarettes in relevant premises.

¹⁶⁴ <http://www.wlga.gov.uk/regulatory-services-publications/enforcement-guidance-and-protocols-smoke-free-public-places/>

326. In the UK a number of individual premises have implemented restrictions on the use of e-cigarettes in their premises. A number of states and cities in the USA (for example, New York, North Dakota and New Jersey¹⁶⁵) have implemented mandatory restrictions on the public use of e-cigarettes. Similar proposals have already been taken forward in Spain¹⁶⁶. Governments in France¹⁶⁷ and the Republic of Ireland¹⁶⁸ have both made announcements that they intend to implement similar measures. The restrictions in the USA and Spain have only been in place for a short period of time and the Welsh Government is not aware of any reviews on the impact of these restrictions. However, some impacts have been reported in the media and these are taken into account alongside the assumptions made.

Costs

Welsh Government

327. The Welsh Government would provide to the managers of relevant places signage that meets the mandatory requirements. The signage would include a new warning message to reflect the extended smoke-free requirements¹⁶⁹. The estimated cost to the Welsh Government of printing and dispatching additional smoke-free signage is a one-off cost of approximately £100,000. This is based on the costs incurred for print and dispatch of the 2007 smoke-free signage, and these costs would be incurred in 2016/17. Premises' owners would not be charged for the signs.

328. There would also be costs associated with communicating the extended smoke-free requirements to the public and to managers of public and work places. Public awareness of the existing smoke-free requirements is high¹⁷⁰, as is businesses' awareness of smoke-free legislation¹⁷¹. The communications strategy includes the design, print and dispatch of a promotional poster to display in the premises in advance of the ban coming into force. Promotional activity would also be carried out using the Business Wales website, social media and trade publications. Costs for this campaign work would be approximately £100,000 in 2016/17.

¹⁶⁵ Regulating e-cigarettes and other devices. Tobacco Control Legal Consortium. <http://www.publichealthlawcenter.org/topics/tobacco-control/product-regulation/e-cigarettes/resources>

¹⁶⁶ <http://www.thelocal.es/20131219/spain-bans-e-cigarettes-in-public-spaces>

¹⁶⁷ http://www.france24.com/en/20140925-france-wants-e-cig-ban-public-plain-cigarette-packs/#/?&_suid=141865240533405920248136771623

¹⁶⁸ <http://www.belfasttelegraph.co.uk/news/local-national/republic-of-ireland/ecigarettes-ban-proposed-for-republic-of-ireland-30950971.html>

¹⁶⁹ The revised signage requirements would be set out in regulations subject to the negative procedure.

¹⁷⁰ Smokefree England factsheet. Public opinion research. <http://www.smokefreeengland.co.uk/thefacts/latest-research/>

¹⁷¹ Smokefree England factsheet. Business research. <http://www.smokefreeengland.co.uk/thefacts/latest-research/>

329. For the public, a media relations campaign would be carried out using partner channels, including local authorities, social media and the Welsh Government website. Costs for this campaign work would be approximately £100,000 in 2016/17.

Local authorities

330. There would be costs to local authorities to enforce the new e-cigarette-free requirement. Funds of £2,000,000 per annum were made available to local authorities when the 2007 Regulations came into force. Enforcement of the extended smoke-free requirements would be expected to be accommodated within this existing budget, as would enforcement officer time and expenses to attend training.
331. Local authority enforcement officers would need to attend training on the new e-cigarette-free requirements. This training would be prepared and run by an accredited organisation. There could be economies of scale by combining this training with other tobacco and nicotine products-related aspects of the Public Health (Wales) Bill. Delegates would be charged a fee to attend the training as the course would support professional development and offer Continuing Professional Development (CPD) points. Delegate fees would be an estimated £40 per officer.
332. A similar training course was run in 2006 by the Chartered Institute of Environmental Health (CIEH) Wales for the Health Act 2006 and the Smoke-free Regulations 2007. Four full-day courses were held (two in South Wales, one in North Wales and one in Mid Wales), which were attended by a total of 258 delegates. In addition, CIEH Wales was asked to provide training to the staff of four local authorities, with 219 delegates attending these sessions. In total, CIEH trained 477 local authority enforcement officers on the Health Act 2006 and the Smoke-free Regulations 2007. Based on an assumption of the same number of enforcement officers attending the new training, the total cost to local authorities would be a one-off cost of approximately £19,100 in 2016/17.
333. There would be no additional costs to local authorities for monitoring compliance with the new requirement. Inspection of premises for compliance with the new requirement would be undertaken as part of enforcement officers' regular schedule of inspections for the pre-existing smoke-free requirements and, for example, food hygiene inspections.
334. The WLGA guidance relating to the Health Act 2006 and the Smoke-Free Regulations 2007 would need to be updated to also reflect a new e-cigarette free requirement. It has been estimated that the costs of updating the existing WLGA smoke-free guidance would be approximately the same as those associated with updating the voluntary Welsh Government guidance under Option 2. This cost of approximately £1,400 would be incurred in 2016/17. Further updates to the guidance could be required and it is estimated that this would cost approximately the same, with these costs being incurred in 2019/20.

Public and work places

335. Managers of public premises and work places would need to ensure the correct signage is in place. Signage that meets the new requirements would be provided by the Welsh Government at no cost to owners of premises covered by the extended smoke-free requirements.
336. Relevant persons within public and work places would be required to ensure their premises adhere to the new smoke free requirements. Given that all public and work places should already be compliant with the existing smoke-free requirements, it is estimated this would be straightforward to achieve as they would simply need to update their existing smoke-free policies and communicate the update to staff. It is estimated this would therefore take a quarter of the time of full consideration of Welsh Government voluntary guidance on the use of e-cigarettes under Option 2. As all premises would need to be compliant with the new legislation, this is a quarter of the full costs estimated under Option 2 (not the reduced costs adjusted for limited uptake). These costs, which would be incurred in 2016/17, are estimated as follows:
- Public sector - £7,400;
 - Schools - £22,600; and
 - Private sector - £2,392,800
 - **Total costs - £2,422,800**
337. Premises would also be required to review their policies against any update to WLGA guidance in 2019/20. However, this would be a cost incurred under the current smoke-free requirements and so is not considered to be an additional cost of Option 3.
338. There may be costs to businesses incurred by e-cigarette breaks, but only where e-cigarette users are currently allowed to use their e-cigarettes whilst working. A 2013 ASH Wales report¹⁷² estimated the cost of smoking breaks to the Welsh economy to be £41 million per year. A similar level of research on e-cigarette breaks is not yet available. However, the ASH Wales report has been used to develop an estimate of potential costs using the assumptions below¹⁷³:-
- According to the latest Welsh Health Survey, 21% of Welsh adults reported smoking¹⁷⁴;
 - According to employment data for Wales for the period October to December 2013, 70.8% of people of working age are in

¹⁷² The economic cost of smoking to Wales: a review of existing evidence. Dr Aimee Grant. ASH Wales and the British Heart Foundation. 2013.

¹⁷³ All data used in these assumptions are from 2013 to align with the year of the ASH Wales report 'The economic cost of smoking to Wales: a review of existing evidence.'

¹⁷⁴ Welsh Health Survey 2013. Welsh Government <http://wales.gov.uk/statistics-and-research/welsh-health-survey/?lang=en>

employment, amounting to 1.387 million people¹⁷⁵, and it is assumed that 21% of these workers smoke (N=291,270);

- The average cost of smoking breaks per smoker in 2013 was therefore £140.73 per annum;
- There are an estimated 2.1 million adult e-cigarette users in the UK¹⁷⁶; on a population basis, this equates to around 100,800 adult e-cigarette users in Wales¹⁷⁷ and it is assumed that approximately 70.8% of these are in employment; and
- Research indicates that almost all e-cigarette users are current or ex-smokers¹⁷⁸.

339. If an assumption is made that e-cigarette users take the same number of breaks per day as smokers, their break lasts the same amount of time, and they are in addition to existing smoking breaks already accounted for in the ASH Wales report, e-cigarette breaks could be estimated to cost the Welsh economy £10.043 million per year (i.e. 71,366 e-cigarette users at £140.73 per person).

340. This estimate can be adjusted to reflect that a number of workplaces already have restrictions in place on the use of e-cigarettes in their premises. E-cigarette breaks in such premises are therefore not additional in Option 3.

341. Table 7.5 sets out the estimates for costs of e-cigarette breaks per size of workplace in the private sector:-

Table 7.5:

Employer size	Large (250+)	Medium (50-249)	Small (10-49)	Micro (0-9)	Total
No. of employees^a	415,794	133,308	158,700	350,198	1,058,000^b
Employers with e-cigarette	89%	67%	50%	24%	n/a

¹⁷⁵ Key Economic Statistics, December 2013. Welsh Government. <http://wales.gov.uk/statistics-and-research/key-economic-statistics/?lang=en#/statistics-and-research/key-economic-statistics/?tab=previous&lang=en>

¹⁷⁶ ASH factsheet: Use of E-cigarettes in Great Britain 20 October 2014 <http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

¹⁷⁷ In 2013, the UK population was 64.1 million and the population of Wales was 3.1 million (4.8% of the UK total). Population Estimates for UK, England and Wales, Scotland and Northern Ireland, Mid-2013. ONS, 26 June 2014. Available at: <http://www.ons.gov.uk/ons/rel/pop-estimate/population-estimates-for-uk--england-and-wales--scotland-and-northern-ireland/2013/index.html>

¹⁷⁸ ASH factsheet: Use of E-cigarettes in Great Britain 20 October 2014 <http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

policy in place^c					
No. of employees working where no restrictions on e-cigarette use (A)	45,737	43,992	79,350	266,151	435,230
Approximate no. of A that use e-cigarettes^d	2,287	2,200	3,968	13,308	21,763
Estimated additional cost of e-cigarette breaks^e	£321,918	£309,672	£558,536	£1,873,234	£3,063,360

^aBased on employment shares by employee size-band, Size Analysis of Welsh Businesses 2013¹⁷⁹

^bBased on Size Analysis of Welsh Businesses 2013¹⁸⁰

^cAccording to responses to Welsh Government workplace survey of e-cigarette policies¹⁸¹

^dBased on an estimate that 5% of the working population use e-cigarettes¹⁸²

^eBased on average cost of smoking break per employee of £140.76 per year¹⁸³

Table 7.6 sets out the estimates for costs of e-cigarette breaks in the public sector:-

Table 7.6

Employer size	Public sector^e
No. of employees^a	331,000

¹⁷⁹ <http://wales.gov.uk/statistics-and-research/size-analysis-welsh-business/?lang=en#/statistics-and-research/size-analysis-welsh-business/?tab=previous&lang=en>

¹⁸⁰ <http://wales.gov.uk/statistics-and-research/size-analysis-welsh-business/?lang=en#/statistics-and-research/size-analysis-welsh-business/?tab=previous&lang=en>

¹⁸¹ Welsh Government. E-cigarette policies: a survey of workplaces in Wales. 2014. <http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

¹⁸² Based on estimate that 71,366 e-cigarette users are in employment and known working population of 1.387 million in Wales.

¹⁸³ Total cost of smoking breaks of £41 million divided by the number of employed smokers (N=291,270)

Employers with e-cigarette policy in place^b	62%
No. of employees working where no restrictions on e-cigarette use (A)	125,780
Approximate no. of A that use e-cigarettes^c	6,289
Estimated additional cost of e-cigarette breaks^d	£885,240

^aBased on Key Economic Statistics, December 2013¹⁸⁴

^bAccording to responses to Welsh Government workplace survey of e-cigarette policies; includes respondents who reported having an e-cigarette policy in place and being in the process of developing one¹⁸⁵

^cBased on an estimate that 5% of the working population use e-cigarettes¹⁸⁶

^dBased on average cost of smoking break per employee of £140.76 per year¹⁸⁷

^ePublic Sector here includes those employed by state maintained schools.

342. The adjusted total estimated additional cost of e-cigarette breaks for the public (£3,063,360) and private (£885,240) sectors above of £3,948,600 is likely to be an over-estimate. This is because, for example, a high proportion of e-cigarette users use e-cigarettes alongside tobacco products (so called “dual users”) and therefore it is likely that a proportion of e-cigarette breaks by such users is already accounted for in the cost of smoking breaks to the Welsh economy. Estimates of the proportion of dual users vary; the estimate of two thirds of dual users¹⁸⁸ has been used in the calculations below.

343. The frequency of use of e-cigarettes compared to tobacco products among dual users is not known and is likely to vary between individuals. Many e-cigarette users, whether dual users or ex-smokers, already voluntarily step outside to use their e-cigarettes. The Welsh Government workplace survey on e-cigarette policies also found that 44% of respondents who stated they did not have an e-cigarette policy in place (N=121/295) gave the reason that people do not use e-cigarettes in their workplace. Given this figure, the top end cost estimate of £3,948,600 has

¹⁸⁴ <http://wales.gov.uk/statistics-and-research/size-analysis-welsh-business/?lang=en#/statistics-and-research/size-analysis-welsh-business/?tab=previous&lang=en>

¹⁸⁵ Welsh Government. E-cigarette policies: a survey of workplaces in Wales. 2014. <http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

¹⁸⁶ Based on estimate that 71,366 e-cigarette users are in employment and known working population of 1.387 million in Wales.

¹⁸⁷ Total cost of smoking breaks of £41 million divided by the number of employed smokers (N=291,270)

¹⁸⁸ ASH factsheet: Use of E-cigarettes in Great Britain 20 October 2014 <http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

been adjusted downwards by 44% to take account of those premises where e-cigarettes are not currently used. This adjusts the total cost to £2,211,200 per annum.

344. Data from ASH England¹⁸⁹ shows that 15% of all current e-cigarette users report using e-cigarettes to overcome the smoking ban (i.e. use them in places where they are not permitted to smoke). The minimum cost of e-cigarette breaks to the Welsh economy is therefore estimated at £331,700. This is based on an assumption that 15% of all e-cigarette users who would normally use them in the workplace would now have to take a break under this option. £331,700 represents 15% of the top end cost estimate.
345. Applying these assumptions, the annual cost of e-cigarette breaks to the Welsh economy is estimated to be within a range of £331,700 to £2,211,200.
346. There would also be costs to industry in respect of fixed penalty notices (FPNs) and fines issued for offences related to the extended smoke-free requirements. These would be aligned to FPN and fine amounts for smoke-free offences. The revenue from FPNs would be retained by the local authority responsible for enforcement of the requirements where the offence was committed. The Health Act 2006 and the 2007 Regulations have achieved high levels of compliance and a similar level of compliance would be anticipated with the extended smoke-free requirements. Data from smoke-free compliance monitoring have therefore been used to approximate costs to public and work places in respect of FPNs and fines. Such data were only collated for the first four years following implementation of the Health Act 2006, and so it has been assumed there was no change from 2010/11 data for the period that followed.
347. FPNs in respect of the offence of failing to display appropriate smoke-free signage are £200 per FPN, discounted to £150 if paid within 15 days of the date of the notice. The table below sets out the estimated cost of FPNs for the first five years following implementation of the extended smoke-free requirement. Data on the amount of FPN paid are not available and so it has been assumed the maximum FPN amount of £200 would be paid.

Table 7.7:

Year	FPNs issued	FPN amount (£)
2016/17	2	400
2017/18	2	400
2018/19	2	400
2019/20	2	400
2020/21	2	400

¹⁸⁹ ASH factsheet: Use of E-cigarettes in Great Britain 20 October 2014
<http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

348. According to compliance records, there have never been any prosecutions in respect of failure to display smoke-free signage. It has been assumed that the new signage requirements under Option 3 would have the same levels of compliance, and so no costs have been attributed to this.

349. The estimated costs from fines associated with prosecutions relating to the offence of failing to prevent smoking in a smoke-free place are set out in the table below. This is an offence which is subject to a fine not exceeding Level 4 on the standard scale, and it has been assumed that all fines issued would be at the maximum level. However, in practice they are usually much lower than this.

Table 7.8:

Year	Successful prosecution	Total Amount of Fine £
2016/17	4	£10,000
2017/18	9	£22,500
2018/19	1	£2,500
2019/20	0	£0
2020/21	0	£0

350. While the FPNs and fines represent a cost to the organisation involved, they are also a source of revenue for the relevant enforcement authority (partially off-setting the costs of enforcement). The net economic impact of the FPNs and fines is therefore zero.

351. There may be other costs to public and work places arising from this option. According to the Welsh Government survey of e-cigarette policies in workplaces¹⁹⁰, only 3% of workplaces (N=10) made changes to support e-cigarette use. Almost all changes were regarding the supply of separate outdoor shelters for e-cigarette users. This would not be a mandatory requirement under Option 3, however, and as such these costs have not been assessed.

E-cigarette industry

352. Similarly to the smoking ban, a restriction on the use of e-cigarettes in enclosed public and work places would not be intended to affect prevalence rates. The Health Survey for England – 2008: Physical Activity and Fitness¹⁹¹ assessed the impact of the smoking ban in England on smoking prevalence, and found there was no significant difference in cigarette smoking prevalence in men and women before and after the implementation of the smoke-free legislation on 1 July 2007. The impact

¹⁹⁰ Welsh Government. E-cigarette policies: a survey of workplaces in Wales. 2014.
<http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

¹⁹¹ Health Survey for England - 2008: Physical activity and fitness . December 17, 2009
<http://www.hscic.gov.uk/pubs/hse08physicalactivity>

of Option 3 on the e-cigarette industry could therefore be insignificant and the minimum cost is estimated to be £0 per annum.

353. However, at the time of the introduction of the smoking ban, the tobacco industry was well established, whereas e-cigarettes are an emerging and rapidly developing industry. It is therefore acknowledged that a restriction on the use of e-cigarettes in enclosed public and work places may impact on the number of e-cigarette users in Wales, particularly those smokers who use e-cigarettes to circumvent the existing smoke-free requirements. This, in turn, may decrease sales of e-cigarettes in Wales.
354. The UK e-cigarette market excluding online sales was estimated to be worth £91.3 million in January 2014.¹⁹² The size of the total market including online sales is likely to be more than twice this figure, as according to the Electronic Cigarette Industry Trade Association (ECITA), “online sales are slightly over retail sales”¹⁹³. An estimate of the size of the total UK market is, therefore, £187.2 million¹⁹⁴. If a population ratio is applied to this figure¹⁹⁵ it can be assumed that the e-cigarette market is worth around £8.986 million in Wales.
355. As 15% of all e-cigarette users state they use e-cigarettes to circumvent the smoke-free requirements¹⁹⁶, it can be considered reasonable to assume that the majority of this type of e-cigarette user would no longer use e-cigarettes at all if their use in enclosed places is restricted. However, as respondents to this survey were given a range of answers and asked to tick all that applied to them, the reasons provided are not mutually exclusive. It is therefore unlikely that all of these users who stated this as one of their reasons would stop using e-cigarettes as a result of this Option being implemented. A 15% drop in the market has been assumed to be the maximum impact of this option, resulting in a cost of approximately £1,347,900 per annum.
356. However, it was estimated earlier that of the 1,389,000 employees working in the public sector and the private sector, 561,010 employees are currently working in places where there are no restrictions on e-cigarette use. This equates to approximately 40% of the workforce for whom the restrictions are likely to have the greatest impact relative to their current

¹⁹² Chittock M (2014). Focus on e-cigarettes: A touch of the vapours. The Grocer, February 15th: 51-52, 54

¹⁹³ PJ Online. (2014). Quote from Katherine Devlin, President of ECITA. Available at: <http://www.pharmaceutical-journal.com/news-and-analysis/news/boots-and-lloydspharmacy-join-the-vaping-fold-by-selling-e-cigarettes/11134333.article>

¹⁹⁴ <https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

¹⁹⁵ In 2013, the UK population was 64.1m and the population of Wales was 3.1m (4.8% of the UK total). Population Estimates for UK, England and Wales, Scotland and Northern Ireland, Mid-2013. ONS, 26 June 2014. Available at: <http://www.ons.gov.uk/ons/rel/pop-estimate/population-estimates-for-uk--england-and-wales--scotland-and-northern-ireland/2013/index.html>

¹⁹⁶ ASH factsheet: Use of E-cigarettes in Great Britain 20 October 2014
<http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

experience. The maximum impact outlined above has therefore been adjusted so that it takes into account only those employees in premises which do not currently restrict the use of e-cigarettes. This has been done by reducing the maximum impact by 60%, which adjusts the top end cost estimate to £539,200. Although it is recognised that restrictions on the use of e-cigarettes in enclosed and substantially enclosed public spaces and the leisure industry are likely to also have an impact, data relating to employment is considered to be most reliable and has therefore been used in order to calculate the impact on the market. The cost to the e-cigarette industry is therefore estimated to be within a range of £0 to £539,200 per annum.

357. Data on how the e-cigarette market is likely to develop over the time period covered by this RIA are not currently available. However, it is considered that any impact on sales would not happen immediately following implementation of restrictions on e-cigarette use; they would be more likely to occur over a period of time. Nevertheless, for accounting purposes, the potential costs to the e-cigarette industry as a result of reduced sales have been allocated as an annual cost.
358. The Welsh Government is not aware of data on the impact of restrictions on the use of e-cigarettes in public and workplaces in other jurisdictions. However, there are media reports¹⁹⁷ of a drop of 70% in e-cigarette sales in Spain where a ban on e-cigarette use in certain public places has been in force since April 2014¹⁹⁸. Market commentators¹⁹⁹ have suggested this drop in the Spanish e-cigarette market cannot be attributed to one cause, as a number of factors may have affected this reduction, including over-saturation of the market by retailers of poor performing products, and new age of sale restrictions introduced at the same time as the restrictions on public use.
359. In Wales, it is possible that the age of sale restrictions on nicotine products²⁰⁰ will have an effect on the e-cigarette market. It is also possible that e-cigarette use and the e-cigarette market may be affected by the revised Tobacco Products Directive²⁰¹, which introduces mandatory requirements on product labelling, ingredients listing and notification requirements, as well as a ban on cross border advertising of e-cigarettes. The Directive is required to be implemented by Member States of the European Union (including the UK) by 20 May 2016. However, the Directive is currently subject to a number of judicial reviews²⁰².
360. The direct impact of a restriction in enclosed and substantially enclosed public and work places on e-cigarette sales remains difficult to disentangle

¹⁹⁷ <http://www.thinkspain.com/news-spain/24345/e-cigarette-sales-in-spain-drop-by-70-per-cent>

¹⁹⁸ http://www.abacoadvisers.com/spain_explained/blog/spanish-law/e-cigarette-legislation-spain#

¹⁹⁹ www.ecigintelligence.com

²⁰⁰ <http://www.legislation.gov.uk/ukdsi/2015/9780111130568>

²⁰¹ <http://ec.europa.eu/health/tobacco/products/revision/>

²⁰² <http://www.bbc.co.uk/news/business-29876574>

from these other measures. Accordingly, a conservative approach has been taken to the estimates, and a ranged reduction to the market has been applied annually. There may also be an impact on the number of new consumers of e-cigarette products, but this cannot be quantified due to a lack of data.

361. In addition, sales of e-cigarettes through traditional stores, including convenience and confectionary tobacco newsagents, have recently stagnated as adult e-cigarette users are switching to online purchases and to purchases from the growing number of specialist e-cigarette stores.²⁰³ If this trend continues, the e-cigarette market in Wales is likely to change irrespective of Welsh Government action. However, the Welsh Government is unable to determine whether this impact will have a negative or positive effect on e-cigarette sales in Wales.
362. Restricting the use of e-cigarettes in enclosed public and work places may impact on e-cigarette cafes. The concept of e-cigarette cafes is a fairly recent phenomenon and the Welsh Government is aware of two e-cigarette cafes²⁰⁴ in Wales, which are operated by the same owner. These types of premises would no longer be able to permit the use of e-cigarettes in their indoor premises, which may affect their trade if they do not have any outdoor areas they could use. Shisha pipes are not permitted to be used in enclosed and substantially enclosed public places but shisha bars still operate in Wales. Arguably this could mean e-cigarette cafes could continue to operate too, using outside areas for e-cigarette use, especially given that they may also sell hot beverages and food items. In any case, the small number of establishments in Wales indicates that any impact would be likely to be limited.
363. There may be an impact on specialist e-cigarette retailers who would be unable to allow customers to try their products within their premises. This may impact on sales but it is feasible that outdoor areas could be used for this purpose, although this would not be an option for retailers located within shopping centres or inside other enclosed premises such as indoor markets. In addition, the practice of allowing customers to try their products may not be universal to all specialist retailers of e-cigarettes. Altogether, the Welsh Government has identified (from an internet search carried out in January 2015) 26 specialist e-cigarette retailers currently based in Wales. Due to a lack of data, it is difficult to quantify the potential impact on these businesses and so no assessment has been made.

Courts

364. There were 24 prosecutions in the first year of the smoking ban in Wales (2 April 2007 to 31 March 2008). 14 of these were successful. The tables below set out the number of prosecutions in respect of failing to prevent smoking in a smoke-free place, and in respect of smoking in a smoke-free place.

²⁰³ <http://www.conveniencestore.co.uk/news/e-cigarette-sales-hit-a-wall-in-grocery-stores/511008.article>

²⁰⁴ <http://vibrant-vapours.co.uk/Coffee-Shop>

Table 7.9:

Period	Failing to prevent smoking in a smoke-free place: cases referred for prosecution	Smoking in a smoke-free place : cases referred for prosecution*	Successful prosecutions
2007/08	6	18	14
2008/09	10	24	18
2009/10	1	4	12
2010/11	0	3	3

*Includes cases referred following non-payment of FPNs and cases referred for immediate prosecution

365. Assuming that a similar level of cases would be referred for prosecution in relation to a restriction on the use of e-cigarettes in enclosed and substantially enclosed public and work places, there would only be a limited impact on the courts in Wales. A detailed costing framework has not yet been discussed between the Welsh Government and the Ministry of Justice, and so these costs are unknown at present.

Public

366. There would be costs to any members of the public who receive FPNs in relation to the extended smoke-free offences; these would be additional to the status quo where they are in respect of use of an e-cigarette in an enclosed or substantially enclosed public or work place. These would be aligned to FPN amounts for existing smoke-free offences. The revenue from FPNs would be retained by the local authority responsible for enforcement of the requirements where the offence was committed. FPNs in respect of the offence of smoking in a smoke-free place are issued at £50 per FPN, discounted to £30 if paid within 15 days of the date of the notice. Based on the experience of the Health Act 2006 and the Smoke-free Regulations 2007, the following table sets out the estimated cost of FPNs for the first five years following implementation of the extended smoke-free requirements, and assumes all fines issued are paid at the maximum.

Table 7.10:

Year	FPNs paid	FPN amount (£) (rounded to nearest £100)
2016/17	62	3,100
2017/18	83	4,200
2018/19	79	4,000
2019/20	40	2,000
2020/21	40	2,000

367. Again, using experience from the Health Act 2006 and the Smoke-free Regulations 2007, the estimated costs from fines associated with

prosecutions relating to the offence of smoking in a smoke-free place are set out in table 7.11. This offence is subject to a fine not exceeding Level 1 on the standard scale and it has been have assumed all fines issued are at the maximum level.

368. As with those imposed on public and work places, the FPNs and fines imposed on individuals are transfer payments which are paid by the individual to the relevant authority. The net economic impact of these FPNs and fines is therefore zero.

Table 7.11:

Year	Successful prosecution	Total Amount of Fine (£)
2016/17	10	2,000
2017/18	9	1,800
2018/19	11	2,200
2019/20	3	600
2020/21	3	600

Health

369. Given the risk referred to above that restricting the use of e-cigarettes in enclosed public and work places may impact on the number of e-cigarette users in Wales, there would also be an associated risk that users who decided to stop using e-cigarettes as a result of the restrictions may return to tobacco products. Evidence to suggest that this would occur is limited. Following implementation of a ban on public use of e-cigarettes in New York, smoking rates have increased from 14% in 2010 to 16.1% in 2014²⁰⁵. However, there are other factors in addition to the ban on e-cigarettes that could have contributed to the increase, for example, a reduction in the budget for anti-smoking programmes and marketing campaigns during the period. It is also worth noting that the data suggests smoking prevalence in New York was increasing before the e-cigarette ban came into effect²⁰⁶. Nevertheless, given the evidence around the negative health implications of tobacco products, even a relatively small increase in smoking prevalence as a result of the policy represents a potentially unintended consequence.

370. It is estimated that there are around 100,800 e-cigarette users in Wales and that two thirds of e-cigarette users use them alongside tobacco products²⁰⁷. Such “dual users” are still exposing themselves to the health harms from tobacco smoking²⁰⁸, which may have negative implications for individual and public health, because even low levels of cigarette smoking confer nearly the same risk of cardiovascular disease as heavy smoking, and duration of smoking (as well as intensity) determines the risk of lung

²⁰⁵ <http://www.churnmag.com/news/smoking-rates-increase-new-york-e-cigs-banned/>

²⁰⁶ <http://www.nydailynews.com/new-york/new-yorkers-smoking-article-1.1940245>

²⁰⁷ ASH factsheet: Use of E-cigarettes in Great Britain 20 October 2014
<http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

²⁰⁸ <http://www.nhs.uk/chq/Pages/2344.aspx?CategoryID=53>

cancer²⁰⁹. On the other hand, there may be some harm reduction benefits from their reduced tobacco consumption²¹⁰. However, there is no way of quantifying the impact of dual users stopping using e-cigarettes as an alternative to some of their tobacco cigarettes. This is due to a lack of data on the number of tobacco cigarettes a typical dual user replaces with e-cigarettes, as well as a lack of data on the balance of health benefits from such a substitution.

371. For the estimated one third of e-cigarette users whose source of nicotine is solely from e-cigarettes, it is considered that there would be a risk that some may relapse to smoking, given that the current advantage of being able to use their e-cigarette in enclosed public and work places would be removed. In Wales, the Welsh Government estimates there are around 33,600 people whose only source of nicotine is from e-cigarettes, and it cannot be anticipated how many of these users would return to smoking as a result of a restriction on the use of e-cigarettes in public places.

372. It is considered highly unlikely that all ex-smokers using e-cigarettes would return to smoking, particularly given that the Welsh Government workplace survey²¹¹ and CIEH hospitality survey²¹² indicate between around one third and a half of such premises already have voluntary bans on indoor e-cigarette use. There are no studies currently available to measure the health effects of a current e-cigarette user returning to tobacco smoking following complete abstinence from tobacco. There is however a study which found that every smoker who quits smoking (long-term) gains an average of between 0.99 and 2.58 Quality Adjusted Life Years (QALYs) (discounted) depending upon the age of the individual²¹³. It could therefore be assumed for every ex-smoker using e-cigarettes who returns to tobacco smoking as a result of a new restriction on the use of e-cigarettes would lose the 0.99 to 2.58 additional years that they had gained from quitting smoking. This assumes that the health impact of moving from e-cigarettes to tobacco smoking is equivalent to moving from tobacco smoking to stopping smoking (albeit in reverse).

373. While it is not possible to say how many e-cigarette users would start smoking tobacco products again as a result of extending the smoke-free requirements, the scale of the potential impact can be demonstrated using an illustrative example. The current smoking prevalence rate amongst

²⁰⁹ Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems). Rachel Grana, PhD MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD. Center for Tobacco Control Research and Education University of California, San Francisco WHO Collaborating Center on Tobacco Control. Prepared for World Health Organization Tobacco Free Initiative December 2013.

²¹⁰ <https://www.nice.org.uk/guidance/ph45>

²¹¹ Welsh Government. E-cigarette policies: a survey of workplaces in Wales. 2014. <http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

²¹² Research into E-cigarette Policies in the Independent Hospitality Sector. CIEH Wales. November 2014. Not published.

²¹³ Wang et al 2006. Cut Down to Quit with Nicotine Replacement Therapies (NRT) in Smoking

adults in Wales is 21%. A relatively small increase in this prevalence rate to 21.1% would mean an additional 2,450 people smoking tobacco products in Wales. Based on the QALY gain/loss figures identified in the paragraph above, this equates to a reduction of between 2,400 and 6,300 QALYs. Given that the value per QALY is estimated to be £60,000, this represents a cost of between £146 million and £380 million. These calculations provide a hypothetical scenario only, and the likelihood and extent of any such impact occurring is not known at present. However, the illustration does suggest that if the policy does result in some e-cigarette users switching to smoking, the potential impacts could be significant. As such, the impact of the policy on smoking prevalence should be closely monitored.

374. As 15% of e-cigarette users state they use e-cigarettes to circumvent the smoke-free requirements²¹⁴, it is possible that these types of e-cigarette users would no longer use e-cigarettes at all if their use in enclosed places is restricted. This may or may not reduce the likelihood of a quit attempt. NICE harm reduction guidance²¹⁵ states that although existing evidence is not clear about the health benefits of smoking reduction, those who reduce the amount they smoke are more likely to stop smoking eventually, particularly if they are using licensed nicotine-containing products. As the main intention behind this type of e-cigarette use may not have been for smoking cessation purposes, and to date only one e-cigarette has been licensed for smoking cessation purposes in the UK, it could also be argued that the likelihood of them quitting smoking altogether is very small. However, the impact on such users may be an increase in the number of tobacco cigarettes they smoke, which may have an impact on health (depending on how many tobacco cigarettes were previously being substituted by e-cigarettes). Neither theory has been tested and so cannot be quantified here.

375. Another issue under this option is that users of e-cigarettes would have to leave premises to use their e-cigarettes. There is therefore a risk they would be exposed to the second-hand smoke of smokers who are already required to leave the premises. The health harms from this exposure cannot be quantified, as it would depend on the proximity of the smoker to the e-cigarette user, as well as the length of time of exposure. Having to leave the premises may also encourage them to revert back to tobacco smoking but there is no evidence to suggest this would be the case. It is estimated that two thirds of e-cigarette users use them alongside tobacco products²¹⁶, and such users therefore continue to expose themselves to the health harms from tobacco smoking²¹⁷. The impact on health of this continued exposure will vary amongst “dual users”,

²¹⁴ ASH factsheet: Use of E-cigarettes in Great Britain 20 October 2014

<http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

²¹⁵ National Institute of Clinical Excellence. Tobacco: harm reduction approaches to smoking
Issued: June 2013. Last modified: July 2013. <http://www.nice.org.uk/guidance/ph45>

²¹⁶ ASH factsheet: Use of E-cigarettes in Great Britain 20 October 2014

<http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

²¹⁷ <http://www.nhs.uk/chq/Pages/2344.aspx?CategoryID=53>

depending on the number of tobacco cigarettes they continue to smoke alongside their e-cigarettes. Any additional risk to health from exposure to second-hand smoke among “dual users” would be marginal. Due to these factors, the potential additional impact on health cannot be quantified.

376. In any case, there would be no requirement for smokers and users of e-cigarettes to congregate in the same areas. There is no requirement to provide shelters for smokers under the Health Act 2006 and the Smoke-free Regulations 2007, although some employers do. In workplaces where smoking shelters are provided, employers could introduce separate break times or even separate shelters for smokers and e-cigarette users if they are permitted to and consider this necessary. This possibility would be covered in guidance.

Table 7.12: Summary of additional costs associated with Option 3

Sector	Year				
	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government					
Print and dispatch of signage	100,000	0	0	0	0
Communications:*					
Premises	100,000	0	0	0	0
Public	100,000	0	0	0	0
Total costs for Welsh Government	300,000	0	0	0	0
Local Authorities					
Training*	19,100	0	0	0	0
WLGA guidance	1,400	0	0	1,400	0
Total costs for local authorities	20,500	0	0	1,400	0
Public and Work Places					
Update smoke-free policies	2,422,800	0	0	0	0
E-cigarette breaks	331,700-2,211,200	331,700-2,211,200	331,700-2,211,200	331,700-2,211,200	331,700-2,211,200
FPNs	400	400	400	400	400
Fines	10,000	22,500	2,500	0	0
Total costs for public and work places	2,764,900-4,644,400	354,600-2,234,100	334,600 – 2,214,100	332,100-2,211,600	332,100-2,211,600
E-cigarette industry					
Impact on sales	0-539,200	0-539,200	0-539,200	0-539,200	0-539,200
Total costs for the e-cigarette	0-539,200	0-539,200	0-539,200	0-539,200	0-539,200

industry					
Public					
FPNs	3,100	4,200	4,000	2,000	2,000
Fines	2,000	1,800	2,200	600	600
Total costs for the public	5,100	6,000	6,200	2,600	2,600
Total costs**	3,090,500-5,509,200	360,600-2,779,300	340,800-2,759,500	336,100-2,754,800	334,700-2,753,400

*For these items there may be economies of scale to be gained from linking up, for example, the training of enforcement teams across different aspects of the Public Health (Wales) Bill.

** The total excludes the value of FPNs and fines paid by organisations and members of the public

Benefits

Health benefits

377. The World Health Organization recently recommended²¹⁸ the banning of the indoor use of electronic nicotine delivery systems (ENDS). On 18 October 2014, parties of the WHO Framework Convention on Tobacco Control (FCTC) agreed to consider this and the other measures recommended in the WHO paper on ENDS, as well as electronic non-nicotine delivery systems (ENNDS), with the aim of achieving at least the following objectives, in accordance with national law:-

- (a) prevent the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups;
- (b) minimize as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions;
- (c) prevent unproven health claims from being made about ENDS/ENNDS; and
- (d) protect tobacco-control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry.

378. Restricting the use of e-cigarettes in public and work places would address points (a) and (b) above, and may minimise the potential risks of e-cigarettes in relation to:

- re-normalisation of smoking behaviours;
- use among children and young people; and
- their impact on air quality.

²¹⁸ Electronic Nicotine Delivery System. Report by WHO. WHO Framework Convention on Tobacco Control. FCTC/COP/6/10. 21 July 2014.

379. In line with the WHO position, the following have been presented as benefits in this RIA. However, given that the health benefits of e-cigarettes are heavily debated with polarised opinions among health professionals^{219,220} both positions have been considered in assessing the evidence.

Re-normalisation of smoking behaviours

380. Some e-cigarettes are manufactured to look like cigarettes. E-cigarettes mimic the sensation and appearance of smoking a cigarette²²¹ and provide some of the additional behavioural cues that are known to be important in nicotine dependence, including the 'hand to mouth' action. E-cigarettes have not been on the market long enough for definitive evidence to be available about whether this effect is occurring. However, the de-normalisation of smoking through smoking bans across the world is well documented.

381. US longitudinal research amongst teenagers aged 12–16 years has identified greater perceived difficulty of smoking in public places and home smoking bans as being associated with a lower likelihood of smoking.²²² Participants rated how difficult it is for someone under the age of 18 to smoke in a variety of public places on a four-point scale from 'very hard' to 'not at all hard'. Perceived difficulty of finding a place to smoke had a similarly powerful effect on both the prevention of, and a reduction in, adolescent smoking²²³. The researchers found reduced likelihood of adolescents being on a smoking trajectory (e.g. non-smoker to occasional or established smoker) for each unit increase in perceptions of difficulty in public smoking. The magnitude of the effect of perceived public smoking difficulty was almost sufficient to offset (and for more advanced levels of smoking did counteract) the influence of pro-smoking factors such as parental smoking²²⁴. There is some evidence, from a US study following young people aged 12–17 years over four years, that living in a town where legislation bans smoking in restaurants is associated with a

²¹⁹ <http://nicotinepolicy.net/n-s-p/1753-who-needs-to-see-ecigs-as-part-of-a-solution>

²²⁰ <https://tobacco.ucsf.edu/129-public-health-and-medical-authorities-31-countries-write-who-dg-chan-urging-evidence-based-appro>

²²¹ Public Health England. Electronic Cigarettes: A report commissioned by Public Health England

²²² Bernat DH, Erickson DJ, Widome R, Perry CL and Forster JL. Adolescent smoking trajectories: results from a population-based cohort study. *Journal of Adolescent Health* 2008;43(4):334–40. Available from: <http://www.jahonline.org/article/PIIS1054139X08001572/fulltext>

²²³ Song A and Glantz S. Pushing secondhand smoke and the tobacco industry outside the social norm to reduce adolescent smoking. *Journal of Adolescent Health* 2008;43(4):315–17. Available from: [http://www.jahonline.org/article/S1054-139X\(08\)00235-8/fulltext](http://www.jahonline.org/article/S1054-139X(08)00235-8/fulltext)

²²⁴ Siegel M, Albers AB, Cheng DM, Hamilton WL and Biener L. Local restaurant smoking regulations and the adolescent smoking initiation process: results of a multilevel contextual analysis among Massachusetts youth. *Archives of Pediatrics and Adolescent Medicine* 2008;162(5):477. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2948204/>

significantly reduced likelihood of progressing from experimental to established smoking²²⁵.

382. As well as physically reducing the places where smoking may occur, reducing opportunities to smoke and making it more difficult to smoke helps to challenge perceptions that smoking is normal behaviour²²⁶ and reduced the social acceptability of smoking²²⁷. Young people are greatly influenced by their sense of what is normal and attractive²²⁸. One Canadian study found that the more frequently young people observe smoking occurring in a range of settings, the more likely they are to have the view that smoking is both socially acceptable and normal²²⁹. Hence bans on smoking in restaurants and other public places can help to reduce the 'normalcy' of seeing people smoking, thereby helping to reshape community norms and perceived social acceptability regarding smoking²³⁰.

²³¹

383. The Health Survey for England – 2008: Physical Activity and Fitness²³² (HSE 2008) includes an assessment of the impact of the smoking ban in England. In the survey, children aged 8-15 were asked about locations where they were often near to people who were smoking. The proportion saying they were not often near other smokers increased after 1 July 2007. Fewer people than before 1 July 2007 reported being near smokers in other people's homes, on public transport or in other places.

384. As part of the CHETS Wales 2 report²³³, children were asked whether they had seen people smoking e-cigarettes inside and outside a range of

²²⁵ Siegel M, Albers AB, Cheng DM, Hamilton WL and Biener L. Local restaurant smoking regulations and the adolescent smoking initiation process: results of a multilevel contextual analysis among Massachusetts youth. Archives of Pediatrics and Adolescent Medicine 2008;162(5):477. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2948204/>

²²⁶ Alesci N, Forster J and Blaine T. Smoking visibility, perceived acceptability, and frequency in various locations among youths and adults. Preventive Medicine 2003;36(3):272-81. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12634018>

²²⁷ Song A and Glantz S. Pushing secondhand smoke and the tobacco industry outside the social norm to reduce adolescent smoking. Journal of Adolescent Health 2008;43(4):315-17. Available from: [http://www.jahonline.org/article/S1054-139X\(08\)00235-8/fulltext](http://www.jahonline.org/article/S1054-139X(08)00235-8/fulltext)

²²⁸ Hastings G and Angus K. Forever cool: the influence of smoking imagery on young people. London: British Medical Association, Board of Science, 2008. Available from: <http://www.management.stir.ac.uk/about-us/?a=19777>

²²⁹ Smart R and Stoduto G. Interventions by students in friends' alcohol, tobacco, and drug use. Journal of Drug Education 1997;27:213-22. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/9366127>

²³⁰ Smart R and Stoduto G. Interventions by students in friends' alcohol, tobacco, and drug use. Journal of Drug Education 1997;27:213-22. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/9366127>

²³¹ Eureka Strategic Research. Youth tobacco prevention research project. Undertaken for the Australian Government Department of Health and Ageing. Canberra: Department of Health and Ageing, 2005. Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/phd-pub-tobacco-literature-cnt.htm>

²³² Health Survey for England - 2008: Physical activity and fitness . December 17, 2009 <http://www.hscic.gov.uk/pubs/hse08physicalactivity>

²³³ <http://wales.gov.uk/statistics-and-research/exposure-secondhand-smoke-cars-ecigarette-use-among-children/?lang=en>

public places in the past month. E-cigarettes were most commonly seen being used at bus stations (29% inside; 32% outside), train stations (24% inside, 27% outside) and cinemas (20% inside; 20% outside). Children also reported seeing e-cigarettes used inside and outside leisure venues (15% inside; 23% outside), hospitals (14% inside; 19% outside) and GP surgeries (12% inside, 17% outside).

385. The ASH Wales survey²³⁴ into e-cigarette use among young people in Wales found that 79.6% of respondents had heard of an e-cigarette, with the most common sources of information reported as the media (40%) and friends or family (39.6%). However, other sources of awareness came from the internet (28.2%), shops (27.8%) or strangers using them in a public place (28.2%). A higher percentage of older respondents (aged 17-18) reported friends or family as a source (48.6%) and saw strangers using them in public (42.9%), compared to those aged 15-16 (35.6% and 24.7% respectively), and those aged 13-14 (39.8% and 24.3% respectively). In this survey the sources of awareness were not mutually exclusive and whilst the results from this survey or the CHETS Wales 2 report do not translate to use among young people, they do indicate that use of e-cigarettes in public places is generating awareness among young people.
386. In a review of e-cigarette marketing²³⁵, researchers found that “*many e-cigarette products replicate cigarettes so closely, both in appearance and how they are consumed, that vaping looks just like – and hence models – smoking*”. They go on to suggest that “*even when the behaviour is unequivocally vaping [in that the device being used does not resemble a conventional cigarette], it still models the idea of nicotine self medication by inhaling vapour into the lungs*”. This, they state, suggests the potential for e-cigarettes to inadvertently promote smoking.
387. One study²³⁶ of 60 young adult daily smokers (aged 18-35 years) looked at whether e-cigarettes and other ENDS could act as a cue to increase smoking desire and urges for regular combustible cigarettes. In this study, participants completed subjective ratings before and after exposure to a study confederate drinking bottled water (control cue), and then smoking either a combustible or e-cigarette (active cue). The study found that passive exposure to both the e-cigarette and the regular cigarette cue significantly increased observers’ ratings of desire and urge to smoke a regular cigarette. Exposure to the e-cigarette cue but not the regular cigarette also increased desire to use an e-cigarette. The authors concluded that the results provide the first evidence in a controlled setting that e-cigarette exposure may evoke smoking urges in young adult daily smokers.

²³⁴ ‘Young People and the Use of E-cigarettes in Wales’. Dr Rosanne Palmer, ASH Wales; Britt Hallingberg, PhD Candidate, DECIPHER, Cardiff University. March 2014

²³⁵ Promotion of electronic cigarettes: tobacco marketing reinvented? Marisa de Andrade, Gerard Hastings and Kathryn Angus. BMJ 2013;347:f7473

²³⁶ Passive exposure to electronic cigarette (e-cigarette) use increase desire for combustible and e-cigarettes in young adult smokers. King et al. Tobacco Control BMJ.

Published online first: 21 May 2014. Abstract available at:

<http://tobaccocontrol.bmj.com/content/early/2014/05/21/tobaccocontrol-2014-051563.abstract>

388. Concern about the use of e-cigarettes in enclosed public and work places undermining the success of tobacco control measures, by re-normalising smoking, has been expressed by some health professionals. The deputy chair of the British Medical Association (BMA), Ram Moorthy has stated that a key rationale for a ban on the use of e-cigarettes in public and work places would be to ensure their use does not undermine the success of tobacco control measures, by reinforcing the normalcy / acceptability of smoking²³⁷. The Association of Directors of Public Health's Interim Position Statement²³⁸ on nicotine vapourisers and associated products states they are concerned that the marketing of nicotine vapourisers and their widespread use in enclosed public spaces will undermine the successful efforts which have been made to de-normalise smoking behaviour.
389. According to the Welsh Government survey of e-cigarette policies in schools in Wales²³⁹, around a third of primary schools and just under half of secondary schools that reported having an e-cigarette policy said a reason for having one was because of concerns relating to possible follow-on effects of using e-cigarettes, such as the possibility that they are a gateway to smoking tobacco, or that they normalise smoking behaviours.

Use of e-cigarettes among children and young people

390. Many young people, including never-smokers, have tried e-cigarettes. However, regular use is less common, and is associated with tobacco cigarette use.²⁴⁰ Based on data from the USA^{241, 242, 243}, it is plausible that the use of e-cigarettes among young people will increase, even among non-smokers. One of the key findings from the recently published CHETS Wales 2' report²⁴⁴ was that e-cigarette use appears to be a new form of childhood experimentation with nicotine which is more prevalent among 10 and 11-year-old children than smoking tobacco. The study found that 6% of children reported having ever used an e-cigarette, compared to 2% who

²³⁷ Friends of the Board of Science bulletin; BMA Board of Science. Issue 9, October 2013.

²³⁸ <http://www.adph.org.uk/category/stc/>

²³⁹ Welsh Government. E-cigarette policies: a survey of schools in Wales. 2014. <http://gov.wales/statistics-and-research/e-cigarette-policies-surveys-schools-workplaces/?lang=en>

²⁴⁰ 'Electronic-cigarette use among young people in Wales: evidence from two cross-sectional surveys.' Dr Graham Moore et al. Published 15 April 2015. <http://bmjopen.bmj.com/content/5/4/e007072>

²⁴¹ Electronic cigarette use and conventional cigarette use among US adolescents: a cross-sectional study. Dutra and Glantz. JAMA Pediatr.doi:10.1001/pediatricsrics.2013.5488. Published online 6 March 2014.

²⁴² Intentions to smoke cigarettes among never-smoking U.S. middle and high school electronic cigarette users, National Youth Tobacco Survey, 2011-2013. Bunnell et al. Nicotine Tob Res (2015) 17 (2): 228-235. doi: 10.1093/ntr/ntu166 First published online: August 20, 2014 <http://ntr.oxfordjournals.org/content/17/2/228>

²⁴³ Johnston, L. D., O'Malley, P. M., Miech, R.A., Bachman, J. G., & Schulenberg, J. E. (2015). Monitoring the Future national results on adolescent drug use: Overview of key findings, 2014. Ann Arbor, Mich.: Institute for Social Research, the University of Michigan

²⁴⁴ <http://wales.gov.uk/statistics-and-research/exposure-secondhand-smoke-cars-ecigarette-use-among-children/?lang=en>

reported having ever smoked a tobacco cigarette. The study also found that the vast majority of children who reported having used an e-cigarette had never smoked a tobacco cigarette²⁴⁵.

391. Researchers based in DECIPHer, Cardiff University, have analysed the datasets from the CHETS Wales 2 report in combination with the datasets from the latest round of the HBSC Wales (Health Behaviour in School-aged Children) study. The following key findings emerged from the analysis:

- Ever use of e-cigarettes is more common than ever use of tobacco for all age groups except the oldest secondary school age group (15 and 16 year olds).
- Overall, 12.3% of young people in secondary school (aged 11-16) reported ever using e-cigarettes, with no differences according to gender, ethnicity or family affluence. This lack of social patterning suggests that e-cigarette use could potentially spread, irrespective of socioeconomic or demographic characteristics.
- Experimentation with e-cigarettes is comparable to experimenting with tobacco – both rise steadily with age. The proportion of young people who had ever used an e-cigarette and reported currently smoking increased from 6.9% among 10-11 year olds to 42.7% among 15-16 year olds.
- Compared with those who had smoked tobacco, never smokers are much less likely to report e-cigarette use. However, as the group of never smokers is by far the larger, in absolute terms it included almost as many young people who had used an e-cigarette a few times than the smaller group of smokers.
- Current weekly smokers were 100 times more likely than non-smokers to report regular e-cigarette use. Current smoking was as strongly associated with e-cigarette use as ever smoking, suggesting that young people are not using e-cigarettes as an effective cessation tool. However, it is important to note that the research did not measure daily use of e-cigarettes.
- Only 1.5% of 11-16 year olds reported regular e-cigarette use (i.e. use of an e-cigarette at least monthly). Regular e-cigarette use was more likely among those who had smoked cannabis.

392. The authors conclude that while many young people (including never smokers) have tried e-cigarettes, regular use is less common and is strongly associated with tobacco use. They state that low prevalence of regular e-cigarette use suggests that they are unlikely, as things stand, to

²⁴⁵ Children are three times as likely to try e-cigarettes as tobacco products, study finds. Jacqui Wise. London. BMJ 2014;349:g7508 doi: 10.1136/bmj.g7508 (Published 5 December 2014)

contribute to adolescent nicotine addiction. They also note, however, that longitudinal research is needed to understand age-related trajectories of e-cigarette use and to understand the temporal nature of relationships between e-cigarette and tobacco use.²⁴⁶

393. A study of 14-17 year olds in North West England identified proportions experimenting with e-cigarettes (in this case having tried or purchased them) which appear to be consistent with other studies with similar age groups.²⁴⁷

394. It could therefore be argued that experimental use of e-cigarettes among young people should not be a concern, as it forms a safer form of youth experimentation than tobacco. Some research suggests e-cigarettes are safer than tobacco smoking²⁴⁸; however other studies have shown the presence of toxins present in conventional cigarettes within e-cigarettes²⁴⁹.

395. Nicotine has been found to be harmful for developing brains²⁵⁰. Nicotine is also addictive; the most susceptible youths lose autonomy over tobacco within a day or two of first inhaling from a conventional cigarette²⁵¹. Adolescents also exhibit heightened sensitivity to the rewarding properties of nicotine compared to adults.²⁵² Addiction per se can have a detrimental impact on health and relationships²⁵³. Most e-cigarettes contain nicotine²⁵⁴ and their use therefore exposes the user to nicotine.

396. The evidence base on e-cigarettes acting as a gateway to tobacco smoking remains limited, but there is not sufficient evidence to rule it out. Qualitative research undertaken in Cheshire and Merseyside found that although some older adolescents appeared to associate e-cigarette use with smoking cessation, generally young people viewed e-cigarettes as a product in their own right, suggesting that many young people use them simply for the sake of it, for fun, or to try something new. According to this

²⁴⁶ Moore G, Hewitt G, Evans J, et al. Electronic-cigarette use among young people in Wales: evidence from two cross-sectional surveys. *BMJ Open* 2015;5: e007072. doi:10.1136/bmjopen-2014-007072 <http://bmjopen.bmj.com/> In press

²⁴⁷ Hughes et al. Associations between e-cigarette access and smoking and drinking behaviours in teenagers *BMC Public Health* 2015, 15:244
<http://www.biomedcentral.com/1471-2458/15/244>

²⁴⁸ Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Hajek et al. *Addiction*. 2014 doi:10.1111/add.12659

²⁴⁹ http://tobaccocontrol.bmj.com/content/23/suppl_2/ii11.full

²⁵⁰ <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/50-years-of-progress-by-section.html>

²⁵¹ Di Franza J et al (2007). Symptoms of tobacco dependence after brief intermittent use: the development and assessment of nicotine dependence in youth, *Archives of Pediatrics and Adolescent Medicine* 162 (7): 704-710

²⁵² The dynamic effects of nicotine on the developing brain. Dwyer, J.B., McQuown, S.C., & Leslie, F.M. (2009) *Pharmacology & Therapeutics*, 122, 125-139.

²⁵³ <http://www.nhs.uk/Livewell/addiction/Pages/addictionwhatisit.aspx>

²⁵⁴ ASH Briefing. Electronic Cigarettes. November 2014. <http://ash.org.uk/information/facts-and-stats/ash-briefings>

research, the main focus for young people was on the different flavours and designs of e-cigarettes, and the opportunity for users to customise their devices and show individuality. The authors suggested that with their colourful designs and variety of flavours, e-cigarettes may provide a more accessible and appealing way for young people who may not like the taste or sensation of tobacco cigarettes to experiment with nicotine²⁵⁵.

397. A small study among 11-12 year old girls in North Wales suggested that girls in specific areas were very knowledgeable about the different flavours of e-cigarettes that are available and where they can be bought. For example, in two focus groups in Wrexham, girls talked about a pizza shop that sells e-cigarettes to children aged seven or older. The research also found that teachers at a local school in Wrexham confiscate e-cigarettes on a daily basis²⁵⁶.
398. There are a reported 7,000 flavours of e-cigarettes currently available in the UK²⁵⁷. Flavoured conventional tobacco products are used disproportionately by young people²⁵⁸ and the revised Tobacco Products Directive (2014/40/EU) will ban flavours in tobacco products for this reason. However, one study looking at the impact of flavour descriptors on non-smoking teens' and adult smokers' interest in e-cigarettes found that the e-cigarette flavours tested appealed more to adult smokers than to non-smoking teens, although interest in flavours was low for both groups²⁵⁹.
399. The CHETS Wales 2 report²⁶⁰ found that there is some suggestion that e-cigarette use may be associated with weaker anti-smoking intentions, specifically that:
- Among non-smoking children who reported having used an e-cigarette, 14% reported they might start smoking within the next two years (compared to 2% of those who had not used an e-cigarette); and

²⁵⁵ Hardcastle, K, Hughes, K, Worsley, J, Bennett, A, Ireland, R and Sweeney, S (2014). "Most people I know have got one": Young people's perceptions and experiences of electronic cigarettes. Centre for Public Health at Liverpool John Moores University, Liverpool.

²⁵⁶ Evans, K. (2014). Smoking in girls aged 11-12 years in North Wales. Social Change UK and Public Health Wales.

²⁵⁷ World Health Organisation. (2014) Electronic nicotine delivery systems. FCTC/COP/6/10 rev.1. Paper for Conference of the Parties to the WHO Framework Convention of Tobacco Control, Sixth Session 13-18 October 2014. [Online]. Available at: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf

²⁵⁸ E-Cigarettes A Scientific Review. Rachel Grana, PhD, MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD http://circ.ahajournals.org/content/129/19/1972.full?ijkey=d28c5d971050a38249828b4dc44736615120eb97&keytype2=tf_ipsecsha

²⁵⁹ The impact of flavour descriptors on non-smoking teens' and adult smokers' interest in electronic cigarettes. Shiffman et al. 2014. Nicotine Tob Res (2015) doi: 10.1093/ntr/ntu333. <http://ntr.oxfordjournals.org/content/early/2015/01/06/ntr.ntu333.short?rss=1>

²⁶⁰ <http://wales.gov.uk/statistics-and-research/exposure-secondhand-smoke-cars-ecigarette-use-among-children/?lang=en>

- While few children said that they will smoke within two years, children who had used an e-cigarette were substantially less likely to say they definitely will not smoke, and more likely to say that they might.

400. On whether e-cigarettes are a gateway into smoking, the UK Faculty of Public Health has stated: “*No longitudinal studies in the UK have examined whether electronic cigarettes serve as ‘gateways’ to future tobacco use. These data are urgently required. Until then, the precautionary principle suggests it would be rash to dismiss the worrying trends in US children.*”

401. One study found that e-cigarette use may facilitate the continued use of nicotine. A study of over 75,000 Korean adolescents²⁶¹ found that e-cigarette use was strongly associated with current and heavier cigarette smoking, and that rather than being used as an alternative to conventional cigarettes, most e-cigarette users were dual users with cigarettes.

Exposure to second-hand e-cigarette vapour

402. There could be health benefits from reduced exposure to second-hand vapour. The German Cancer Research Center in their 2014 supplement on e-cigarettes²⁶² stated that several new studies confirm that e-cigarette use in indoor rooms impairs air quality, albeit to a markedly lesser extent than conventional cigarettes. Some studies suggest that particles of e-cigarettes aerosol may be deposited deep in the lung and justify health concerns. One study referenced in this supplement suggested there should be no health concerns about second-hand vapour as the levels of potentially hazardous substances in e-cigarette aerosol are not at a level that would warrant health concerns by the standards that are used to ensure safety of workplaces. This follows similar findings in two other reviews^{263, 264} of the safety of e-cigarettes, which found that pollutant levels in e-cigarette vapour are much lower than the smoke from cigarettes.

403. However, the German Cancer Research Centre argues the use of toxicological exposure limits for passive vaping is questionable for a number of reasons. Firstly, for cancerogenic substances, no upper limits can be given below which these substances would be harmless. Secondly, threshold limit values are fixed for single substances and cannot be applied to mixtures of different substances as in e-cigarette aerosol. Thirdly, threshold limit values assess health effects for exposure at

²⁶¹ Lee, S. et al. (2014). “Electronic cigarette use among Korean adolescents: a cross-sectional study of market penetration, dual use, and relationship to quit attempts and former smoking” in *Journal of Adolescent Health* 2014; 54(6), pp.684-690.

²⁶² Electronic Cigarettes – An Overview – Supplement March 2014. Volume 19. German Cancer Research Center, Heidelberg. DKFZ. Red Series Tobacco Prevention and Tobacco Control.

²⁶³ Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Hajek et al. 2014. *Addiction*, 109, 1801–1810 doi:10.1111/add.12659

²⁶⁴ Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. Farsalinos and Polosa. *Therapeutic Advances in Drug Safety*. Apr 2014; 5(2): 67–86. doi: 10.1177/2042098614524430
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/>

workplaces that are generally much higher; they do not consider exposure to sensitive groups, such as allergic people, people suffering from chronic disease or children. Fourthly, voluntary inhalation of vapour differs significantly from involuntary exposure to substances at workplaces.

Local authorities

404. One of the main benefits of Option 3 would be to support enforcement of the current smoke-free requirements. Several prosecutions under the smoke-free requirements have failed due to the defendant claiming that they were using an e-cigarette at the relevant time, rather than smoking. Option 3 would make smoking or use of an e-cigarette in a smoke-free public or work place an offence. There would also be benefits to local authority enforcement teams who, under the current status quo, have to provide advice on a case-by-case basis on the use of e-cigarettes in premises. This is time consuming and the costs associated with such enquires are outlined under Option 1. The intention to align e-cigarette-free requirements to the existing smoke-free requirements would make the law simple and straightforward to apply, understand and enforce for premises, members of the public and local authorities.

Public and work places

405. Establishments that have already taken the decision to restrict the use of e-cigarettes in their premises would benefit, as their policies would be supported by legislation and their concerns about the enforcement of the existing smoke-free legislation most effectively dealt with.

406. Evidence about the potential health benefits related to e-cigarette use as a tool for smoking cessation and the risks associated with their use among young people and for bystanders is constantly evolving. Establishments that are currently unsure whether to restrict the use of e-cigarettes in their premises, possibly due to these conflicting issues, would benefit from not having to consider this question themselves. Establishments which have already implemented voluntary restrictions on the use of e-cigarettes in their premises would benefit from not having to review their policies on a regular basis. Although there may be a need to review WLGA guidance intermittently, for example to reflect new devices entering the market, this would not be a regular review and consideration would not be time intensive for smoke free premises. Based on the costs estimated under Option 2 for reviewing existing e-cigarette policies against Welsh Government guidance, it is therefore estimated establishments which already have policies on e-cigarette use in place could save up to £2,320,200 every three years. These potential savings have been spread evenly across three years from 2018/19, a saving of £773,400 per annum.

Table 7.13: Cost savings for premises with existing policies on e-cigarette use

Establishment type	Saving (£)
Public sector	9,200

organisations	
Schools	26,700
Private sector: large employers	74,300
Private sector: SMEs	2,210,000
All establishments	2,320,200

407. There may be other cost savings for employers. The American Industrial Hygiene Association in its 2014 White Paper 'Electronic Cigarettes in the Indoor Environment' suggested that *"if e-cigarettes are not regulated in public places, contaminants produced by them in the ambient air may keep customers away. At this point, most Americans would not want to be an airplane passenger or be eating in a restaurant where traditional cigarette smoking is freely permissible. If e-cigarettes are not regulated in workplaces, the real and/or perceived effects will likely result in lost productivity, comparable to the lost productivity associated with poor indoor environmental quality."*²⁶⁵

408. The Advisory, Conciliation and Arbitration Service (ACAS) offers similar guidance for employers on the use of e-cigarettes in the workplace. ACAS suggests that employers may want to consider whether such devices are likely to upset other workers, particularly if they are pregnant or trying to give up smoking themselves - or whether their use indoors is in keeping with the professional image of an organisation, especially if clients or members of public are likely to come into the workplace. Its guidance also suggests that since the smoking ban came into being, it is broadly recognised that smoking is now associated with break times rather than work time. As such, employers may be reluctant to allow e-cigarettes into a working environment and may prefer them to be treated in exactly the same way as conventional cigarettes.²⁶⁶

409. It is possible, therefore, that introducing an e-cigarette-free requirement may result in cost savings for employers in terms of public relations and staff productivity. However, these potential cost savings cannot be quantified. These benefits could also be accrued under Option 2 but would not be as straightforward to achieve, as they would lack the backing of legislation.

Table 7.14: Summary of cost savings associated with Option 3

Sector	Year				
	2016/17	2017/18	2018/19	2019/20	2020/21

²⁶⁵ 'White Paper: Electronic Cigarettes in the Indoor Environment.' American Industrial Hygiene Association. October 19, 2014.

²⁶⁶ <http://www.acas.org.uk/index.aspx?articleid=4391>

	£	£	£	£	£
Local authorities					
Dealing with queries / cases	1,200	1,500	1,900	2,300	2,700
Total savings for local authorities	1,200	1,500	1,900	2,300	2,700
Public and Work Places					
Reviewing policies against guidance	0	0	773,400	773,400	773,400
Total savings for public and work places	0	0	773,400	773,400	773,400
Total Savings	1,200	1,500	775,300	775,700	776,100

Summary and preferred option

410. Option 1 does not meet the policy objective and continues existing practice.

411. Option 2 may encourage some establishments to take action to restrict the use of e-cigarettes in public and work places. However, given the estimation that between one-third and a half of premises have already taken action, further voluntary action is anticipated to be low, especially considering there are other schemes and advice already available. In addition, it is recognised that SMEs have limited resources to implement interventions²⁶⁷ and are less likely to take voluntary action. The impact of Option 2 in meeting the policy objectives is therefore expected to be low.

412. Option 3 is the preferred option, as it meets the policy objective to prevent e-cigarettes undermining the current smoke-free requirements. Providing additional clarity and certainty through legislation would remove the current confusion over where e-cigarettes can and cannot be used.

413. Option 3 also meets the Welsh Government's preventative approach to avoidable harm to health, by reducing the risk of renormalisation of smoking behaviours as well as e-cigarette use becoming a gateway to tobacco smoking, particularly among children and young people. This measure would complement other legislative measures being pursued,

²⁶⁷ WILLIAMS, S.J. and SNOW, D.M. (2012) Promoting health in small and medium-sized enterprises. *Journal of Small Business and Enterprise Development*. 19 (4). p.729-744.

including introduction of an age of sale for e-cigarettes and other nicotine products²⁶⁸.

414. It is estimated that, on average, preventing the uptake of smoking results in an average one year life gain per individual.²⁶⁹ This life gain is valued at £60,000 per person.²⁷⁰ Using the aggregate figures for costs and savings, Option 3 would therefore need to prevent a minimum of 36 people in Wales from taking up tobacco smoking over the five year period and a maximum of 237 for this measure to be cost neutral.
415. As identified in the analysis, there is a risk of unintended consequences from extending the smoke-free requirements - principally the risk that the consumption of tobacco products will increase. This is something that will need to be closely monitored.

Register of retailers of tobacco and nicotine products (Part 2, Chapter 2)

Options

416. Four options have been considered:
- Option 1 - Do nothing;
 - Option 2 – Introduce a voluntary register of retailers who sell tobacco or nicotine products;
 - Option 3 – Introduce a national register on which retailers have to register in order to sell tobacco products and/or nicotine products, combined with an enhanced Restricted Premises Order regime. This is the preferred option; and
 - Option 4 – Introduce a positive licensing scheme for retailers who sell tobacco and/or nicotine products.

Option 1 – Do nothing

Description

²⁶⁸ <https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

²⁶⁹ Age of Sale for Nicotine Inhaling Products: Impact Assessment.
<https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

²⁷⁰ A value of £60,000 is assigned to a Quality Adjusted Life Year. Where Quality Adjusted Life Year estimates are not readily available, and it is appropriate this value is used for Life Years. This is consistent with similar valuation of policies that mitigate mortality or morbidity risk by other Government departments, based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes.

417. There would be no changes to current legislation under this option. Local trading standards officers would continue to monitor existing legislation in relation to tobacco, and would need to monitor any new legislation on nicotine products. In doing so they would use only local intelligence or data sources, without access to a national register.

Costs

Welsh Government

418. There would be no new costs to the Welsh Government from this option. £2m was previously transferred into the local government Revenue Support Grant to support enforcement activities in relation to tobacco, as a result of the Smoke-free Premises etc (Wales) Regulations 2007.²⁷¹ This funding would continue to be part of the Revenue Support Grant for future years.

Local authorities

419. There would be no additional costs to local authorities or trading standards departments from this option. The existing funding would continue to be provided as part of the Revenue Support Grant to support enforcement activities.

Retailers

420. This option would not incur any new costs to retailers. There could still be some costs from fines relating to failing to adhere to existing legislation, but those costs would already exist. In 2013/14 a total of £1,500 worth of fines were paid by retailers in relation to underage sales of tobacco.

Benefits

421. This option maintains the current policy position and as such there would be no additional benefits associated with this option.

Option 2 - Introduce a voluntary register for retailers who sell tobacco or nicotine products

Description

422. This option would involve developing a national voluntary register of retailers who sell tobacco products and/or nicotine products. This could be hosted by a lead local authority or other body. Retailers who sell these products would choose to register their premises. Trading standards officers would have access to the data, which would provide some detail

²⁷¹ The Smoke-free Premises etc. (Wales) Regulations 2007 (S.I. No. 2007/787 (W.68) came into force on 2 April 2007.

on retailers in their area who sell these products. As the register would be voluntary, there would be no registration fee for retailers.

Costs

Welsh Government

423. There would be an initial cost in developing the register. It would be developed and hosted online, with an online application form for retailers. The development of the register could be procured by the Welsh Government, or be undertaken through a lead local authority. Based on information from Scotland (where a statutory register has been put in place), it is estimated that the costs of developing the register would be approximately £26,900. These costs would be split between 2016/17 (£21,500) and 2017/18 (£5,400). An alternative paper application form would also be developed for retailers who may not have access to the online version and this would be covered within these developmental costs.
424. In addition, some staff time would be required to procure and manage the contract throughout its development. It is estimated that this would take approximately three weeks FTE of a Higher Executive Officer's time, costing approximately £2,800.²⁷² These costs would be split between 2016/17 (£2,200) and 2017/18 (£600).
425. In addition to the developmental costs there would be ongoing ICT costs for the main database. These would cover, for example, back-ups to avoid data losses, server costs and costs to resolve technical issues. Based on information from Scotland it is anticipated that these annual costs would be approximately £10,000. This annual cost would be incurred from 2018/19 onwards.
426. To support the launch of a voluntary register there would also need to be some publicity during the initial period to raise awareness and encourage retailers to register. It is expected that the majority of this publicity would be generated by free news stories through the press, as well as stakeholder networks (for example trading standards, the third sector and groups representing the retail sector). It is anticipated that this would require approximately six weeks FTE of a Higher Executive Officer's time, equating to approximately £5,500²⁷³. These costs would be split between 2016/17 (£2,800) and 2017/18 (£2,700).
427. There would also need to be some staff resource allocated to manage and monitor the register, as well as to log any registrations from retailers which are received in paper format. Due to the voluntary nature of the register it is difficult to judge how many of the estimated 8,225²⁷⁴ retailers

²⁷² Based on Welsh Government staff planning costs

²⁷³ Based on Welsh Government staff planning costs

²⁷⁴ This figure is based on approximately 6,525 tobacco retailers (adjusted from Scottish data provided in the Enhanced Tobacco Sales Enforcement Programme Report 2010-14 produced

of tobacco products and nicotine products would register, and therefore how much staff time this would take. Given the low percentage of uptake of the Landlords Accreditation Scheme²⁷⁵ (0.02%), a voluntary registration scheme, it is estimated that a 1.0 FTE Higher Executive Officer post would be needed to cover the management of the register as this officer would also have a role in encouraging retailers to register in order to maximise the level of uptake. It is expected that due to the voluntary nature of the register more time would be needed to encourage retailers to join, compared to a statutory register. The cost of the post would be approximately £40,600 in the first year (2017/18). In addition, there would be some staff support costs to cover the administration of the register. It is anticipated that this would take approximately 0.1 FTE Team Support Officer per annum, equating to approximately £2,600. Based on these assumptions it is anticipated the total staff costs would equate to approximately £43,200 for the first 12 months (2017/18).

428. It is likely that the time needed to manage and administer the register would decrease over time. It is estimated that 12 months following the launch, a 0.2 FTE Higher Executive Officer would be needed to manage the register and continue to work with retailers to encourage further registrations. This would equate to approximately £8,100 annually. There would also be a need for continued administrative support, although this would be likely to reduce to a 0.05 FTE Team Support, equating to an annual cost of £1,300. It is likely that most retailers would have joined the register during the initial period, with only a small percentage subsequently joining. This would reduce the annual staff costs to approximately £9,400 from 2018/19.

429. The staffing costs outlined above would be met by the Welsh Government, or alternatively the management and administration of the register could be outsourced (for example to a local authority or other body to run on behalf of the Welsh Government). If the register were to be outsourced then funding would be provided by the Welsh Government to cover the associated costs.

Local authorities

430. There would be no additional costs to local authorities or trading standards departments from this option. Existing funding for enforcement activities and providing guidance and information for retailers would continue to be provided through the Revenue Support Grant. As the register would be voluntary there would be no new offences linked to it, and therefore there would be no additional enforcement costs.

Retailers

by Trading Standards in Scotland) and an estimated 1,700 retailers of nicotine products (no reliable data available)

²⁷⁵ Housing (Wales) Bill Explanatory Memorandum. Welsh Government November 2013
[http://www.assembly.wales/laid%20documents/pri-ld9784-em-r%20-%20explanatory%20memorandum%20housing%20\(wales\)%20bill/pri-ld9784-em-r-e.pdf](http://www.assembly.wales/laid%20documents/pri-ld9784-em-r%20-%20explanatory%20memorandum%20housing%20(wales)%20bill/pri-ld9784-em-r-e.pdf)

431. This option would not involve any registration costs for retailers, except for the staff time which it would take to consider registration and undertake the task of registering. The intention would be to keep the registration process as simple as possible, taking a similar approach to that adopted in Scotland²⁷⁶.
432. Retailers may incur some costs from staff time in considering if they wish to join the voluntary register. Based on an hourly rate for retailers of tobacco/nicotine products of £11.90^{277,278}, an estimation of there being approximately 3,290 separate businesses covering the estimated 8,225 retailers of tobacco products and nicotine products in Wales (it is assumed that a decision would be made centrally by a business, not individually within each outlet), and an assumption that the above actions would take approximately one hour, costs to retailers would amount to approximately £39,200 in 2017/18. The actual cost could vary depending on how long retailers spend on considering whether or not to join the register.
433. It is estimated that the staff time involved in completing an application for the register would be approximately five to ten minutes to register one premise, and an additional one to two minutes for each additional premise. Staff costs have been estimated at the upper end of this range using the same assumptions as above.
434. As stated above there are an estimated 3,290 businesses selling tobacco products and nicotine products in Wales. It is anticipated that the completion of applications for these businesses, taking 10 minutes each, would cost approximately £6,500 in staff time. Applications taking two minutes each would then be required for the remaining 4,935 retailers, at a cost of approximately £2,000. The total cost to retailers of completing applications would therefore be £8,500.
435. As this option would involve a voluntary register, it is unlikely that all retailers would register. If a similar percentage of retailers registered as for the Landlords Accreditation Wales scheme, then only 0.02% of tobacco retailers would register, equating to approximately 165 retailers. This would reduce the total cost of retailers registering to approximately £200²⁷⁹. Every effort would be made by the Welsh Government, local authorities and stakeholders (such as retail representative groups) to encourage retailers to register. The cost incurred by retailers who actually register is therefore estimated to be within a range of £200 to £8,500 in 2017/18.

²⁷⁶ Scottish Tobacco Retailers Register <http://www.tobaccoregisterscotland.org/> accessed Jan 2015.

²⁷⁷ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Managers and Directors in Wholesale and retail). <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-337425>

²⁷⁸ Hourly rates have been increased by a factor of 30% to incorporate on costs.

²⁷⁹ Housing (Wales) Bill, November 2013, Welsh Government. 0.02% of landlords registered under the Landlords Accreditation Wales Scheme registered over a five year period.

436. Due to the voluntary nature of the register, it is not possible to accurately determine how many retailers would register each year. As such, the costs outlined in the table below are based on a range, from an estimated minimum level of uptake (0.02% of the estimated 8,225 total retailers of tobacco and nicotine products) to a maximum (100% of the 8,225 total retailers of tobacco and nicotine products). As it is likely that a smaller number of retailers would join the register each year the maximum staff costs to retailers has been reduced by £200 per year from 2018/19. This is based on an estimated 165 retailers joining the register and therefore not being factored into the range for the following year.

Table 7.15 – Summary of additional costs associated with Option 2

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government					
Development of the register	23,700	6,000	0	0	0
Ongoing ICT costs	0	0	10,000	10,000	10,000
Communications and publicity	2,800	2,700	0	0	0
Ongoing Staff costs	0	43,200	9,400	9,400	9,400
Total Cost to Welsh Government	26,500	51,900	19,400	19,400	19,400
Retailers					
Staff costs to undertake registrations	0	200 - 8,500	200 - 8,300	200 - 8,100	200 - 7,900
Staff costs to consider joining the voluntary register	0	39,200	0	0	0
Total cost to retailers	0	39,400 – 47,700	200 - 8,300	200 - 8,100	200 - 7,900
Total cost	26,500	91,300 – 99,600	19,600 - 27,700	19,600 – 27,500	19,600 - 27,300

Benefits

437. Implementing a voluntary register for retailers of tobacco products and/or nicotine products would provide local authorities with additional intelligence on the number of retailers in their area who sell these products. This additional intelligence would support enforcement activities. However the benefits would vary according to how many retailers chose to register. If a similar percentage of retailers registered as with landlords who joined the Landlord Accreditation Wales Scheme (0.02%), then the

benefit of the intelligence gathered would be very low. In addition, it is plausible to assume that a voluntary register may become out of date, as there would be no incentive for retailers who do register to report any subsequent changes of details.

438. The main benefit that could be offered to retailers would be that by being included on a national voluntary register, trading standards officers would be able to circulate information and/or guidance to them which they may otherwise miss.

Option 3 - Introduce a national register on which retailers have to register in order to sell tobacco products and/or nicotine products, combined with an enhanced Restricted Premises Order regime.

Description

439. This option would involve the development of a national register of retailers who sell tobacco products and/or nicotine products. This could be hosted by a lead local authority or other body, who would perform the role of the Registration Authority. Retailers would have to register if they sell either of these products, and it would be an offence to sell them if they were unregistered. There would be a fee for retailers to register, which would be set at £30 for the first premise and £10 for each additional premise. There would not be a requirement for retailers to periodically re-register, but retailers would instead be required to report any relevant changes to their details to the agency with responsibility for maintaining the register.

440. In addition to the creation of the register, additional tobacco offences would be added to the current list of offences which can trigger a local authority applying for a restricted premises order (RPO). This would be intended to create a more effective negative licensing scheme for Wales, which would reinforce the importance of retailers complying with relevant legislation. Negative licensing means that all retailers have the ability to sell tobacco and nicotine products unless they are serving an RPO, at which point this is temporarily revoked. Once the RPO has expired a retailer could once again sell these products.

Costs

Welsh Government

441. There would be an initial cost for developing the register. These would be in line with those outlined under Option 2, that is £23,700 in 2016/17 and £6,000 in 2017/18.
442. To support the launch of the register there would also need to be some publicity to raise awareness and encourage retailers to register. It is expected that the majority of this publicity would be generated by free

news stories through the press as well as stakeholder networks (for example trading standards, the third sector and groups representing the retail sector). This approach has been used for other tobacco legislation such as the display ban. It is expected that the costs for publicity would be similar to those outlined under Option 2, i.e. £2,800 in 2016/17 and £2,700 in 2017/18.

Local authorities

443. There would be a need for staff resource to manage and monitor the register on an ongoing basis. It is anticipated that a 0.5 FTE local authority enforcement officer could undertake this function for all local authorities across Wales, for the first six months, decreasing to 0.05 FTE thereafter due to the likelihood of a high level of initial enquiries. This would equate to approximately £13,200 in the first year and then £2,400 annually.²⁸⁰ In addition to managing the register there would be a need for administrative support to log any paper registrations and monitor the register. It is anticipated that this would require a 0.5 FTE administrator for the initial six months, which would subsequently decrease to 0.1 FTE. This is because it is likely that a greater amount of administrative support would be needed for the initial six months, as this is when the bulk of the registration applications would be expected. It is therefore anticipated that this support would cost approximately £7,700 for the first year, decreasing to approximately £2,600 annually. The total local authority staff costs for managing and monitoring the register are therefore £20,900 in 2017/18 and £5,000 per annum in subsequent years.

444. There would be some ICT costs associated with maintaining the register (for example creating back-ups, server costs), and these would be identical to those outlined under Option 2 (£10,000 per annum from 2018/19). As a local authority would potentially be designated as the leading registration authority, these costs would fall to the local authority with this responsibility. However, costs would be covered by a combination of the registration fees raised from retailers and funding provided by the Welsh Government.

445. Guidance for retailers would also need to be produced. It is anticipated that this would be developed by trading standards representatives, and would take approximately one month of a FTE Local Authority Enforcement Officer's time (based on 6,000 words). This would also equate to £3,800. In addition to developing the guidance there would be associated translation and design costs. It is anticipated that design and typesetting would cost approximately £300. It is estimated that translation and proofreading would cost approximately £600.²⁸¹ The total cost for the development, design and translation of guidance would therefore be £4,700. This cost will be incurred in 2016/17.

²⁸⁰ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

²⁸¹ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

446. The guidance would be updated every three years. It is anticipated that this would require approximately one week of a FTE Local Authority Enforcement Officer, which would equate to approximately £900. Design and translation costs would amount to half the original costs, a total of £500. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,400, incurred every three years. The first review would be held in 2019/20.
447. Training sessions would need to be held during 2017/18 for Local Authority Enforcement Officers, and it is envisaged that these would be run by trading standards officers. Each session would be approximately a half day and it is envisaged that two sessions would be held, one in North Wales and one in South Wales. These sessions are estimated to cost approximately £1,200, based on room hire and refreshments for 35 people for each session. There would also be some staff time involved in developing and running the training, which it is anticipated would equate to approximately two weeks of a FTE Local Authority Enforcement Officer's time, costing approximately £1,800 (the cost of developing the training is assumed to be incurred in 2016/17). In addition to the costs for running the sessions, there would be costs to local authorities for enforcement officers to attend. It is estimated that this would cost approximately £9,200²⁸². The training cost incurred in 2017/18 is therefore estimated to be £10,400.
448. Whilst local authorities have funding through the Revenue Support Grant to cover enforcing existing legislation, such as legislation on the display of tobacco products at point of sale and age of sale legislation, they do not receive funding to cover any of the offences linked to the creation of the retailers' register. In Scotland, in 2010-11 it was estimated there were 19,678 tobacco retailers, and following the launch of the Scottish Tobacco Retail Register this number decreased to 11,114 in 2012/13. Whilst a number of factors could have contributed to this reduction, it is possible that some retailers have not registered. A similar situation could therefore happen in Wales. This would mean there would be a requirement for trading standards officers to investigate reports of unregistered retailers selling tobacco products and/or NIDs. In Scotland seven retailers were issued with Fixed Penalty Notices for carrying on a tobacco business while unregistered²⁸³.
449. The inclusion of additional offences which could trigger an RPO would also have an impact on staffing resources for taking retailers to court for an RPO. It is expected that there would be a minimal number of cases going to court.

²⁸² Based on 5 hours at an hourly rate of £26.40 for a Local Government Enforcement Officer (to include the half day training session and travel time) for 70 enforcement officers to attend.

²⁸³ Enhanced Tobacco Sales Enforcement Programme Report 2010-14. Trading Standards in Scotland

Retailers

450. Retailers may incur some costs from time spent familiarising themselves with the guidance and legislation, in order to ensure they comply with the changes. Based on the hourly rate of retailers who sell tobacco (£11.90^{284,285}), the estimation of there being 3,290 separate businesses covering the estimated 8,225 retailers of tobacco products and nicotine products in Wales and that the above actions would take two hours, costs to retailers would amount to approximately £78,300 in 2017/18.
451. While the intention would be to keep the registration process as simple as possible, similar to the process adopted in Scotland, there would be some degree of staff time involved in completing an application. It is expected that this would take approximately five to ten minutes to register a premise, and an additional one to two minutes for each additional premise. These costs would be similar to those outlined under Option 2. However, as the register proposed under this option would be mandatory the costs have been calculated on all the estimated 8,225 retailers of tobacco and nicotine products registering. It is estimated that this would cost the retail sector approximately £8,500 in 2017/18 (this is based on the upper estimate of the time required to register in Option 2).
452. In addition to the staff time involved in following the registration process, there would be a registration fee for retailers. It is proposed that this would be set at £30 for the first premise, and £10 per additional premise. It was estimated under Option 2 that there are 8,225 retailers of tobacco products and nicotine products in Wales, made up of 3,290 businesses. Applying these estimates would mean it would cost approximately £148,100 for all retailers who sell tobacco products and/or nicotine products to register. As retailers would have six months to register following the register going live it is expected that these costs would fall in 2017/18. While the registration fee represents a cost to retailers, it is a source of revenue for the lead authority which would be used to offset maintenance, administration and staff costs.
453. There would be no re-registration fee or fee for amending a retailer's details on the register. There would, however, be fees for a registered business to add additional premises, or for a new application to the register. Following introduction of the register, existing retailers would have an initial six months in which to register. Following this initial period the only fees generated would be for new retailers or premises selling tobacco and/or nicotine products. Data are not available on how many new retailers would register each year, however it is expected that the number will be minimal. In Scotland the total number of retailers on the tobacco register has decreased year on year.

²⁸⁴ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Managers and Directors in Wholesale and retail).

<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-337425>

²⁸⁵ Hourly rates have been increased by a factor of 30% to incorporate on costs.

454. Retailers may also incur costs from the new offences which would be linked to the register, as well as existing offences linked to other relevant legislation. The majority of the costs linked to the register would be in the form of Fixed Penalty Notices (FPNs), and therefore would not result in additional legal costs unless a retailer chooses not to or fails to pay the FPN. Based on Scottish data²⁸⁶, it is estimated that approximately seven FPNs for carrying on a tobacco business whilst unregistered and two fines (for non payment of a FPN) would be issued per annum. It is estimated that this could amount to a total cost to retailers of approximately £11,100. However, it is likely that the actual costs would be less, as there would be a discount for early payment of FPNs and the fines actually issued may also be lower.

455. Due to linking other tobacco related offences to the RPO process, there could be an increase in the number of retailers who are issued with a RPO. This would prevent them from either selling tobacco products or nicotine products, depending on which RPO is issued. This would have an effect on their potential income, not only from the sales of these products, but also there would be a risk of losing custom of other products to competitors. Based on Scottish data²⁸⁷ it is estimated that approximately two applications for a RPO would be processed per annum.

456. While these are additional costs that retailers in England would not incur, there is unlikely to be an impact on competitiveness due to the scale of the cost imposed on each business and the activity involved.

Courts

457. Based on the number of cases referred for prosecution in Scotland from offences relating to the retail register it is estimated that approximately four cases would be referred to the courts in Wales. As such there would only be a limited impact on the courts in Wales. A detailed costing framework has not yet been discussed between the Welsh Government and the Ministry of Justice, and so these costs are unknown at present.

Table 7.16: – Summary of additional costs associated with Option 3

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government costs					
Development of the Register (including staff costs).	23,700	6,000	0	0	0

²⁸⁶ Enhanced Tobacco Sales Enforcement Programme Report 2010-14. Trading Standards in Scotland

²⁸⁷ Enhanced Tobacco Sales Enforcement Programme Report 2010-14. Trading Standards in Scotland

Communications and Publicity	2,800	2,700	0	0	0
Total Cost to Welsh Government	26,500	8,700	0	0	0
Local authorities					
Ongoing maintenance and administration	0	0	10,000	10,000	10,000
Staff costs	0	20,900	5,000	5,000	5,000
Costs to produce guidance	4,700	0	0	1,400	0
Training costs	1,800	10,400	0	0	0
Total cost to local authorities	6,500	31,300	15,000	16,400	15,000
Retailers					
Staff costs for familiarisation the new legislation	0	78,300	0	0	0
Staff costs to make registrations	0	8,500	0	0	0
Registration fees	0	148,100	0	0	0
Costs from FPNs or fines ²⁸⁸	0	11,100	11,100	11,100	11,100
Total cost to retailers	0	246,000	11,100	11,100	11,100
Total cost	33,000	286,000	26,100	27,500	26,100
Fee revenue to Local Authorities	0	148,100	0	0	0
Net cost	33,000	137,900	26,100	27,500	26,100

458. Registration fees incurred by retailers have not been included in the net cost as they are used to off-set local authority costs. As there would only be a one-off registration fee, local authority revenue from registration fees in 2017/18 would be higher than local authority administration costs in that year. Any excess would be used to fund maintenance and administration of the register in subsequent years. Any eventual shortfall between the fees and costs would be offset by the Welsh Government.

Benefits

459. The main benefit of compelling retailers to register would be the production of a comprehensive list of retailers which sell tobacco or nicotine products. This would assist trading standards officers in their enforcement activities, for example in tackling underage sales of tobacco.

²⁸⁸ Only new offences linked to the register (or the chance of more RPOs based on the changes proposed by the Public Health (Wales) Bill) have been included. The numbers have been based on offences in Scotland.

460. This could be further supported through providing resources, training and guidance. By having access to a comprehensive list of all retailers who sell tobacco and/or nicotine products, trading standards officers and health authorities would be able to target advice, guidance and campaigns relevant to these industries more effectively, ensuring that all registered retailers receive this information.
461. Whilst it is unlikely that a retailers' register supported by an enhanced RPO regime would have the same level of impact as a positive licensing scheme, researchers have concluded the removal of licences for infringements of the law as one of the strategies most likely to successfully reduce under-age sales.²⁸⁹
462. Provided there is adequate enforcement of the legislation, the enhanced RPO should act as a powerful deterrent as retailers would be concerned about losing an important source of revenue. There would also be a recognition that failure to adhere to tobacco and nicotine products legislation could result in loss of a retailer's ability to sell these products. This could bring with it the loss of revenue in other areas if customers choose to go elsewhere to make purchases.
463. It is estimated that, on average, preventing the uptake of smoking results in an average one year life gain per individual.²⁹⁰ This life gain is valued at £60,000 per person.²⁹¹ The net cost of Option 3 over the initial five year period is £241,900; therefore in order to be cost neutral approximately four young people would have to not start smoking.

Option 4 - Introduce a positive licensing scheme for retailers who sell tobacco products and/or nicotine products

Description

464. This option would involve developing a tobacco and nicotine products licensing scheme, which would mean that, unlike Option 3, retailers would need to obtain a licence before being able to sell tobacco and/or nicotine products. It is anticipated that a lead authority would manage the licensing scheme and maintain the database, but officers based within each local authority area would review applications for a licence or a licence renewal.

²⁸⁹ Licensing of Tobacco Retailers and Wholesalers. Published by The Allen Consulting Group. December 2002

²⁹⁰ Age of Sale for Nicotine Inhaling Products: Impact Assessment.

<https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

²⁹¹ A value of £60,000 is assigned to a Quality Adjusted Life Year. Where Quality Adjusted Life Year estimates are not readily available, and it is appropriate this value is used for Life Years. This is consistent with similar valuation of policies that mitigate mortality or morbidity risk by other Government departments, based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes.

In addition, these local officers would be responsible for enforcing the licensing scheme. Retailers would have to evidence how they meet minimum criteria in order to be given a licence, and this evidence would need to be reviewed prior to a licence being granted. It would be an offence to sell tobacco and/or nicotine products without a licence. The licence would only be valid for one year, which would mean retailers would have to apply for a licence renewal each year, similar to an alcohol licence which requires an annual renewal.

465. Under this option existing retailers would need to apply for a licence in order to continue to sell tobacco and/or nicotine products, and new retailers wishing to sell these products would also need to apply for a licence. The intention would be to include a transitional period from the commencement of the provisions for existing retailers to apply for a licence. There would be likely to be a transitional period of six months, but the appropriateness of this would be first discussed with the stakeholders affected.

Costs

Welsh Government

466. There would be an initial cost in developing the ICT element of the licence system. This would include a database of existing tobacco retailers who have been awarded a licence, as well as the provision for online applications and payments. It is anticipated that this database would be similar to that used for the register in Options 2 and 3, and therefore the costs would be similar to those options. This would equate to costs of £23,700 in 2016/17 and £6,000 in 2017/18 to cover the development of the database and associated staff costs.

467. It would be necessary to alert retailers to the new statutory obligations and what would be required of them. This would be achieved through no-cost press and media articles, existing local authority communication channels (for example website, trading standards networks) and through stakeholders. This approach has been used for other tobacco legislation such as the display ban. These costs would be similar to the equivalent costs outlined under Option 3.

Local authorities

468. The costs to local authorities would be higher than Options 2 and 3 due to the increased requirements under a licensing system. Retailers could apply for a licence either by post or online, and local authorities would be responsible for checking the eligibility of the retailer and issuing a licence. It is anticipated that these costs would be mitigated by the fees paid by retailers to obtain a licence.
469. It is estimated that 22 FTE Local Authority Enforcement Officers would be required to manage a licence scheme in 2017/18. This estimation is

based on the time it would take to support retailers in completing an application for a licence, reviewing applications for a licence or licence renewal, enforcing offences relating to tobacco/nicotine products licences, and reviewing appeals. Based on this estimation it is anticipated that this would cost a total of £1,019,600 in the first year.²⁹² There would be an ongoing requirement for 22 0.75 FTE Local Authority Enforcement Officers to manage the scheme. This would amount to an annual cost of £764,700. In addition, the scheme would require a FTE Administrator to support the scheme, including monitoring the database, processing paper applications on to the electronic database, issuing licences, and providing a first point of contact for retailers. This post would be based with the local authority with lead responsibility for managing the scheme and would cover all of Wales. It is anticipated that this would cost approximately £25,700 annually.

470. ICT costs of £10,000 per annum, incurred under Options 2 and 3 for the maintenance of the register, would be repeated under this option.

471. Guidance would also need to be produced to support a new licence scheme. Whilst a licensing scheme would be more complex for local authorities, it is anticipated that the guidance for retailers would be 6,000 words or less. As such it is envisaged that these costs would be the same as those outlined under Option 3.

472. Training sessions for Local Authority Enforcement Officers would also need to be held during 2017/18 to support the scheme, and would be likely to be led by trading standards officers. It is anticipated that the training would take longer than Option 3 due to the extra complexity that a licensing scheme creates. It is envisaged that each session would take approximately a day (lasting approximately six hours including breaks), with one being held in North Wales and one in South Wales. These sessions would cost approximately £1,900, based on room hire and refreshments for 35 people for each session. There would also be some staff time involved in developing and running the training, and it is anticipated that this would equate to approximately three weeks of a FTE Local Authority Enforcement Officer's time, costing approximately £2,600²⁹³, incurred in 2016/17. In addition to the costs for running the sessions, there would be costs to local authorities for enforcement officers to attend. It is estimated that this would cost approximately £14,800²⁹⁴.

Retailers

473. Retailers may incur some costs from time spent to familiarise themselves with the new licence scheme to ensure they comply with it.

²⁹² Based on local authority staff planning costs. On-costs have been incorporated into these costs.

²⁹³ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

²⁹⁴ Based on 8 hours at an hourly rate of £26.40 (to include the training session and travel time) for 70 enforcement officers to attend.

As it is likely that this may be more complex than existing practices (where an application for a licence is not required in order to sell tobacco products and/or nicotine products), it is estimated that this could take retailers approximately three hours to fully familiarise themselves with the changes. Based on an hourly rate of £11.90²⁹⁵ and the estimation of there being 8,225 retailers of tobacco products and nicotine products in Wales which would need to apply for a licence costs to retailers would amount to approximately £293,600 in 2017/18.

474. It is estimated that the cost of a new licence would be approximately £130 for a new licence. There would then be an annual charge of £90 per premise. This is based on the cost to local authorities to administer the scheme. It is anticipated that the cost to retailers in licence fees would be £1,069,200 in the initial year (2017/18) to obtain new licences, and an annual cost of £781,400 for the annual renewal fees. This is based on an estimated 8,225 retailers across Wales who sell either tobacco products or nicotine products. In addition to these costs, any new retailers from 2017/18 who wish to sell tobacco and/or nicotine products would need to obtain a licence before they could sell these products. There are no data on how many new retailers there are per year selling these products, however it is expected that the number of new retailers each year would be low. As with Option 3, these fees represent a source of revenue to local authorities and would be used to offset the administrative costs associated with the scheme.
475. In addition to the fee there would also be costs in relation to the staff time taken to complete an application and provide the required supporting evidence. It is anticipated that it would take approximately two hours to complete an application for a new licence, and approximately one hour for an application for a licence renewal. Assuming a total of 8,225 retailers of tobacco and nicotine products and an hourly pay rate of £11.90 per hour^{296,297}, this would amount to £195,800 in initial staff costs for all tobacco and retailers of nicotine products and £97,900 per annum from 2018/19 for licence renewals.
476. Finally there would be costs to retailers in relation to enforcement actions linked to the licensing scheme, such as fines or loss of sales from having a licence revoked. Where a retailer has its licence revoked, therefore preventing them from selling tobacco products and/or nicotine products, regular customers who purchase these products would take their custom to a competitor who is able to sell these products and, as a result, could also lose trade of non tobacco/nicotine goods.

²⁹⁵ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Managers and Directors in retail and wholesale).
<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-337425>

²⁹⁶ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Managers and Directors in retail and wholesale).
<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-337425>

²⁹⁷ Hourly rates have been increased by a factor of 30% to incorporate on costs.

Table 7.17: – Summary of additional costs associated with Option 4

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government costs					
Development of the database	23,700	6,000	0	0	0
Communications	2,800	2,700	0	0	0
Total Cost to Welsh Government	26,500	8,700	0	0	0
Local authorities					
Ongoing maintenance of the database	0	0	10,000	10,000	10,000
Staff costs	0	1,045,300	790,400	790,400	790,400
Costs to produce guidance	4,700	0	0	1,400	0
Training costs	2,600	16,700	0	0	0
Total cost to local authorities	7,300	1,062,000	800,400	801,800	800,400
Retailers					
Staff costs for familiarisation with the new licensing scheme	0	293,600	0	0	0
Staff costs to apply for licence/renewal	0	195,800	97,900	97,900	97,900
Fees for licence/renewal*	0	1,069,200	781,400	781,400	781,400
Total cost to retailers	0	1,558,600	879,300	879,300	879,300
Total cost	33,800	2,629,300	1,679,700	1,681,100	1,679,700
Fee revenue to Local Authorities		1,069,200	781,400	781,400	781,400
Net cost	33,800	1,560,100	898,300	899,700	898,300

*Registration fees incurred by retailers have not been included in the net cost as they are used to off-set local authority costs.

Benefits

477. Introducing a positive licensing scheme would provide an opportunity for targeted education and information to be provided to retailers through the licence application process, and through the provision of a comprehensive record of all retailers who sell tobacco products and/or nicotine products.

478. This would also be consistent with the message that selling tobacco is similar to other activities that carry a potential health risk, in that it is a conditional privilege rather than an unconditional right to sell tobacco products. It may also increase retailers' awareness of their legal responsibilities, and an offence of selling tobacco products and/or nicotine products without a licence would act as a further deterrent.
479. Evidence suggests that out of the three different models of tobacco retailer licensing (registration, negative licensing or positive licensing), a positive licensing scheme has been identified as best practice in relation to tobacco control. In California youth tobacco sales have dropped by over 30% in eleven communities with the introduction of strong local licensing laws.²⁹⁸

Summary and preferred option

480. Option 1 retains the current position. It would involve existing legislation continuing to be monitored by trading standards officers and breaches of existing legislation being dealt with accordingly. Considering the trend of underage sales has not reduced to an acceptable level since the change of age of sale from 16 to 18 in 2007, it is unlikely that this option would achieve any noticeable decrease in the prevalence of under-age sales of tobacco products. In addition, following the introduction of legislation of age of sale for nicotine products, there will be a risk that these products would also be sold to under 18s, in a similar way to other age restricted products such as tobacco and alcohol.
481. Option 2 proposes the introduction of a voluntary register. It is unlikely a voluntary register would provide trading standards officers with a comprehensive list of all retailers in their area who sell tobacco and/or nicotine products. This would be considered to greatly diminish the benefit of a register, and could mean that any impact on the reduction of prevalence of underage sales of tobacco and access to tobacco and nicotine products by young people would be minimal. As such it is unlikely to have a significant effect on reducing the number of young people smoking. It is also envisaged that this would not have a major impact on preventing underage sales of nicotine products, nor help with enforcement.
482. Option 4 proposes introducing a positive licensing scheme. Evidence suggests that introducing a positive licensing scheme can have a positive effect in reducing smoking prevalence levels, although the evidence is unclear on the benefit in reducing underage sales compared to negative licensing. However, the costs associated with delivering a positive licensing scheme are significantly higher than any of the other options. In

²⁹⁸ Tobacco Supply Strategies in a Local Government Context. Published by Cancer Society Auckland Health Promotion Team in October 2013

particular, this option would impose an additional ongoing cost on tobacco retailers in Wales due to the need to renew the licence on an annual basis.

483. Option 3 proposes the introduction of a national register combined with an enhanced RPO regime, and is the preferred option. It is considered that the threat of licence withdrawal, by issuing a RPO, as well as increased monitoring and communication channels, would strengthen retailers' compliance with tobacco control legislation, and therefore be more likely than current practice to impact on under-age sales. In relation to legislation on nicotine products it would be reasonable to assume the effect would be similar.

484. Creating a mandatory national register of retailers would ensure local trading standards officers have a comprehensive list of retailers in their area. This would help them to enforce existing legislation such as age of sale and display regulations. As it is considered unlikely that a high number of retailers would register on a voluntary register, a statutory register is considered more likely to be effective in ensuring local authorities have a comprehensive list of retailers within their area who sell tobacco products and/or nicotine products. In addition, the register would enable local trading standards officers to target advice, guidance and support to retailers who sell tobacco products and nicotine products.

485. Adding additional appropriate offences, such as the sale of illegal tobacco, to the list of offences which can trigger a local authority application for a RPO would therefore enhance the effectiveness of the RPO process. This would have the additional benefit of imposing a period of time, determined by the Magistrates' Court, for which retailers who have committed a number of offences from the enhanced list would be unable to sell tobacco products or nicotine products. The enhanced RPO regime will reinforce the importance of retailers complying with legislation aimed at protecting young people from accessing tobacco products and nicotine products.

Handing over tobacco etc to persons under 18

Options

486. Three options have been considered:

- Option 1 – Do nothing;
- Option 2 – Issue guidance to retailers on remote sales and handing over of tobacco and nicotine products; and
- Option 3 – Introduce legislation to prohibit the handing over of tobacco and nicotine products to persons under the age of 18, and issue supporting guidance to retailers who offer remote sales, covering the handing over of these products. This is the preferred option.

Option 1 – Do nothing

Description

487. As this option proposes no change it would result in retailers continuing to decide their own policies on remote sales and handing over of tobacco and nicotine products, without any guidance or steer from the Welsh Government. Currently it is against the law to sell tobacco products to a person under the age of 18. However, this does not extend to the delivery of these products. Currently all of the major supermarkets have policies in place which seek to prevent home shopping deliveries from being handed over to customers under the age of 18. However, there are other retailers who could offer a home delivery or 'click and collect' service, whose terms and conditions may not cover handing over of tobacco products or nicotine products to someone under the age of 18. Most of the major supermarkets' terms and conditions state that a sale is complete when money has been exchanged and not when the products are delivered.

Costs

488. There would be no additional costs from this option. A number of retailers have developed their own Terms and Conditions on remote sales and the handing over of their products, including tobacco and nicotine products, and there would be no requirement for these to change. There would also be no obligation for any retailers who do not currently have such policies to implement any changes.

Benefits

489. This option would not address the potential risk of access to tobacco products and nicotine products by children and young people under the age of 18 from remote sales and handing over of these products. As such, there are no additional benefits from this option.

Option 2 – issue guidance to retailers on delivery of tobacco and nicotine products

Description

490. This option would involve the production of guidance by the Welsh Government, working with stakeholders from the retail sector and other interested parties (e.g. trading standards representatives). The guidance would identify best practice for retailers to follow, and identify actions which retailers could take to reduce the risk of tobacco and nicotine products being handed over to persons under the age of 18.

Costs

Welsh Government

491. There would be costs to the Welsh Government associated with producing and issuing the guidance. Staffing costs to produce the guidance (based on 6,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £7,500. This is based on approximately five weeks of a FTE Higher Executive Officer (£4,600) to develop the guidance, and five weeks of a FTE Team Support for administration support (approximately £2,900).²⁹⁹
492. It is anticipated that design and typesetting would require one week of a 0.5 FTE Executive Officer, which would cost approximately £300. It is estimated that translation and proofreading would cost approximately £600.³⁰⁰ The total cost for the development, design and translation of guidance would therefore be £8,400.
493. The intention would be to provide electronic versions of the guidance, with a small number of paper copies produced and distributed to local authorities. It is anticipated that printing costs would be approximately £900. The costs associated with producing the guidance will be incurred in 2016/17.
494. The guidance would be updated every three years. It is anticipated that this would require approximately one week of a FTE Higher Executive Officer, which would equate to approximately £900. Design and translation costs would amount to half the original costs, a total of £500. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,400, incurred every three years. The first review would take place in 2019/20.
495. Training sessions would need to be held for trading standards staff who would be supporting retailers in implementing the guidance. It is envisaged that trading standards representatives would run these sessions, though costs would be met by the Welsh Government. Each session would be approximately a half day and it is envisaged that two sessions would be held, one in North Wales and one in South Wales. These sessions would cost approximately £2,000, which covers room hire and refreshments for 35 people for each session (approximately £1,200)³⁰¹, and possible costs for external trainers to run part of the sessions (£800). This cost would be incurred in 2016/17.

Local authorities

496. Trading standards would also incur some staff costs, initially focused on helping to develop the guidance and attending the training sessions.

²⁹⁹ Based on Welsh Government staff planning costs

³⁰⁰ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

³⁰¹ Based on costs from similar training sessions organised by Welsh Government.

Based on a total of 70 Local Authority Enforcement Officers attending the training this would cost approximately £9,200³⁰² in 2016/17.

497. Once the guidance is published, trading standards would engage retailers to encourage them to implement actions from the guidance, to reduce the risk of young people gaining access to tobacco products and nicotine products. This would be an essential element due to the voluntary nature of the guidance. In addition, trading standards may need to deal with queries and support retailers in implementing the guidance. It is anticipated that this support would be higher in the first year following the publication of the guidance, but would then reduce as demand declines. It is estimated that for the initial 12 months the cost would be the equivalent of a 0.05 FTE enforcement officer post per local authority, then reducing to a 0.025 post per local authority. This would equate to approximately £50,300 in total in 2016/17, reducing to £25,100 per annum from 2017/18.
498. In addition, a small number of retailers would be likely to require a paper copy of the guidance. It is expected this would cost approximately £400. These costs would be met by local authorities, though costs would be minimal per local authority.
499. Following the publication of the guidance trading standards departments would identify retailers who offer remote sales and handing over of tobacco and nicotine products, to ensure that they are aware of the new guidance. It is anticipated that one local authority would perform this function on behalf of all local authorities in Wales. This would take one month's time of a FTE Enforcement Officer post, costing approximately £3,800. This is included with "communications / postage" in the Option 2 summary of costs table.

Retailers

500. Retailers may incur some costs from time spent helping to develop the guidance, familiarising themselves with the final guidance and implementing any changes they make to reduce the risk of tobacco products and nicotine products being delivered to young people aged under 18. Based on the hourly rate of retailers who sell tobacco (£11.90³⁰³, ³⁰⁴), the estimation of there being 3,290 separate businesses covering the estimated 8,225 retailers of tobacco products and nicotine products in Wales and that the above actions would take one hour, costs to retailers would amount to approximately £39,200 in 2016/17. However, this is likely to overestimate the costs as it is likely not all of these retailers will offer a remote sale service, including handing over tobacco products and nicotine products.

³⁰² Based on 5 hours at an hourly rate of £26.40 (to include the half day training session and travel time) for 70 enforcement officers to attend.

³⁰³ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Managers and Directors in retail and wholesale).

<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-337425>

³⁰⁴ Hourly rates have been increased by a factor of 30% to incorporate on costs.

501. Similarly, when the guidance is updated every three years, retailers may incur some time familiarising themselves with the revised guidance and on implementing any changes they need to make to reduce the risk of tobacco and nicotine products being delivered to young people under the age of 18. As it is anticipated that only limited changes would be made to the guidance, these costs would be expected to be no more than half those experienced in 2016/17. These costs are therefore estimated at £19,600, and would be incurred in 2019/20.

Table 7.18: – summary of additional costs associated with Option 2

Costs	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government					
Staff costs for the development of guidance	7,500	0	0	0	0
Design and translation	900	0	0	0	0
Printing costs	900	0	0	0	0
Costs to review guidance	0	0	0	1,400	0
Costs to cover training	2,000	0	0	0	0
Total costs for Welsh Government	11,300	0	0	1,400	0
Local authorities					
Staff costs to encourage and support retailers implementing the guidance.	50,300	25,100	25,100	25,100	25,100
Staff time to attend training	9,200	0	0	0	0
Communications/postage	4,200	0	0	0	0
Total costs for local authorities (combined)	63,700	25,100	25,100	25,100	25,100
Retailers					
Cost to amend or develop Terms and Conditions and policies on the delivery of tobacco products	39,200	0	0	19,600	0
Total cost for retail sector	39,200	0	0	19,600	0
Total cost	114,200	25,100	25,100	46,100	25,100

Benefits

502. Producing the guidance and circulating it to retailers who offer remote sales of tobacco products and nicotine products to customers may help to improve their policies and procedures around the handing over of these

products, to help protect young people from accessing them. While there is no definitive evidence on the extent of access of tobacco and nicotine products purchased remotely by persons aged under 18, producing guidance could help reduce access. However, as there would be no legislation to underpin the guidance, it would be reliant on retailers taking voluntary action. It has not been possible to quantify these benefits.

Option 3 - Introduce legislation to prohibit the handing over of tobacco and nicotine products to persons under the age of 18, and issue supporting guidance to retailers who offer remote sales, including the handing over of these products.

Description

503. This option is similar to Option 2 but in addition to the production of guidance for retailers, would also involve the creation of an offence to knowingly hand over tobacco products and/or nicotine products to a person or persons under the age of 18. It would be an offence if, when handed over, the tobacco products or nicotine products are not contained in a package which is sealed and has the person's name and address.

Costs

Welsh Government

504. Costs for producing the guidance and training costs are estimated to be identical to those outlined in Option 2.

505. It would be necessary to alert retailers to the new statutory obligations and what would be required of them. In order to achieve this, the Welsh Government would work with stakeholders and representative groups, in order to generate no-cost press and media articles on the new legislation in relevant trade publications and Welsh press, similar to other tobacco legislation such as the display ban. It is anticipated this would take five weeks of a FTE Higher Executive Officer in the build up to the legislation coming into force. This would cost approximately £4,600³⁰⁵.

Local authorities

506. To support the communications work outlined above, trading standards officers would identify retailers who offer remote sales, including the handing over of tobacco and nicotine products, to ensure that they are aware of their statutory obligations. It is anticipated that one local authority would perform this function on behalf of all local authorities in Wales. This would take one month's time of a FTE Enforcement Officer, costing approximately £3,800.

³⁰⁵ Based on Welsh Government staff planning costs

507. In addition, a small number of retailers would be likely to require a paper copy of the guidance. It is expected this would cost approximately £400. These costs would be met by local authorities.
508. Trading standards departments would incur some costs from helping to develop the guidance and supporting retailers in implementing any actions following the guidance being published. It is anticipated that this would be the equivalent of a 0.05 FTE Local Authority Enforcement Officer post for the first year, reducing to a 0.01 FTE post per annum for each local authority. Total costs would equate to £50,300 in 2016/17, reducing to an annual cost of £10,000 from 2017/18.
509. In addition to costs in supporting retailers, local authorities would incur costs in releasing enforcement officers for training covering enforcement issues. It is anticipated that this could be covered in a half day's training session, and as such these costs are identical to those outlined under Option 2.
510. Trading standards officers would need to perform test purchases relating to the new offence. It is anticipated that each test purchase scenario would cost approximately £1,300 for staff time and £90 for purchasing the goods used in the test purchase.³⁰⁶ This covers the cost of locating a suitable vacant house that can be used for the test purchase scenario, recruiting a young volunteer to take part, supervising the test purchase, and the costs to cover the purchase of the tobacco and nicotine products being delivered. Each test purchase scenario would cover three test purchases. In order to conduct a reasonable sample size, but limited by the time taken to set up the testing, it is anticipated that between one and three test scenarios (covering three – nine test purchases) for each local authority would be run per year. This would give a total of between 66 and 198 across Wales, compared to 332 age of sale test purchases conducted in 2012/13. These tests would therefore cost a total of between £31,000 and £93,000 annually
511. As there are currently no data on the levels of tobacco products being sold remotely in Wales, and as a result no knowledge on how many young people are purchasing tobacco remotely, Scottish data on the number of FPNs issued to stores selling tobacco to under 18s have been used to estimate how many FPNs would be issued on the handing over of tobacco products to under 18s. As there is not an option to issue a FPN for underage sales of tobacco in England and Wales, equivalent Welsh data on the number of FPNs issued does not exist.
512. In Scotland a total of 169 FPNs were issued in 2013-14³⁰⁷. Trade statistics indicate that internet sales account for approximately 0.3% of all cigarettes sales. Taking into account the estimated number of retailers

³⁰⁶ Based on information provided by local authorities

³⁰⁷ SCOTTS. Enhanced Tobacco Sales Enforcement Programme Report 2010-14. SCOTTS 2014

who sell tobacco and nicotine products in Wales of 8,225, it is estimated that approximately four offences per year might occur³⁰⁸. It is unlikely, given the small number of FPNs in Scotland going to court (approximately 15%), that any of these would result in a court case and could instead result in a warning, with trading standards officers working with the retailer to avoid repeat offences. It is anticipated that these warnings would form part of the normal work routine of enforcement officers.

Cost to Retailers (including delivery drivers)

513. Retailers may incur some costs from time spent helping to familiarise themselves with the guidance, and on implementing any changes they make to reduce the risk of tobacco and nicotine products being handed over to young people under the age of 18. Based on a two hour familiarisation period, an hourly rate of £11.90^{309,310}, and the estimation of there being 3,290 separate businesses covering the estimated 8,225 retailers of tobacco products and nicotine products in Wales, costs to retailers would amount to approximately £78,300 in 2016/17. However, this is likely to overestimate the costs as it is likely that some of these retailers do not offer a remote sale service.
514. Similarly, when the guidance is updated every 3 years, retailers may incur some time familiarising themselves with the revised guidance and on implementing any changes they need to make to reduce the risk of tobacco and nicotine products being delivered to young people under the age of 18. As it is anticipated that only limited changes would be made to the guidance, these costs would be expected to be no more than half those experienced in 2016/17, at an estimated £39,200.
515. There could also be a cost to delivery drivers from fines being issued as a result of handing over tobacco products and/or nicotine products to a person or persons under the age of 18 while unaccompanied by a person aged 18 or over. Based on a maximum of four cases³¹¹ going to court per year (although it is likely that no cases would go to court and would instead be dealt with by warnings), and an assumption that each case results in a £250 fine and £250 costs (as per a case for an offence for selling tobacco to a person under the age of 18 in October 2014), it is estimated that the total cost per annum would equate to £2,000. The proceeds from these fines would be retained by HM Courts and Tribunals Service.

³⁰⁸ This has been calculated by a pro rata number of FPNs for under age sales of tobacco (68.7% of Scotland's data as Wales has 31.3% less tobacco retailers) and estimating that 0.3% of these could be made by delivering tobacco.

³⁰⁹ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Managers and Directors in retail and wholesale).
<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-337425>

³¹⁰ Hourly rates have been increased by a factor of 30% to incorporate on costs.

³¹¹ This has been calculated by a pro rata number of FPNs for under age sales of tobacco (68.7% of Scotland's data as Wales has 31.3% less tobacco retailers) and estimating that 0.3% of these could be made by delivering tobacco.

516. As the offence would only occur in situations where the delivery driver is aware that they are handing over either tobacco or nicotine products to someone who is under the age of 18, services where a fully enclosed and addressed package is being delivered would not be covered by the offence. There are therefore likely to be minimal costs to businesses outside Wales.

Table 7.19: – Summary of additional costs associated with Option 3

Costs	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government					
Staff costs for the development of guidance	7,500	0	0	0	0
Design and translation	900	0	0	0	0
Printing costs	900	0	0	0	0
Communications	4,600	0	0	0	0
Costs to review guidance	0	0	0	1,400	0
Costs to cover training	2,000	0	0	0	0
Total costs for Welsh Government	15,900	0	0	1,400	0
Local authorities					
Staff costs to support retailers implementing the guidance	50,300	10,000	10,000	10,000	10,000
Staff costs for staff to attend training	9,200	0	0	0	0
Communications/postage	4,200	0	0	0	0
Test purchases	31,000 – 93,000	31,000 – 93,000	31,000 – 93,000	31,000 – 93,000	31,000 – 93,000
Total costs for local authorities	94,700-156,700	41,000 – 103,000	41,000 – 103,000	41,000 – 103,000	41,000 – 103,000
Retail sector (including delivery drivers)					
Cost to retailers to amend or develop Terms and Conditions and policies on the delivery of tobacco products and nicotine products	78,300	0	0	39,200	0

Costs from fines ³¹²	2,000	2,000	2,000	2,000	2,000
Total cost for retail sector	80,300	2,000	2,000	41,200	2,000
Total Cost	190,900-252,900	43,000-105,000	43,000-105,000	83,600-145,600	43,000-105,000

Benefits

517. The benefits outlined under Option 2 would also be applicable to Option 3. These are therefore not repeated here.

518. Additionally, creating an offence to prohibit the handing over of tobacco and nicotine products to persons under the age of 18 would further reinforce the importance of preventing access to these products by children and young people. The offence would strengthen the legislative framework in this area and also help to reinforce a retailer's own policy, as well as improve clarity and consistency.

519. The offence would be supported by accompanying guidance for retailers, produced by the Welsh Government, which would outline actions they can take to reduce the risk of their employees or third party delivery agents handing over tobacco and nicotine products to under 18s. Retailers would be required to implement this guidance in order to avoid committing an offence and receiving a fine, increasing the impact of any guidance.

520. It is anticipated that the introduction of this offence, along with the guidance for retailers, would reinforce other existing legislation, such as age of sale legislation³¹³ and the ban on selling tobacco from vending machines³¹⁴. When combined, these measures aim to reduce the risk to young people's health from the harms associated with nicotine use, although the specific contribution of this additional measure is not able to be quantified.

521. It is estimated that, on average, preventing the uptake of smoking results in an average one year life gain per individual.³¹⁵ This life gain is valued at £60,000 per person.³¹⁶ The total cost of the preferred option

³¹² Based on a maximum of 3 cases going to court (although it is likely that no case would go to court as they would be dealt with warnings), and each case receiving a £250 fine and £250 costs (as per a case for an offence in October 2014).

³¹³ Children and Young Persons Act 1933

³¹⁴ Protection from Tobacco (Sales from Vending Machines) (Wales) Regulations 2011

³¹⁵ Age of Sale for Nicotine Inhaling Products: Impact Assessment.

<https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

³¹⁶ A value of £60,000 is assigned to a Quality Adjusted Life Year. Where Quality Adjusted Life Year estimates are not readily available, and it is appropriate this value is used for Life Years. This is consistent with similar valuation of policies that mitigate mortality or morbidity risk by other Government departments, based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes.

(Option 3) over the initial five year period would be between £403,500 and £713,500. Therefore in order to be cost neutral approximately 7-12 young people would have to not start smoking.

Summary and preferred option

522. Option 1 does not meet the policy objective as it would continue existing practice, and the current risks of persons under the age of 18 accessing these products would remain. Option 2 may encourage retailers to take action to strengthen their existing policies regarding the handing over of tobacco products and nicotine products, or encourage those retailers who do not currently have a policy to develop one. However, there is a significant risk that the coverage would be limited, resulting in a limited impact.

523. Option 3 is the preferred option, as it combines two approaches, legislation and guidance, to restrict access to tobacco products and nicotine products purchased remotely by persons aged under 18. These two approaches working collectively are considered to present the greatest likelihood of reducing the risk of young people aged under 18 from accessing tobacco products and nicotine products via remote ordering and subsequent handing over of these products. This option would support other legislation to prevent children and young people from accessing tobacco and nicotine products, thereby making a cumulative positive impact on young people's use of such products.

524. This option would also strengthen retailers' current practices rather than relying on the retail sector to self-regulate its policies in this area. Applying evidence relating to alcohol³¹⁷ indicates that the current approach may mean children and young people could still access tobacco and nicotine products remotely. In addition, evidence indicates that voluntary action on smoking in general has a negative impact on health inequalities, as groups with higher levels of inequalities are relatively disinclined to adopt them.³¹⁸

Special Procedures

Options

525. Three substantive options have been considered, with the third split into two sub-options:

³¹⁷ Alcohol Concern (2013) '*On your doorstep: Underage access to alcohol via home delivery services*'

³¹⁸ European Commission. Identifying best practices in actions on tobacco smoking to reduce health inequalities. European Commission 2014.

http://ec.europa.eu/health/social_determinants/docs/2014_best_practice_sum_en.pdf.

Accessed December 2014.

- Option 1 - Do nothing;
- Option 2 – Develop and issue guidance in relation to best practice for acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis, and undertake an awareness raising campaign;
- Option 3A – Introduce a Special Procedures licensing system. This is the preferred option; and
- Option 3B – Introduce a Special Procedures licensing system with an added central register of all licensed practitioners and approved premises or vehicles providing special procedures in Wales.

Option 1 – Do Nothing

Description

526. There would be no change to the current legislation under this option. Local authorities' main powers for regulating businesses that carry out the procedures of acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis in their area are provided by the Local Government (Miscellaneous Provisions) Act 1982³¹⁹. This Act includes the power to issue byelaws for the purpose of securing the cleanliness of registered premises and fittings, cleanliness of persons registered (and those assisting them), and the cleansing and sterilisation of equipment. The Welsh Ministers have developed comprehensive model byelaws which reflect current infection control guidance and industry best practice³²⁰. The powers provided by the Local Government (Miscellaneous Provisions) Act 1982 are adoptive and therefore local authorities are able to choose which procedures are subject to their control, and whether or not to issue byelaws.

527. All local authorities in Wales have adopted the relevant provisions in the Act and to date six have chosen to adopt the Welsh Government model byelaws. The other local authorities have byelaws in place; however these vary in scope and content. For example, some local authorities have byelaws covering specific procedures such as tattooing, whereas others have byelaws that apply to all procedures.

528. Local authorities have the ability to charge businesses that carry out any of the procedures a one off fee for registration under the Local Government (Miscellaneous Provisions) Act 1982. The fee structures vary according to local authority. All local authorities charge a registration fee in relation to premises where the procedures are performed, whilst some charge registration fees in respect of premises and individual practitioners.

³¹⁹ Sections 14 and 15, Local Government (Miscellaneous Provisions) Act 1982
<http://www.legislation.gov.uk/ukpga/1982/30>

³²⁰ Welsh model byelaws for acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing, and electrolysis.
<http://wales.gov.uk/topics/health/protection/communicabledisease/acupuncture/?lang=en>

529. The fee amount also varies between local authorities. For premises, the registration fee is between £49 and £300 (average £130); a personal registration fee is between £38 and £117 (average £73). Additional fees are also charged by local authorities for the variation of an existing registration³²¹. These registration fees, in addition to the core funding provided to the local authority via the Revenue Support Grant, are currently used by local authorities to meet the costs of enforcement within this sector.

530. The Health and Safety at Work etc. Act 1974³²² applies across Wales and makes general provision for workplace health, safety and welfare. This legislation applies to all persons engaged in special procedures, including peripatetic workers who carry out treatments in the client's home.

Costs

531. As this is the baseline option, there are no additional costs. The following section provides an estimate of the costs currently incurred by the various parties.

Welsh Government

532. There are no costs to the Welsh Government associated with supporting local authorities in relation to their powers under the Local Government (Miscellaneous Provisions) Act 1982.

533. In addition to the Local Government (Miscellaneous Provisions) Act 1982, local authorities have powers under the Public Health (Control of Disease) Act 1984 to apply to a Justice of the Peace to make a Part 2A order for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination. The order may relate to persons, things or premises. Since the powers came into force in 2010, some local authorities in Wales have used them to apply for an order if they perceive there is risk of infection or contamination where procedures such as tattooing and cosmetic piercing are being carried out in unhygienic conditions. The Welsh Government undertakes an annual review of the use of these powers, utilising advice from local authority and medical professionals. This annual review is estimated to cost £2,500 in staff time each year (based on £1,700 Welsh Government costs, £400 local authority costs and £400 Public Health Wales costs). The outcome of the review is published bilingually on the Welsh Government website at minimal cost.

Local authorities

³²¹ Information provided by local authorities

³²² Health and Safety at Work Act 1974

<http://www.legislation.gov.uk/ukpga/1974/37/introduction>

534. Local authorities are responsible for the control of businesses that undertake the procedures in commercial settings, and undertake inspections and compliance work with these businesses to ensure they are working hygienically and within their statutory obligations (including their Health and Safety obligations).
535. As stated above, six local authorities have to date adopted Welsh Government model byelaws. The cost per local authority of adopting these model byelaws is estimated to be approximately £5,000.³²³ The spend by local authorities to date is therefore estimated to be £30,000. As local authorities would continue to be encouraged to adopt these model byelaws there could be a further cost to the sixteen remaining local authorities in Wales of up to £80,000 by the end of the five year period. For the summary table of costs at the end of this section it has been assumed that all local authorities would adopt the model byelaws over the next five years, and that costs would be split across the five years.
536. The inspection regime varies according to the procedure undertaken and the level of risk. A local authority will undertake an initial inspection upon application for registration of premises. This inspection is estimated to cost around £170 and is recovered from the business applying for registration. It is estimated that there are 190 new premises registrations per year across Wales, which amounts to an annual cost of £32,300. These costs are met by the registration fees paid by businesses and practitioners.
537. Annual compliance visits are generally undertaken for those businesses providing tattooing and cosmetic piercing. It is estimated that there are around 462 businesses providing these procedures in Wales.³²⁴ One compliance visit is estimated to cost £170. Across all local authorities, compliance visits are therefore estimated to cost approximately £78,500 per year.
538. Intelligence provided by local authorities indicates that complaints are predominately received in relation to businesses providing tattooing and cosmetic piercing. It is estimated there are 70 complaints in relation to businesses and practitioners performing these procedures per year³²⁵. The costs to investigate and undertake follow up work in relation to a complaint can vary, as some complaints are resolved quickly, whereas others require detailed investigation and, in infrequent cases, the pursuit of a prosecution. An estimate of the cost to a local authority of investigating a complaint is £170³²⁶ per complaint, which equates to a total of approximately £11,900 annually across Wales. With regard to successful prosecutions, local authorities have the option of pursuing cost recovery.

³²³ Based on information provided by local authorities

³²⁴ Based on data provided by local authorities

³²⁵ Based on local authority data which indicates complaints in relation to 15% of tattooing and cosmetic piercing businesses.

³²⁶ Based on data provided by local authorities

The following table sets out estimated inspection and compliance costs over five years.

Table 7.20

Local authority inspection and compliance costs					
	2016/17 (£)	2017/18 (£)	2018/19 (£)	2019/20 (£)	2020/21 (£)
New registration initial inspections	32,300	32,300	32,300	32,300	32,300
Compliance visit costs	78,500	78,500	78,500	78,500	78,500
Complaints investigation costs	11,900	11,900	11,900	11,900	11,900
Total	122,700	122,700	122,700	122,700	122,700

539. Local authorities currently have limited powers to stop individuals who perform the procedures without being registered, particularly if there is a risk to public health. Some local authorities have used powers in the Public Health (Control of Disease) Act 1984³²⁷ to apply for an order to prevent a person from practicing, for example tattooing, due to the risks they present to public health. In total, 27 orders (called Part 2A Orders under the Public Health (Control of Disease) Act 1984) have been made in relation to tattooing since the legislation was introduced in 2010. The estimated cost to a local authority to seek and execute a Part 2A order is estimated to range between £800 and £3,000. This includes a £210 fee that some Magistrates' Courts have also imposed on local authorities applying for an order. The table below shows the projected annual number of Part 2A orders over the next five years and the estimated costs associated with these. The number of orders in future years is assumed to be the same as those sought and granted in 2013/14.

Table 7.21

Public Health (Control of Disease) Act 1984 – Part 2a Orders for tattooing					
	2016/17	2017/18	2018/19	2019/20	2020/21
Projected number of cases	11	11	11	11	11
Associated	£8,800 –	£8,800 –	£8,800 –	£8,800 –	£8,800 –

³²⁷ Public Health (Control of Disease) Act 1984 as amended by Part 3 of the Health and Social Care Act 2008 <http://www.legislation.gov.uk/ukpga/2008/14/part/3> The Health Protection (Part 2A Orders) (Wales) Regulations 2010. Available on the Welsh Government website:

<http://wales.gov.uk/topics/health/protection/communicabledisease/legislation/?lang=en>

costs	£33,000	£33,000	£33,000	£33,000	£33,000
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540. There is therefore an estimated total annual spend by local authorities of between £146,500 and £170,700 (which will reduce once all local authorities have adopted the model byelaws). The total annual spend amounts to a cost per local authority of between £6,700 and £7,600. However approximately £52,400 of the total is recoverable from new practitioner and business registrations in the year through their registration fees, as set out under costs to practitioners and businesses.

Costs to the NHS

541. There are costs to the Welsh NHS as a result of treating complications arising from the procedures, such as skin infections. The majority of costs arise from tattooing and cosmetic piercing procedures. The following paragraphs therefore provide some assessment of costs for these procedures for illustrative purposes but as an accurate assessment of all costs is not available, these have not been included in the summary table at the end of this option (table 7.24). Although there are costs to the NHS associated with treating complications following acupuncture, semi-permanent skin-colouring and electrolysis³²⁸, these are considered to be minimal and have not been assessed.

542. It is known that cosmetic piercing can result in complications, such as swelling, infection, bleeding, allergy and tear or other injury³²⁹. Nerve damage and scarring may also occur if procedures are poorly performed. Whilst rare, complications from a cosmetic piercing can result in a hospital admission and may be particularly serious for those with underlying health conditions.

543. Currently there are no data on the number of people having a cosmetic piercing in Wales, nor is there any specific evidence on the rate of health complications from cosmetic piercings. As data from other countries are also limited, an estimate of the health costs has been based on the most relevant data available. These data are from Bone et al's study³³⁰ in England. This showed that 10% of people 16 years of age and over (range 9.4% - 10.6%) reported ever having had a piercing other than the ear lobe. There are 2,527,247³³¹ people who are aged 16 or older in Wales and, assuming a prevalence of 10%, this would mean there are at least 252,725 people with piercings other than the earlobe. This figure is likely to be an underestimate as it does not include those under the age of 16.

³²⁸ BMJ 2001;323:486

³²⁹ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

³³⁰ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

³³¹ <https://stats.wales.gov.uk/Catalogue/Population-and-Migration/Population/Estimates/Local-Authority/PopulationEstimates-by-LocalAuthority-Year>

544. As only 4.1% of those aged 45 and over have one or more body piercings³³², it is assumed the vast majority of body piercing procedures are performed on 16-44 year olds. There is therefore a 29 year period within which most piercings are received. Using this assumption, a total of 8,715 body piercings are likely to be performed in Wales each year. This is considered to be a conservative estimate given that it does not account for those individuals with multiple piercings or those under the age of 16.
545. The Bone et al study found that complications were reported with 27.5% of body piercings (this would equate to approximately 2,400 people experiencing complications in Wales each year), with problems serious enough to seek further help in 12.9% of cases (this would equate to 1,124 people seeking further help in Wales each year).
546. The study undertook a more detailed analysis of complications associated with body piercings in 16-24 year olds and estimated that 5.1% of these piercings resulted in help being sought from a pharmacist, 3% from a GP, 0.6% requiring attendance at an A&E Department and 0.9% requiring hospital admission. Those not seeking further help from NHS services are assumed to revisit the practitioner who performed the procedure. Assuming that this pattern of access to NHS services is replicated across all age groups, these data has been used as a basis to estimate the number of individuals accessing NHS services in Wales and the associated costs (table 7.22 below). Where there is a range of possible treatment options, a range of costs has been provided.

Table 7.22:

Costs of access to NHS services following piercing procedure			
Description of help sought following piercing procedure	Number of those aged 16 and over seeking help each year	Unit Cost	Yearly Cost (£)
Consultation with a Pharmacist	444	£5.44 (4.6 minute consultation) £13.85 (11.7 minute consultation)	2,400 – 6,100
GP consultation and antibiotic treatment	261	£34.33 (£31.70 for consultation and £2.63 for a 7 day course of oral antibiotics)	9,000
Attendance at A&E	52	Cost unknown. Used weighted average of all outpatient procedures - £91 (lower quartile)	4,700
Hospital	78	Non-elective inpatient	31,100 – 148,400

³³² Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

Admission		short stay £399 (based on lower quartile). Non-elective inpatient long stay £1,902 (lower quartile)	
Total	835	-	47,200 – 168,200

547. Tattooing is the other main source of costs to the NHS from the procedures. There are no published data on the prevalence of tattooing in the UK and so the most relevant data available is from outside the UK. According to the Harris Poll 2012, 21% of all adults in the US have at least one tattoo³³³. This finding is comparable with a study carried out in the US in 2006, which found that 24% of respondents had tattoos³³⁴.

548. There are estimated to be 357 premises providing tattooing procedures in Wales and an average of two practitioners employed by each premises. It has been assumed that each practitioner works three days a week, 44 weeks a year, undertaking three procedures each day.³³⁵ Based on these assumptions it is estimated that the number of tattooing procedures undertaken in Wales each year is approximately 282,700. It is noted that some tattoos often require multiple procedures.

549. The complication rate associated with tattoos in the US is 2-3%.³³⁶ Applying this rate to Wales, and assuming a complication rate at the upper end of this scale, the number of patients experiencing complications each year is estimated to be 8,500. However, it is unlikely that all complications would result in an individual reporting to NHS services. Many individuals experiencing difficulties are likely to revisit the practitioner who performed the procedure, or attempt to self medicate. It is estimated that approximately 10% of all complications would result in NHS presentations (approximately 850 cases per year).

550. There are a range of complications and associated treatments relating to tattooing procedures. As with cosmetic piercing complications, individuals could seek help from a range of sources including pharmacists, GPs and A&E departments. There are no data available relating to NHS treatment of these complications, so it has been assumed that treatment costs would be equal to the mean range of treating complications arising from piercings (£56-£201). Using these assumptions, it can be estimated that the total cost of treating complications arising from tattoos each year is £47,600 – £170,900.

Table 7.23 – Summary of NHS costs from body piercing and tattooing procedures (as assessed in paragraphs 541-550)

³³³ <http://www.harrisinteractive.com/NewsRoom/HarrisPolls/tabid/447/mid/1508/articleId/970/ctl/ReadCustom%20Default/Default.aspx>

³³⁴ <http://www.ncbi.nlm.nih.gov/pubmed/16908345>

³³⁵ Based on information provided by local authorities

³³⁶ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3236178/>

NHS costs from piercing and tattooing procedures					
Costs (£)	2016/17	2017/18	2018/19	2019/20	2020/21
Complications from body piercings of those aged between 16 and 24 years	47,200 – 168,200	47,200 – 168,200	47,200 – 168,200	47,200 – 168,200	47,200 – 168,200
Complications from Tattooing – all ages	47,600– 170,900	47,600– 170,900	47,600– 170,900	47,600– 170,900	47,600– 170,900
Total costs	94,800-339,100	94,800-339,100	94,800-339,100	94,800-339,100	94,800-339,100

551. A number of other serious conditions can occur as a result of these procedures, as discussed below. Due to the rarity and irregularity of such conditions arising in Wales, the costs have not been included in calculations.
552. Any procedures involving skin penetration can potentially lead to the transmission of blood-borne viruses such as hepatitis B, hepatitis C and HIV³³⁷. The cost of treatment for these infections varies significantly but by way of example a course of treatment for hepatitis C ranges between £39,000 and £80,000³³⁸.
553. There are also serious complications that can arise from infections acquired during a procedure, such as pseudomonas infection associated with cartilaginous piercings. Serious cases can require reconstructive surgery and this cost alone is estimated to be approximately £1,329³³⁹ per case.
554. In unusual cases, where there have been significant deficiencies identified in a business' infection control practices, it may be necessary to undertake a client notification ("look-back") exercise. A "look-back" exercise is undertaken to identify any clients potentially infected with blood borne viruses and involves identifying clients via customer records to contact them and offer blood borne virus testing. A recent look-back exercise, conducted in response to serious infection control deficiencies, is estimated to have cost at least £22,500.³⁴⁰ These costs are likely to vary greatly from case to case and would predominantly fall to the NHS. However, due to the intermittent, unpredictable nature of these look-back

³³⁷ Hayes, MO. Harkness, GA. (2001) Body piercing as a risk factor for viral hepatitis: an integrated research review. American Journal of Infection Control. 29, 271-274.

³³⁸ NICE consults on draft guidance recommending ledipasvir-sofosbuvir (Harvoni) for treating chronic hepatitis C (3 March 2015). <https://www.nice.org.uk/news/press-and-media/nice-consults-on-draft-guidance-recommending-ledipasvir-sofosbuvir-harvoni-for-treating-chronic-hepatitis-c>

³³⁹ Based on data provided by Public Health Wales.

³⁴⁰ Based on data provided by Public Health Wales.

exercises, these costs have not been factored into annual costs for the NHS or local authorities. Although these costs would be incurred infrequently, each occurrence is likely to incur considerable expense.

555. Other health complications such as pain, discomfort and anxiety have costs to individuals as well as the NHS. Although the level of such complications cannot be quantified, any reduction in them would be of benefit to the NHS. Complications can be particularly serious for those with underlying health conditions, and cases of individuals who have died following a cosmetic piercing have been recorded^{341,342}.

556. In addition to the treatment costs incurred by the NHS, any health complications from the procedures may also impose costs on employers in Wales if they result in sickness absence or reduced productivity. It has not been possible to quantify this economic cost.

Practitioners and businesses that carry out acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis

557. Businesses that provide the procedures are currently required to pay a one off registration fee. As set out above, the registration fees vary between local authorities. It is estimated that there are around 190 premises registrations each year and 380 individual registrations per year. Using the average fees of £130 for premises registration, and £73 for individuals, this would amount to £24,700 for the registration of new businesses and £27,700 for the registration of new practitioners each year. The total annual cost to business is therefore estimated at approximately £52,400. Due to the variable charging mechanisms utilised by local authorities, such as the discretion on whether to charge for personal registrations, these numbers are indicative only.

558. There is also a cost to these new practitioners and businesses for the time taken to complete an application. Although local authority application systems vary, it is estimated that an application takes approximately 30 minutes to complete. Assuming a gross hourly rate for practitioners of £15.94^{343,344}, and that there would be 380 individual applications and 190 premises applications, it is estimated that costs incurred through making applications amount to approximately £4,500 annually. There is currently no requirement to renew applications.

559. There would be no other costs for businesses providing these procedures under this option.

³⁴¹ BBC News online (2005) Lip piercing death 'misadventure'. Available at: http://news.bbc.co.uk/1/hi/england/south_yorkshire/4429298.stm

³⁴² BBC News online (2010) Caerphilly woman's infection death after tongue pierce. Available at: <http://www.bbc.co.uk/news/uk-wales-11543757>

³⁴³ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (artist). <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-337425>

³⁴⁴ Hourly rates have been increased by a factor of 30% to incorporate on costs.

Table 7.24 – summary of costs associated with Option 1*

Costs (£)	2016/17	2017/18	2018/19	2019/20	2020/21
Welsh Government costs					
Annual review of Part 2A Orders	2,500	2,500	2,500	2,500	2,500
Total Welsh Government Costs	2,500	2,500	2,500	2,500	2,500
Local authority costs					
New registration initial inspections	32,300	32,300	32,300	32,300	32,300
Compliance visit costs	78,500	78,500	78,500	78,500	78,500
Complaints investigation costs	11,900	11,900	11,900	11,900	11,900
Part 2A Orders	8,800 – 33,000	8,800 – 33,000	8,800 – 33,000	8,800 – 33,000	8,800 – 33,000
Adoption of model byelaws	15,000	15,000	15,000	15,000	20,000
Total Local Authority Costs	146,500-170,700	146,500-170,700	146,500-170,700	146,500-170,700	151,500-175,700
Local Authority Net Costs**	94,100-118,300	94,100-118,300	94,100-118,300	94,100-118,300	99,100-123,300
Business costs					
One-off registration fees	52,400	52,400	52,400	52,400	52,400
Application time	4,500	4,500	4,500	4,500	4,500
Business Costs	56,900	56,900	56,900	56,900	56,900
Total Cost **	153,500 – 177,700	153,500 – 177,700	153,500 – 177,700	153,500 – 177,700	158,500-182,700

* As explained earlier at paragraph 541, the NHS costs have not been included in the table.

** The one-off registration fees incurred by businesses and practitioners have not been included here as they are used to offset local authority costs.

Benefits

560. This option maintains the current policy position and as such there would be no additional benefits.

Option 2 – Develop and issue guidance in relation to best practice for acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis, and undertake an awareness raising campaign.

Description

561. Non-statutory, best practice guidance for practitioners would be developed and produced by the Welsh Government in relation to acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis. The development of the guidance would involve working with stakeholders from the sector, local authorities and other interested parties. The guidance would be evidence based and identify actions practitioners and businesses can take to employ safe working practices, with the aim of promoting safety and consistency across the sector. Copies of the guidance would be available online or in paper copy for distribution to those businesses and practitioners carrying out these procedures.

562. The Welsh Government would also undertake an awareness raising campaign. The campaign would have two major components; awareness raising among practitioners and businesses, and disseminating information to the general public.

563. The guidance would be implemented in partnership with local authorities. Current local authority records would be used to identify relevant businesses in order to target the guidance. There would be no enforcement by local authority enforcement teams, although they would be expected to provide advice on the applicability of the guidance to individual practitioners and businesses. Awareness training on the guidance for local authority staff would be provided, along with an awareness campaign to inform the public of the possible health issues surrounding these procedures.

564. The guidance under this option would be in addition to the limited registration system under Option 1. All current costs incurred under Option 1 are therefore carried forward under this option.

Costs

Welsh Government

565. There would be a cost to the Welsh Government for the development, design and translation of the guidance; staff costs would be included within these overall costs.
566. The guidance would be modelled on the Tattooing and Body Piercing Guidance: Toolkit³⁴⁵ and would focus on effective control of risks, standards of practice and practical requirements. It would therefore provide information for enforcing authorities, practitioners and businesses. This guidance would need to cover each of the procedures, with each having distinctive issues. As such it is envisaged the guidance would need to be a comprehensive document and would require significant levels of staff input. To produce the guidance (approximately 20,000 words), it is anticipated it would take approximately six months of a 0.5 FTE Senior Executive Officer (equating to approximately £13,000) and six months of a 0.2 FTE Team Support (equating to approximately £2,600).³⁴⁶
567. It is anticipated that design and typesetting would require two weeks of a FTE Executive Officer, which would cost approximately £1,400. It is estimated that translation and proofreading would cost approximately £1,900.³⁴⁷ The total cost for the development, design and translation of guidance is therefore £18,900.
568. To achieve maximum impact, copies of the guidance would be sent to all premises performing the procedures in Wales (approximately 890 registered premises in Wales). Five copies of the guidance would also be sent to each local authority, resulting in a total of approximately 1,000 paper versions being produced. Printing of this guidance would cost approximately £3,800 and distribution £1,500, amounting to a total of £5,300.³⁴⁸ Electronic versions of the guidance would also be available.
569. The guidance would be updated every three years. It is anticipated that this would require approximately one week of a FTE Higher Executive Officer, which would equate to approximately £900. Design and translation costs would amount to half the original costs, a total of £1,700. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £2,600, incurred every three years. The first review would take place in 2019/20.
570. Training sessions may be necessary for Environmental Health Officers (EHOs) or other relevant local government staff to support them in encouraging practitioners and businesses to take up the advice provided in the guidance. It is envisaged that these costs would be met by the Welsh Government and be contracted out to a supplier credible to the

³⁴⁵ Chartered Institute of Environmental Health, Health and Safety Laboratory, Public Health England and the Tattoo and Piercing Industry Union (2013) Tattooing and body piercing guidance: Toolkit.

³⁴⁶ Based on Welsh Government staff planning costs

³⁴⁷ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

³⁴⁸ Based on previous work undertaken by the Welsh Government

environmental health profession. It is anticipated that two sessions would be held, one in North Wales and one in South Wales. These training sessions would take place in 2016/17. The cost of the development of the course material and hand-outs would be approximately £900, and the cost of running the two sessions with 35 people attending each would be approximately £2,000, giving a total cost of £2,900. The time required to attend training would be incorporated into annual training time. If the training was combined with that for a prohibition on the intimate piercing of persons under the age of 16, the expectation is that savings could be made overall.

571. To maximise the potential impact of the guidance, there would need to be publicity to raise awareness amongst businesses and practitioners. This would be primarily through free news stories in trade journals, stakeholder networks, utilisation of online resources and social media. Wider communications work would also be required to alert the public, including young people and parents to the possible health issues surrounding these procedures and the importance of ensuring the practitioner and business visited for an acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing or electrolysis procedure is registered with the local authority. Such a campaign would include public relations, social media and working with schools/youth organisations and cost approximately £10,000. As this option would require voluntary action, it is expected that the communications work would need to be repeated every two years. If the communication work was integrated with that for a prohibition on the intimate piercing of persons aged under 16, the expectation is that savings overall could be made in 2016/17 and every subsequent two years.

Local authorities

572. Whilst local authority staff would be encouraged to support the uptake of the guidance as part of their normal work routines, it is recognised that there would be some associated staff costs. These would cover helping to develop the guidance, attending training sessions and engaging with practitioners and businesses to encourage them to follow the guidance. As businesses and practitioners would be able to choose whether or not to implement the guidance, encouragement from local authority staff to do so could play an important role.
573. It is also likely that EHOs and other relevant staff may need to deal with ad hoc queries from practitioners and businesses on the guidance. This additional work would be likely to be greater in the run up to and during the first year following the introduction of the guidance, and in total would amount to no more than the equivalent of half a month of a FTE EHO³⁴⁹ per local authority in these two years, reducing to half this amount for subsequent years. This would equate to approximately £38,000 (£1,725

³⁴⁹ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

per local authority) in 2016/17 and 2017/18, with the cost subsequently reducing to approximately £19,000 (£862 per local authority) per year. However, if this work was integrated with that for a prohibition on the intimate piercing of persons under the age of 16, the expectation is that savings could be made overall.

Practitioners and businesses that carry out acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis

574. Practitioners and businesses would be likely to incur costs from time spent familiarising themselves with the guidance, and on implementing any changes to their practice. Although the guidance is estimated to be approximately 20,000 words in length, the guidance would outline the recommended practices for each procedure in detail. It is therefore unlikely that practitioners would be required to read the whole document in detail. It is assumed that practitioners would only read in detail the guidance relevant to the procedure(s) they perform, estimated to be a quarter of the total guidance. Assuming a gross hourly rate for practitioners of £15.94³⁵⁰,³⁵¹, there are approximately 2,086 practitioners undertaking the specified procedures in Wales³⁵², and that the above actions would take two hours per practitioner, costs to practitioners/businesses would amount to approximately £66,500 in 2016/17. There would be also an annual cost of approximately £12,100 for new practitioners to familiarise themselves with the guidance. However, this may overestimate the costs as it is likely that some of these practitioners and businesses already follow best practice methods, whilst others may decide not to follow the guidance as it would be voluntary.

575. Similarly, when the guidance is updated every three years, practitioners and businesses may incur some time familiarising themselves with the revised guidance and on implementing any changes. As it is anticipated that only limited changes would be made, the cost per practitioner would be expected to be no more than half those incurred in 2016/17, at an estimated total of £33,300.

Table 7.25 – summary of additional costs associated with Option 2

Costs (£)	2016/17	2017/18	2018/19	2019/20	2020/21
Welsh Government costs					
Staff costs for development of guidance	15,600	0	0	900	0
Translation and design	3,300	0	0	1,700	0
Printing and	5,300	0	0	0	0

³⁵⁰ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime;(artist). <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-337425>

³⁵¹ Hourly rates have been increased by a factor of 30% to incorporate on costs.

³⁵² Based on information provided by local authorities

distribution of guidance					
Training	2,900	0	0	0	0
Publicity	10,000	0	10,000	0	10,000
Total Welsh Government Costs	37,100	0	10,000	2,600	10,000
Local authority costs					
Staff time dealing with ad hoc queries from practitioners and businesses on the guidance	38,000	38,000	19,000	19,000	19,000
Total Local Authority Costs	38,000	38,000	19,000	19,000	19,000
Business costs					
Time spent familiarising themselves with the guidance and implementing any changes to their practice	66,500	12,100	12,100	33,300	12,100
Total Business Costs	66,500	12,100	12,100	33,300	12,100
Overall Total Cost	141,600	50,100	41,100	54,900	41,100

Benefits

576. It is estimated under Option 1 that there are complaints relating to 70 practitioners and businesses of the procedures in Wales each year. It is possible that producing and circulating guidance on safe working practices for those performing these procedures, along with educational messaging and increased public awareness, could help to reduce this number. The production of guidance may also introduce a consistent approach with regard to enforcement. Any improvements would result in reductions to the NHS costs outlined under Option 1. However, as there would be no legal requirement underpinning the guidance, its impact is not likely to be high.

Option 3A – Introduce a Special Procedures licensing system

Description

577. This option would involve introducing legislation to create a compulsory, national licensing system for the practice of special procedures in Wales. These special procedures would be defined in the legislation as acupuncture, body piercing, electrolysis and tattooing. In order to perform any of these special procedures, an individual would need to be licensed and the premises (including vehicles) which they practice from approved. Local authorities would be responsible for screening practitioners and inspecting premises to ensure they meet specified criteria before a licence could be granted or premises approved. It is anticipated that the licensing system would become operational in 2017/18 (until this point, the existing registration system is expected to continue).
578. Similarly to Option 2, the Welsh Government would develop guidance in relation to special procedures to assist practitioners and businesses in their understanding of the legislation and its requirements. Guidance aimed at local authorities would also be produced to assist local authorities with their enforcement of the legislation. The development of the guidance would involve working with practitioners and businesses from the sector, local authorities, Public Health Wales and other interested parties. Copies would be available online or in paper copy, and be distributed to local authorities and businesses and practitioners providing special procedures.
579. The Welsh Government would provide training and guidance to local authorities on the content and enforcement of the legislation.
580. In addition, the Welsh Government would undertake an awareness raising campaign on the licensing system. The campaign would have two major components:
- a. Raising awareness of the licensing system amongst practitioners and businesses. This would involve direct correspondence with those who will be subject to the legislative requirements; and
 - b. Dissemination of information to the public to inform them of the licensing system, and the risks of not visiting a licensed practitioner/ approved premises.
581. The licensing system proposed under this option would replace the system outlined under Option 1. The costs outlined below would be incurred in place of the costs under Option 1 (i.e. the costs presented below are not additional to those under Option 1).

Costs

Welsh Government

582. There would be costs to the Welsh Government for the development, design and translation of two sets of guidance (one aimed at practitioners and businesses, the other at local authorities). To produce both sets of guidance (25,000 words for the practitioners and businesses guidance document and 25,000 words for the local authority guidance document), it is anticipated that it would take approximately six months of a 0.75 FTE Senior Executive Officer (equating to £19,500) and six months of a 0.4 FTE Team Support (equating to £5,200). This would give a total cost of £24,700.³⁵³
583. It is anticipated that design and typesetting would require four weeks of a FTE Executive Officer, which would cost approximately £2,800. It is estimated that translation and proofreading would cost approximately £4,800.³⁵⁴ The total cost for the development, design and translation of guidance is therefore £32,300.
584. As set out in Option 2, distribution of the guidance would involve sending a copy to all premises undertaking special procedures in Wales (approximately 890 registered premises). Five copies of the local authority guidance would be sent to each local authority in Wales, resulting in a total of approximately 1,000 paper versions being produced. Printing would cost approximately £4,400 and the distribution £1,500, giving a total cost of £5,900 (based on previous work undertaken by the Welsh Government). Electronic versions of the guidance would also be available.
585. It would therefore cost a total of approximately £38,200 for the initial development, production and distribution of the guidance. These costs would be incurred in 2016/17.
586. The guidance would be updated every three years. It is anticipated that this would take approximately two weeks of a FTE Higher Executive Officer's time, which would equate to approximately £1,800. Design and translation costs would amount to half the original costs, a total of £3,800. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £5,600, incurred every three years. The first review would take place in 2019/20.
587. Similar to Option 2, training sessions would be provided to Environmental Health Officers or other relevant local authority staff to support them in their enforcement of the legislation. The training would be paid for by the Welsh Government and be contracted out to a supplier credible to the environmental health profession. It is anticipated that four sessions would be held across Wales. These training sessions would take place in 2016/17. The cost of the development of course material and hand-outs would be approximately £1,800, and the cost of running the four sessions with 35 people attending each would be approximately £4,000,

³⁵³ Based on Welsh Government Staff Planning Costs

³⁵⁴ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

giving a total cost of £5,800. If this training was combined with that for the implementation of the prohibition on the intimate piercing of persons under the age of 16, the expectation is that savings could be made overall. The time required to attend training would be incorporated into annual training time.

588. The awareness raising campaign would focus on informing practitioners and businesses, as well as the public, of the licensing system. As the legislation would include new offences, it is envisaged a more extensive communications package would be required than that outlined in Option 2. To communicate with practitioners and businesses providing special procedures, the Welsh Government would communicate directly with those who would be subject to the legislation via direct mail, prior to the legislation coming into force. Local authorities currently register those providing these procedures and therefore those contact details would be utilised. News stories would be provided to trade journals and other stakeholder networks, as well as social media and targeting relevant websites would further raise awareness amongst the trade. This work is estimated to cost up to £10,000 and would be a one-off cost incurred in 2016/17. However, as part of the review process, consideration would be given to the need to repeat communications work at a later date, in order to maintain awareness of the new legislation. The precise costs associated with this work would depend upon the outcome of the review and are therefore currently unknown.

589. Wider communications work would focus on alerting the public, including young people and parents, of the possible health issues surrounding special procedures and the importance of ensuring the practitioners/business visited for an acupuncture, body piercing, electrolysis or tattooing procedure are licensed and the premises they operate from are approved. This would include public relations, social media and working with schools/youth organisations. The public awareness raising campaign is estimated to cost £10,000. As with Option 2, if the communications work for special procedures were integrated with that for a prohibition on the intimate piercing of persons under the age of 16, savings could be made. Although it is anticipated the communication costs would be incurred in 2016/17, consideration would be given to the need to repeat communications work at a later date, in order to maintain or enhance awareness of the new legislation. The precise costs associated with this work would depend upon the outcome of the review and are therefore currently unknown.

Local authorities

590. The legislation would require local authorities to enforce the requirements of the licensing system. Local authorities would be required to licence those individuals they consider to meet the defined criteria and to monitor their adherence to the licensing conditions, as well as to approve premises from which special procedures can be performed. In addition, local authorities would be required to enforce the legislation when

necessary, including taking forward action to prevent special procedures being undertaken by unlicensed practitioners and in unapproved premises. As detailed in Option 1, local authorities already have limited powers to control businesses providing acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis, and already undertake enforcement activity in relation to these businesses. However, the new licensing system would introduce more stringent requirements in order to protect public health, and therefore it is expected that enforcement activity in relation to these procedures would need to increase.

591. With regard to the licensing of individual practitioners, local authorities would be required to consider and process an application and if agreed, produce a licence. It is anticipated the cost to local authorities would be around £60 per licence³⁵⁵. The legislation requires the licence to contain a photograph of the licence holder; the cost of producing a photographic licence is included in the £60. In some cases, the local authority may need to meet the applicant to discuss their application, but this would be decided on a case by case basis. Accordingly, no cost estimate has been included for such discussions.

592. It is estimated that there are currently 2,086 individuals undertaking special procedures in Wales.³⁵⁶ Taking this figure as an estimate of the number of personal licences that would be issued, it is estimated the total cost to local authorities to process and issue personal licences would be £125,200. This would be incurred shortly following the licensing system becoming operational in 2017/18. It has been assumed that there are 380 new individual practitioners each year, resulting in licence costs for these new practitioners of £22,800 per annum from 2018/19. As the practitioner licences would be valid for three years, these costs would recur on a three yearly basis. However, for the purposes of cost calculations it has been assumed that an equal number of practitioners will cease trading each year (i.e. 380 individual practitioners will cease trading each year). Therefore the renewal costs in 2020/21 would be lower than the licence costs in 2017/18.

593. In order to approve premises from which special procedures are performed, it is expected that the local authority would process the application and undertake an inspection visit. If the premises were to meet the required conditions, it would be approved by the local authority. It is anticipated the cost to the local authority would be around £170 per premises approval.³⁵⁷ It is estimated that there are currently 890 premises from which the defined special procedures are currently performed in Wales³⁵⁸. Taking this figure as an estimate of the number of premises approvals that would be issued under the new licensing system, it is estimated the cost to local authorities to process and issue premises approvals would be £151,300 in 2017/18. It has been assumed that there

³⁵⁵ Figure provided by local authorities

³⁵⁶ Based on information provided by local authorities

³⁵⁷ Figure provided by local authorities

³⁵⁸ Based on information provided by local authorities

are 190 new businesses opened per year, resulting in costs for these new businesses of £32,300 per annum from 2018/19.

594. As the premises approval would be valid for three years, these costs would recur on a three yearly basis. However, for the purposes of cost calculations it has been assumed that an equal number of businesses will cease trading each year (i.e. 190 premises will cease trading each year). Therefore the renewal costs in 2020/21 would be lower than the costs in 2017/18, as shown in the table below. There would be ongoing renewal costs from 2021/22, but these would be lower than in 2020/21.

Table 7.26

Registration administration costs					
	2016/17 (£)	2017/18 (£)	2018/19 (£)	2019/20 (£)	2020/21 (£)
Practitioner licences and Premises approval admin costs	32,300*	276,500	55,100	55,100	55,100
Renewal admin costs	0	0	0	0	166,300
Total costs	32,300	276,500	55,100	55,100	221,400

*registration costs incurred under the existing system (Option 1).

595. Should a local authority intend to refuse to grant, renew or vary a licence or application for approval of a premises, it would have to issue a notice to the applicant, who could then make representations to the local authority's Licensing Committee. The applicant could appeal against the Committee's decision to a magistrates' court. As it is anticipated that local authorities would work closely with those seeking a licence/premises approval, it is not expected that there would be a high number of representations to be heard by a Licensing Committee or appeals heard by the magistrates' court. On that basis, it is estimated that costs associated with representations or appeals would be minimal, but are unknown at present.

596. Local authorities would also be responsible for monitoring compliance with the legislation during the duration of the licence or premises approval. This would involve working with licence holders and approved premises to ensure compliance. As is the case under the current registration scheme, it is expected that local authorities would undertake risk based compliance visits, with more frequent visits to those providing tattooing and body piercing than other special procedures. As described in Option 2, it is estimated that there are around 462 businesses providing tattooing and

body piercing procedures in Wales, and one compliance visit is estimated to cost £170. Across all local authorities, compliance visits are estimated to cost a total of approximately £78,500 per year.

597. If a local authority had concerns (raised for example during a compliance visit or via a complaint) that a licence holder or an approved premises was contravening their mandatory licensing conditions and there was a significant risk of harm to human health, it could issue a Remedial Action Notice (RAN) to the licence holder or the person holding the premises approval to require specified action. There would be a compliance period of at least 14 days within which the prescribed action must be taken to avoid committing an offence. It is estimated that 5% to 10% of those holding a licence or premises approval would be issued with a RAN annually. The cost of a RAN is estimated to be £380³⁵⁹, including officer time, visits and administration. Assuming that there would be between 150 and 300 RANs issued in the first year, the total cost is estimated to be between £57,000 and £114,000. It is assumed that businesses and the public would become more familiar with the legislation over time, and that this would drive up standards, leading to a 10% reduction in the number of RANs issued year on year until 2020/21, after which the number issued would level off.

598. Local authorities would also have the power to prevent special procedures being carried out by unlicensed persons or in unapproved premises. Local authorities would need to identify unlicensed individuals and then issue a stop notice, which would have the effect of prohibiting the performance of a special procedure. As outlined in Option 2, local authorities currently use powers under the Public Health (Control of Disease) Act 1984 to apply for a Part 2A Order to prevent a person from carrying out unregistered tattooing. It is estimated that 11 Part 2A Orders are applied for and granted annually in relation to this practice.

599. This option would provide more comprehensive powers to deal with prohibited activity, via a more straightforward process. Given this more comprehensive approach, it is estimated that there could be approximately 50 instances across Wales in the first year where a local authority would issue a stop notice. Whilst the process set out under this option would be different to that provided for by the Public Health (Control of Disease) Act 1984, there would be parallels in relation to the cost of investigating and executing a Part 2A Order. It is therefore estimated that the costs associated with preventing unlicensed/unapproved activity in the first year would be between £40,000 and £142,000 (the cost per case is estimated to be between £800 and £2,840, depending on the complexity of the case)³⁶⁰. It is assumed that businesses and the public would become more familiar with the legislation over time, and that this would drive up

³⁵⁹ Data provided by local authorities

³⁶⁰ Based on the costs associated with current Part 2A Orders

standards, leading to a 10% reduction in the number of stop notices issued year on year until 2020/21, after which the number issued would level off.

600. Some of these costs could be met if the magistrates' court awarded a contribution towards the prosecution costs to the local authority if the case was successful. However, the court could also order the local authority to compensate an individual for loss of income. These costs have not been included as they are difficult to estimate due to their variability.

601. This option would also require local authorities to maintain a register of special procedures licences and approved premises, to be available to the public. It is expected that local authorities would utilise their own websites to make this information available to the public, at minimal additional cost. There would however be a cost to maintain the information and ensure it is up to date. The annual administrative cost to local authorities to maintain the accuracy of their data is estimated to be approximately £9,200 (2 hours of administrative time per month per local authority).

602. There would also be likely to be other local government staff costs associated with developing the guidance, attending training sessions, raising general awareness and dealing with ad hoc queries on the new legislation. It is estimated that this work would be greater in the run up and during the first year following the introduction of the new legislation, and in total would amount to no more than the equivalent of a month of a FTE EHO³⁶¹ per local authority each year in the first two years, reducing to half this amount for subsequent years. This would equate to approximately £76,000 (£3,450 per local authority) in 2016/17 and 2017/18, with the cost subsequently reducing to approximately £38,000 (£1,725 per local authority). However, if this work was integrated with that for a prohibition on the intimate piercing of persons under the age of 16, the expectation is that some savings could be made overall. At this stage, it is not possible to accurately estimate these potential cost savings.

Table 7.27

Compliance and other administrative costs					
	2016/17 (£)	2017/18 (£)	2018/19 (£)	2019/20 (£)	2020/21 (£)
Annual compliance checks	78,500*	78,500	78,500	78,500	78,500
Issuing of RANS	-	57,000 - 114,000	51,300 - 102,600	46,200 - 92,300	41,600 - 83,100
Preventing unlicensed activity	8,000 - 33,000*	40,000 - 142,000	36,000 - 127,800	32,400 - 115,000	29,200 - 103,500
Maintenance of data on register	-	9,200	9,200	9,200	9,200
Other general costs	76,000	76,000	38,000	38,000	38,000

³⁶¹ Costs based on spine point 37 of the NJC pay scale plus an uplift of 30% to cover on costs.

Total costs	162,500	260,700	213,000	204,300	196,500
	–	–	–	–	–
	187,500	419,700	356,100	333,000	312,300

*cost under existing registration system (Option 1)

603. This option would enable local authorities to set fees in relation to licence and premises approvals. These costs must not exceed the costs of administering the system and ensuring compliance by those who are licensed or approved, and therefore would be kept at a proportionate level. The fees would not include the cost of enforcing the legislation against those who are not licensed or who operate from unapproved premises. There would therefore be a degree of cost recovery to local authorities in running the system, which would help them meet the costs. These fees, in addition to the core funding provided to local authorities via the Revenue Support Grant would meet the cost of running the licensing system.

Practitioners and businesses that carry out special procedures (acupuncture, body piercing, electrolysis and tattooing)

604. Practitioners and businesses would be likely to incur costs from time spent familiarising themselves with the new requirements and associated guidance. Although the guidance is estimated to be approximately 25,000 words in length, it would outline the recommended practices for each special procedure in detail. It is therefore unlikely that practitioners would be required to read the whole document in detail. It is assumed that practitioners would only read the guidance relevant to the procedure(s) they perform, estimated to be a quarter of the total guidance. As failing to comply with the new legislation could lead to a prosecution, it is envisaged that a longer period would be required for this familiarisation work (three hours) than with Option 2. However, the other assumptions relating to this work outlined for Option 2 are considered to remain relevant. This would suggest a total cost for this familiarisation work to business of approximately £99,800 in 2017/18. This equates to a cost per practitioner of £48, given a total of 2,086 practitioners. There would be ongoing annual costs for new practitioners to familiarise themselves with the new legislation

605. As with Option 2, the guidance would be updated every three years at which time practitioners and businesses may incur some costs from familiarising themselves with the revised guidance and in implementing any required changes. As this would be a revision of guidance it is anticipated that costs would be no more than half those experienced in 2017/18, at an estimated £49,900. The first update is expected to take place in 2020/21.

Table 7.28

Practitioner familiarisation cost

	2016/17 (£)	2017/18 (£)	2018/19 (£)	2019/20 (£)	2020/21 (£)
Familiarisation costs	0	99,800	18,600	18,600	18,600
Review familiarisation costs	0	0	0	0	49,900
Total cost	0	99,800	18,600	18,600	68,500

606. Practitioners and businesses would be required to apply to the local authority for a licence or premises approval. This application process is expected to be straightforward and in most cases would be undertaken online. Whilst the intention would be to keep the application process as simple as possible, there would be some degree of staff time involved in completing an application. It is expected that an application would take approximately 30 minutes. The legislation would require a practitioner's special procedures licence to contain a photograph of the licence holder. In some cases this may require the applicant to visit the local authority office to have the photograph taken. The total time to apply for a special procedures licence would therefore be around 1.5 hours.

607. Assuming a gross hourly rate for practitioners of £15.94^{362,363}, and that there would be 2,086 applications for licences and 890 for premises approvals³⁶⁴, it is estimated that costs incurred through making applications would amount in total to approximately £57,000. There would be annual costs for the completion of new applications of £10,600. Renewal of licences would take place every three years, although it is assumed that the cost to business for the completion of applications would be halved as the process would be more straightforward.

Table 7.29

Opportunity cost of application completion					
	2016/17 (£)	2017/18 (£)	2018/19 (£)	2019/20 (£)	2020/21 (£)
Premises applications	4,500*	7,100	1,500	1,500	1,500
Practitioner applications		49,900	9,100	9,100	9,100
Renewal of premises approval	0	0	0	0	1,300
Renewal of	0	0	0	0	

³⁶² ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (artist). <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-337425>

³⁶³ Hourly rates have been increased by a factor of 30% to incorporate on costs.

³⁶⁴ Based on information provided by local authorities

practitioner licence					11,300
Total costs	4,500*	57,000	10,600	10,600	23,200

*cost under existing registration system (Option 1)

608. In addition to the staff time involved in following the application process, there would be a fee to obtain an individual licence or receive approval of a premises. The fee structure would be set by each local authority but the Welsh Government would encourage local authorities to set proportionate universal fees. Fees could not exceed the cost to local authorities of administering the process. It is anticipated that an individual licence would cost £60 and premises approval would cost £170. This would amount to an initial total cost of £276,500 which would be incurred in 2017/18. Assuming 190 new businesses starting each year and 380 new practitioners registering, there would be ongoing annual costs of £55,100 for new registrations. Renewal of licences would take place every three years as detailed in the table below:

Table 7.30

Registration costs					
	2016/17 (£)	2017/18 (£)	2018/19 (£)	2019/20 (£)	2020/21 (£)
Individual and premises costs	52,400*	276,500	55,100	55,100	55,100
Renewal costs	0	0	0	0	166,300
Total costs	52,400*	276,500	55,100	55,100	221,400

*costs incurred under the existing registration system (Option 1)

609. It is expected that there would be a high compliance rate with the legislation. Contraventions of the legislation, such as performing special procedures without being licensed or performing special procedures from premises that have not been approved would result in a stop notice. A stop notice would be subject to a Level 3 fine (currently a maximum of £1,000). It was estimated earlier that in the first year there could be approximately 50 cases where a person would be issued with a stop notice. It is anticipated that approximately 10 of these would result in a fine. There would therefore be a total annual cost of up to £10,000 to unregistered practitioners in the first year (2017/18). It was estimated earlier that there would be a 10% reduction in the number of stop notices issued year on year. The same reduction would apply to fines issued. The proceeds from these fines would be retained by HM Courts and Tribunals Service. It is envisaged there would be minimal appeals against stop notices.

610. It was estimated above that between 150 and 300 RANs would be issued to registered practitioners and premises in the first year, setting out required action in order to meet the mandatory licensing conditions. It was also estimated that there would be a 10% reduction in the number of RANs issued year on year. It is anticipated that in the vast majority of cases, practitioners and premises would work with the local authority to fulfil the recommended action. As the cost of remedial action could vary greatly, and is currently largely unknown, it has not been estimated here.
611. Contravention of a RAN would be subject to a Level 3 fine (currently a maximum of £1,000). It is estimated that 5% of RANs issued would result in a fine for non compliance. Assuming the maximum fine was issued, the total cost of fines to practitioners and businesses could therefore be between £7,500 and up to £15,000 in the first year (2017/18). It is anticipated that this cost would reduce by approximately 10% year on year until 2020/21 after which the number issued would level off.
612. The legislation under this option would provide an appeals process to the magistrates' court for an appeal to be made against a local authority's decision. Given the low number of cases expected to be considered by a magistrates' court, there would only be a limited impact on the courts in Wales. A detailed costing framework has not yet been discussed between the Welsh Government and the Ministry of Justice, and so these costs are unknown at present.
613. It is recognised that the requirements on those businesses undertaking special procedures in Wales will impose additional costs on the sector. However, it is considered that these additional costs are justified on the grounds of protecting public health.
614. As the costs incurred by businesses would be proportional to the size of the business it is anticipated that any impact on competition would be minimal. Furthermore, better regulation may increase confidence in the special procedures sector in Wales and generate additional custom.

Courts

615. Appeals in relation to the legislation (such as an appeal against a refusal to grant a licence or premises approval application, or against fines levied in relation to enforcement action such as contravention of a RAN) could be made to the magistrates' court. However, it is expected that local authorities would assist practitioners and businesses, and provide the opportunity for them to become compliant with the legislation before any further action was taken. As many representations would be heard in the first instance by a local authority's licensing committee, it is expected that only a very small number of appeals would be made to a magistrates' court, estimated at 10-15 cases annually in Wales. A detailed costing framework of the cost for these appeals has not yet been discussed

between the Welsh Government and the Ministry of Justice, and so these costs are unknown at present.

Table 7.31: summary of costs associated with Option 3A

Sector	Year				
	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government costs					
Development, design, translation, production and distribution of two sets of guidance	38,200	0	0	3,800	0
Staff costs for review of the guidance	0	0	0	1,800	0
Training sessions	5,800	0	0	0	0
Awareness raising campaigns for both practitioners/businesses and members of the public	20,000	0	0	0	0
Total cost to Welsh Government	64,000	0	0	5,600	0
Additional costs	61,500	-2,500	-2,500	3,100	-2,500
Local Authority costs					
Practitioner licences and Premises registration costs	32,300*	276,500	55,100	55,100	55,100
Renewal costs	0	0	0	0	166,300
Annual compliance checks	78,500*	78,500	78,500	78,500	78,500
Issuing of RANS / compliance checks	11,900	57,000 – 114,000	51,300 – 102,600	46,200 – 92,300	41,600 – 83,100
Preventing unlicensed activity	8,800 – 33,000*	40,000 – 142,000	36,000 – 127,800	32,400 – 115,000	29,200 – 103,500
Maintenance of data on register	-	9,200	9,200	9,200	9,200
Other general	76,000	76,000	38,000	38,000	38,000

costs					
Total cost to local authorities	207,500 – 231,700	537,200 – 696,200	268,100 – 411,200	259,400 – 388,100	417,900 – 533,700
Additional costs	61,000	166,600-301,400	118,900-237,800	110,200 - 214,700	97,400-189,000
Business costs					
Guidance familiarisation costs	0	99,800	18,600	18,600	68,500
Application opportunity costs	4,500*	57,000	10,600	10,600	23,200
Registration costs	52,400*	276,500* *	55,100**	55,100* *	221,400 **
RANs resulting in a Level 3 fine	0	7,500-15,000	6,800-13,500	6,100-12,200	5,500-10,900
Total cost to businesses	56,900*	440,800 – 448,300	91,100-97,800	90,400-96,500	318,600 - 324,000
Additional Costs	0	383,900-391,400	34,200-40,900	33,500-39,600	261,700 - 267,100
Unregistered practitioner costs					
Stop Notices issued – Level 3 fine	0	10,000	9,000	8,100	7,300
Additional Costs	0	10,000	9,000	8,100	7,300
Total cost**	276,000-300,200	711,500-878,000	313,100-443,200	308,400 - 443,200	512,400 - 633,600
Costs additional to Option 1	122,500	558,000-700,300	159,600-285,200	154,900 - 265,500	363,900 - 460,900

*costs under the existing registration system (Option1)

**one-off registration fees incurred by practitioners and businesses have not been included in the total cost as they are paid to local authorities and used to off-set the costs incurred in administering the licensing scheme.

Benefits

NHS savings

616. The main benefit from the licensing system would be in savings to the NHS and individuals' health. As explained earlier, there are known and well reported health risks which can be attributed to any skin piercing procedures. Under Option 1, it was estimated that the complications

associated with tattooing and cosmetic piercing result in a minimum annual cost to the NHS of £49,200 - £175,400. Any reduction in the complications arising from special procedures would result in a reduction in costs to the NHS.

617. Any avoided complications would also lead to QALY gains for individuals, though they cannot be quantified here. One QALY is valued at £60,000. Given that the cumulative net cost of Option 3A over and above maintaining the status quo outlined in Option 1 is between £1,358,900 and £1,834,400 over the five year period, the licensing scheme would need to lead to between 23 and 31 QALY gains in order to be cost neutral.

Other benefits

618. It is considered that current legislation is inadequate to sufficiently protect the public, a view supported by stakeholder responses to the Public Health White Paper consultation.³⁶⁵ The licensing system under this option would impose requirements on practitioners and businesses which would be expected to drive up standards and ensure that all special procedures are undertaken in a safe and appropriate manner. As the legislation would also provide appropriate enforcement mechanisms, it is expected that local authorities would find they are able to deal with contraventions in a more straightforward way, and therefore more effectively safeguard public health. In addition, it is unlikely that local authorities would need to pursue Part 2A Orders as they would have more effective mechanisms to deal with unauthorised practices.
619. The majority of licence holders who perform special procedures, and the premises where they are performed, would also gain reputational benefits. By meeting the licensing requirements, they would be able to independently demonstrate to the public that they practice to appropriate standards of hygiene and cleanliness, as well as protecting themselves from health risks by undertaking appropriate infection control procedures.
620. The communications package outlined earlier would be important in making practitioners and businesses, as well as the public, aware of the licensing system. Public knowledge of the dangers of utilising unlicensed practitioners and unapproved premises, and also of undertaking the procedures on themselves or their friends, would increase. As local authorities would be required to make information available to the public on the licences they have issued and the premises they have approved, anyone seeking to have a special procedure would be able to find out from their local authority's website which practitioners and businesses have met the national standards. This would help to further improve transparency and ensure people are better informed about the practice of special procedures.

³⁶⁵ <http://wales.gov.uk/consultations/healthsocialcare/publichealth/?lang=en>

621. In addition to the potential NHS cost savings identified above, the licensing system may have wider economic benefits if an improvement in standards within the sector results in fewer instances of workplace absence due to health complications following a procedure.

Option 3B - Introduce a Special Procedures licensing system with an added central register of all licensed practitioners and approved premises (or vehicles) providing special procedures

622. In addition to the compulsory, national licensing system detailed in Option 3A, this option would also involve developing a website to host a central, national register of all licensed practitioners and approved premises (including vehicles) providing special procedures in Wales. The central register would be hosted by a lead local authority and would be available to all local authorities for enforcement purposes, as well as for viewing by members of the public. The assessment of costs and benefits under Option 3B therefore focuses solely on the element which is additional to Option 3A.

Costs

Welsh Government

623. All costs discussed under Option 3A would be replicated in this option. In addition, there would be costs for the development of the central register and for its ongoing management.

624. There would be an initial cost in developing the register. It would be developed and hosted online, with information on practitioners and premises gathered under the licensing system (fully outlined under Option 3A) and inputted onto the central register. The development of the register could be procured by the Welsh Government, or be undertaken by a lead local authority. Based on information from the Scottish Tobacco retailers' register, it is estimated that the initial cost of development could be approximately £26,900, in 2016/17.

625. Staff time would be required to procure and manage the web development contract. It is estimated that this would require approximately three weeks' FTE of a Higher Executive Officer's time, costing approximately £2,800, incurred in 2016/17.

Local authorities

626. Staff time would be required to populate the central register with data collected by each local authority. It is estimated that in order to transfer the data to a central register, approximately three weeks FTE of an administrative officer's time would be required, amounting to £2,100 incurred in 2017/18.

627. Once a central register was established, each local authority would be required to maintain the data relevant to its area, and update it as necessary. This would be similar to the requirement in Option 3A whereby each local authority will be required to provide details to the public of all special procedures licences and approved premises. Under Option 3A, it was estimated the annual administrative cost to local authorities would equate to approximately £9,200 from 2017/18 onwards (two hours of an administrative officer's time per month per local authority). It is anticipated that these costs would be replicated under this option, as local authorities would be required to publish the data within a central register.

628. In addition to the development costs there would be ongoing ICT management costs. These ongoing costs would cover maintenance issues such as back up to avoid data loss, server costs, and costs to resolve technical issues. Based on information from Scotland (in relation to its tobacco retailers' register), it is anticipated that these annual costs could be approximately £10,000, to be shared between local authorities. These would be incurred annually from 2017/18.

Practitioners and businesses that carry out special procedures (acupuncture, body piercing, electrolysis and tattooing)

629. There would be no additional costs to practitioners and businesses beyond those outlined under Option 3A. There would be no need to provide any information beyond the requirements set out in the licensing system under Option 3A.

630. All costs outlined under Option 3A would apply to this option. The costs outlined below are in addition to the costs set out in Option 3A.

Table 7.32: summary of additional costs associated with Option 3B

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government					
Management of web development contract	2,800	0	0	0	0
Development of Central Register	26,900	0	0	0	0
Total cost to Welsh Government	29,700	0	0	0	0
Local authorities					
Initial data transfer	0	2,100	0	0	0
Maintenance	0	9,200	9,200	9,200	9,200

and updating of data					
ICT Maintenance Costs	0	10,000	10,000	10,000	10,000
Total cost to Local authorities	0	21,300	19,200	19,200	19,200
Total Cost (additional to Option 3A)	29,700	21,300	19,200	19,200	19,200

Benefits

NHS savings

631. The NHS savings outlined under Option 3A would all be repeated under this option.

Local authorities

632. As all information in relation to licence holders and premises would be located within one central database, with enforcement information available for viewing by all local authorities in Wales, it is expected that a central register would assist local authorities in their monitoring and enforcement responsibilities. This would particularly be the case with respect to practitioners operating across local authority boundaries. This benefit is not able to be quantified.

Practitioners and businesses that carry out special procedures (acupuncture, body piercing, electrolysis and tattooing)

633. The central register would assist practitioners and businesses to raise awareness of their status as having met the licensing requirements, and enable potential clients to contact them. Also, if a practitioner, business or member of the public became aware of a person acting in contravention of the legislation, they would be able to check the central register and inform the local authority.

The public

634. The public would have access to a central accessible, searchable facility from which to find a practitioner in their area who is licensed, or premises that has been approved. Whilst this information would also be available under Option 3A, there would be no need for members of the public to be aware of local authority boundaries in order to search for local practitioners and seek confidence that the practitioner or business they choose for a special procedure has met the national standards.

Summary and preferred option

635. Option 1 maintains the status quo and does not meet the policy objective. It continues the position whereby there is an inconsistent approach to enforcement adopted by local authorities, and the powers that are available to control businesses providing acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis are considered insufficient.
636. Option 2 takes a voluntary approach to the provision of guidance. This could encourage practitioners and businesses to take action to strengthen their existing practice and policies in relation to the performance of the procedures, or encourage those who do not currently have a policy to develop one. There may also be increased awareness amongst the public of the possible health issues surrounding these procedures, and the importance of ensuring the practitioner/ business they visit is registered. However, as this option is based on voluntary action alone, the impact is not likely to be significant.
637. Option 3A proposes mandatory licensing of those who provide special procedures in Wales, to which national standards would be attached. As such, it would aim to drive up standards and ensure an improved and consistent approach to the regulation of these procedures across Wales. The supporting guidance and communications activity is considered to provide the best balance between cost and the likelihood of achieving the policy objective, and the resulting tangible and intangible benefits for clients, the NHS, practitioners and businesses.
638. Whilst Option 3A provides for a licensing scheme and creates a duty for local authorities to publish information relating to practitioners and businesses, Option 3B extends these further by creating a central register of practitioners and premises. It is recognised that such a central register would confer some benefits for local authorities, businesses and the public, increasing the ease with which information could be accessed. However, given the provisions which would already be made under Option 3A, it is anticipated that any further benefits under this option would be marginal and not a cost effective means of meeting the policy objective. Option 3A is therefore the preferred option at the current time. Option 3B could be given further consideration in due course.

Intimate piercing (Part 4)

Options

639. Three options have been considered:
- Option 1 – Do nothing;

- Option 2 – Issue guidance to practitioners/businesses discouraging the performing of an intimate piercing on a person who is under the age of 16; and
- Option 3 – Introduce a prohibition on the performing of an intimate piercing on a person who is under the age of 16. This is the preferred option.

Option 1 – Do nothing

Description

640. There would be no change to the current situation under this option. While some practitioners/businesses in Wales already do not perform intimate piercing (a piercing of the nipples, breast, genitalia or buttocks) on young people, it would still be legally possible for a person under the age of 16 years to have an intimate piercing if they wished.

Costs

641. As this option proposes no change, there would be no additional costs. However, it is likely that there will be some health costs which the NHS would continue to bear. It is known that body piercing can result in complications, such as swelling, infection, bleeding, allergy and tear or injury³⁶⁶. Nerve damage and scarring may also occur if procedures are poorly performed. Whilst rare, complications from a body piercing can result in a hospital admission and may be particularly serious for those with underlying health conditions.

642. The health costs associated with one case of an infected intimate piercing treated within primary care can be estimated at around £34, as shown in the table below:-

Table 7.33

Description	Cost (£)
Consultation with a General Practitioner ³⁶⁷	31.70
Treatment cost to treat a skin infection attributable to an intimate piercing ³⁶⁸	(7 day course of oral antibiotics) 2.63

³⁶⁶ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

³⁶⁷ Cost estimated by the Welsh Government, on the basis that the direct cost of providing GMS services through the contract is £430 million, there are 16,953 consultations for Wales' 3.082,400 population and that 25% of the consultations are excluded as they are with a nurse or other health professional at a weighting of 25% of GP cost.

³⁶⁸ British National Formulary (68) September 2014- March 2015. Clarithromycin, 500mg 14-tab pack.

643. It is not possible, however, to accurately scale up these costs to the NHS in Wales. Currently there are no data on the number of young people having an intimate piercing in Wales, nor is there any specific evidence on the rate of health complications from intimate piercing for this age group.

644. As data from other countries are also limited, an estimate of the health costs arising from this option has been based on the most relevant data available. These data are from Bone et al's study³⁶⁹ of 16-24 year olds in England, which show that 3.5% (range 2.6% - 4.7%) reported having a nipple piercing and 0.8% (0.4%-1.5%) a genital piercing. 3.0% (1.8%-4.8%) of those having body piercings reported seeking help for complications from a general practitioner.

645. Using these data the following assumptions have been made:-

- there are 62,056 14 and 15 year olds in Wales³⁷⁰;
- the prevalence of intimate piercing for under 16 year olds varies from 0.04% (10% of the lower end of the range for genital piercing from Bone et al's study) to 2.6% (the lower end of the range for nipple piercing from Bone et al's study). It is considered likely that the prevalence of intimate piercing among under 16 year olds will be less than in Bone et al's study as it covered an older age group (16-24 year olds); and
- the rate of seeking help for complications with an intimate piercing from a general practitioner is 4.8% (the upper end of the range from Bone et al's study). It is considered that the rate of seeking help with complications from intimate piercing will be at the upper end of the range in Bone et al's study, as persons under the age of 16 may have less experience or knowledge of how to clean or maintain a piercing to prevent infection.

646. Applying these assumptions suggests that there are between 25 and 1,614 under 16 year olds having an intimate piercing in Wales each year, with between one and 77 seeking help from a general practitioner for complications from the procedure. The estimated costs to the NHS, assuming that all of those presenting to their general practitioner with complications from an intimate piercing have the same treatment as that set out earlier under this option, would be between £34 and £2,600.

647. It should be noted that caution is required in utilising these figures as they are based on assumptions derived from a single study. They might in reality be lower if the prevalence of intimate piercing is less than estimated above. Equally, the figures could in reality be higher, as intimate piercings

³⁶⁹ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

³⁷⁰ Welsh Government Mid-year population estimates (1991 onwards) by Welsh local authorities, English regions and UK countries, for single age of year and gender. Released 26 June 2014.

have higher complication rates than piercings in most other sites³⁷¹. It is also possible that persons aged under 16 with an infected intimate piercing may require more expensive NHS treatment than primary care, such as attending an A&E Department or being admitted to hospital.

648. In addition, there may be longer term issues requiring NHS care. As young people continue to grow during their teenage years, an intimate piercing performed at a young age could result in complications as a result of the changing physiology of the young person as they develop, or there might be psychological issues to address.

649. There may also be some costs to local authorities for the provision of advice to practitioners/businesses on the provision of intimate piercing of young people, but these are considered to be very limited.

Benefits

650. There are likely to be no additional benefits from this option. Piercing practitioners/businesses could continue with their current activities as there would be no restrictions on their clientele.

Option 2 – Issue guidance to piercing businesses/practitioners discouraging the performing of an intimate piercing on a person who is under the age of 16

Description

651. This option would involve the Welsh Government producing non-statutory guidance working with stakeholders from the body piercing sector and other interested parties (e.g. Environmental Health Officers). The guidance would identify actions businesses/practitioners could take to reduce the likelihood of persons under the age of 16 having an intimate piercing, such as seeking age verification of their clients before piercing them. Copies of the guidance would be available on-line or in paper copy for distribution to those practitioners carrying out intimate piercings.

652. There would be no enforcement of the guidance by local authority enforcement teams, although they would be expected to provide advice on the applicability of the guidance to individual practitioners/businesses. Awareness training on the guidance for local authority staff would be provided, along with an awareness raising campaign to inform young people of the risks and complications associated with intimate piercing.

Costs

Welsh Government

³⁷¹ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piecing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

653. There would be costs to the Welsh Government associated with producing and issuing the guidance. Staffing costs to produce the guidance (based on 4,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £4,600. This is based on approximately three weeks of a FTE Higher Executive Officer (£2,800) to develop the guidance, and three weeks of a FTE Team Support for administration support (approximately £1,800).³⁷²
654. It is anticipated that design and typesetting would require one week of a 0.3 FTE Executive Officer, which would cost approximately £200. It is estimated that translation and proofreading would cost approximately £400.³⁷³ The total cost for the development, design and translation of guidance would therefore be £5,200, incurred in 2016/17.
655. Currently, local authorities have powers under the Local Government (Miscellaneous Provisions) Act 1982 to register those businesses that provide cosmetic piercing, but as it is not possible to consistently identify which piercing procedures each business provides, it is not known how many practitioners/businesses in Wales are undertaking intimate piercing. However, assuming that a third of the approximately 260 businesses currently registered³⁷⁴ provide intimate piercing, and that priority would be given to providing electronic versions of the guidance, it is anticipated that only a small number of paper versions of the guidance would be produced. These would cost no more than £400. This cost would be incurred in 2016/17.
656. The guidance would be updated every three years. It is anticipated that this would require approximately one week of a FTE Higher Executive Officer, which would equate to approximately £900. Design and translation costs would amount to half the original costs, a total of £300. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,200, incurred every three years. The first review would take place in 2019/20.
657. Training sessions may be necessary for Environmental Health Officers (EHO) or other relevant local government staff to support them in encouraging practitioners/businesses to take up the advice in the guidance. It is envisaged that this would be paid for by the Welsh Government and be contracted out to a supplier credible to the environmental health profession. It is anticipated that two sessions would be held, one in North Wales and one in South Wales. These training sessions would take place in 2016/17. The cost of the development of the course material and hand-outs would be approximately £900, and the cost of running the two sessions with 35 people attending each would be approximately £2,000, a total of £2,900. If this training was combined with

³⁷² Based on Welsh Government staff planning costs

³⁷³ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

³⁷⁴ Data provided by local authorities

that for the implementation of the special procedures provisions, the expectation is that savings could be made overall.

658. To maximise the potential impact of the new guidance, there would need to be some publicity to raise awareness of the guidance amongst businesses/practitioners who provide intimate piercing, such as through free news stories in trade journals and through stakeholder networks. Wider communications work would also be required to alert young people and parents to the possible health and child protection issues surrounding intimate piercing. Such a campaign would be likely to include public relations, social media and working with schools/youth organisations and cost £5,000. As this option requires voluntary action, it is expected that the communications work would need to be repeated every two years. If the communication work was integrated with that for special procedures the expectation is that savings overall could be made in 2016/17, and every two years thereafter. The precise cost savings would depend upon the activity undertaken and are therefore currently unknown.

Local authorities

659. While local government staff would be encouraged to support the uptake of the guidance as part of their normal work routines, it is recognised that there would be some local government staff costs. These would cover helping to develop the guidance, attending the training sessions and engaging with practitioners/businesses to encourage them to follow the guidance. As businesses/practitioners would be able to choose whether or not to implement the guidance, encouragement from local government staff to do so could play an important role.

660. It is also likely that EHOs and other relevant local government staff may need to deal with ad hoc queries from practitioners/businesses on the guidance. This additional work would be likely to be greater in the run up to and during the first year following the introduction of the guidance, and in total would amount to no more than the equivalent of half a month of a FTE EHO³⁷⁵ per local authority in these two years, reducing to half this amount for subsequent years. This would equate to approximately £38,000 (£1,725 per local authority) in 2016/17 and 2017/18, with the cost subsequently reducing to approximately £19,000 per annum (£862 per local authority). However, if this work was integrated with that for special procedures the expectation is that savings could be made overall. The precise cost savings would depend upon the activity undertaken and are therefore currently unknown.

Practitioners/Businesses

661. Practitioners/businesses may incur some costs from time spent helping to develop and familiarising themselves with the guidance, and on

³⁷⁵ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

implementing any changes they make to prevent young people from having an intimate piercing. Assuming that the average gross hourly rate for cosmetic piercers falls within the Office of National Statistics category of skilled trades (£15.94)^{376,377}, there are 87 practitioners/businesses undertaking intimate piercing in Wales³⁷⁸ and the above actions would take two hours, costs to practitioners/businesses would amount to approximately £2,800 in 2016/17. However, this may overestimate the costs as it is likely that some of these practitioners already do not perform intimate piercing on those under the age of 16, while others may decide not to follow the guidance as it would be voluntary rather than statutory. It is anticipated that this option would lead to little loss of income for the piercing industry in Wales, although this cannot be accurately assessed.

662. Similarly, when the guidance is updated every three years, practitioners/businesses may incur some time familiarising themselves with the revised guidance and on implementing any changes they make to prevent young people from having an intimate piercing. As it is anticipated that only limited changes would be made to the guidance, these costs would be expected to be no more than half those incurred in 2016/17, at an estimated £1,400.

Summary of additional costs associated with Option 2

Table 7.34

Costs	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government					
Staff costs for the development of guidance	4,600	0	0	0	0
Design and translation	600	0	0	0	0
Printing costs	400	0	0	0	0
Review of guidance				1,200	
Training	2,900	0	0	0	0
Communication	5,000	0	5,000	0	5,000
Total costs for Welsh Government	13,500	0	5,000	1,200	5,000
Local authorities					
Staff costs to	38,000	38,000	19,000	19,000	19,000

³⁷⁶ ASHE 2014 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (artist - non Wales data). <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-337425>

³⁷⁷ Hourly rates have been increased by a factor of 30% to incorporate on costs.

³⁷⁸ Based on information provided by local authorities

attend training and encourage the implementation of the guidance					
Practitioners/businesses					
Staff costs to familiarise themselves with the guidance	2,800	0	0	1,400	0
Total cost	54,300	38,000	24,000	21,600	24,000

Benefits

663. While there is a lack of data on the number of under 16s having an intimate piercing, it is estimated earlier under Option 1 that there are between 25 and 1,614 persons aged under 16 having an intimate piercing in Wales each year. It is possible that producing and circulating guidance discouraging the performing of an intimate piercing on a person who is under the age of 16, along with educational messaging for young people and parents on this issue, could help reduce this number. However, as there would be no legal requirement underpinning the guidance, and as some practitioners/businesses already do not perform intimate piercing on persons under the age of 16, the impact of this option is not likely to be high.

Option 3 – Introduce a prohibition on the performing of an intimate piercing on a person who is under the age of 16

Description

664. This option would introduce legislation that prohibits the performance of an intimate piercing on a person who is under the age of 16. This would make it an offence for a practitioner to perform such a piercing. It would also be an offence to make arrangements to perform an intimate piercing on a person who is under the age of 16, and local authorities would be provided with the powers to investigate and bring forward a prosecution against any person found to be breaking the law.

665. In addition (and similar to that outlined in Option 2), the Welsh Government would produce guidance to assist local authorities in their enforcement of the legislation, and an awareness raising campaign to inform young people of the risks and complications associated with intimate piercing would take place.

Costs

Welsh Government

666. The costs to the Welsh Government for producing and reviewing the guidance and for training EHOs or other relevant local government staff would be similar to those outlined under Option 2. As with Option 2, if the training was integrated with that for the implementation of special procedures, the expectation would be that savings could be achieved overall.

667. As this option would make it an offence for a practitioner to make arrangements to perform or to perform an intimate piercing on a person who is under the age of 16, it is envisaged that a more extensive communications package would be required than under the promoting good practice/raising awareness approach outlined in Option 2. Such a communications package might target both practitioners and young people.

668. This package might include:

- an awareness campaign for all piercing practitioners/businesses on the new offence utilising, for example, trade publications and social media, with direct marketing for those known to offer intimate piercing; and
- a campaign alerting young people and parents to the new legislation and the possible health and child protection issues surrounding intimate piercing. This may include public relations, social media and working with schools/youth organisations.

669. It is anticipated that such a communications package would cost £10,000, although savings could be made if it was integrated with the communications work for special procedures. This one off cost would be incurred in 2016/17, although as part of the review process consideration would be given to the need to repeat communications work at a later date, in order to maintain or enhance awareness of the new legislation. The precise cost savings would depend upon the outcome of the review and are therefore currently unknown.

Local authorities

670. Whilst the legislation would not require a regular timetable of inspections of premises, and EHOs already have duties in respect of businesses providing piercing procedures, it is recognised that there would be some additional local government staff costs. These would include helping to develop the guidance, attending the training sessions, raising general awareness, and dealing with ad hoc queries on the new legislation. In addition, the legislation would provide new powers to local authorities and require them to undertake enforcement action.

671. Whilst it is expected the legislation would have a high level of compliance, there may be some practitioners/businesses that do not

comply with the ban. It is likely that these cases would be identified to local authorities through complaints or by local authorities undertaking test purchasing exercises. It is expected that complaints are likely to be low in number and, depending on the intelligence available, each local authority would conduct an average of one test purchasing exercise per annum. On that basis, it is assumed that there would be no more than three prosecutions conducted by EHOs across Wales each year.

672. Taking into account the preceding paragraphs, it is anticipated that the workload for local authority staff would be greater in the run up to and during the first year of the implementation of the new legislation. In total this would amount to no more than the equivalent of one month of an EHO's time per local authority in these two years, reducing to half this amount for subsequent years. This would equate to £76,000 (£3,450 per local authority) in 2016/17 and 2017/18, with the cost subsequently reducing to approximately £38,000 (£1,725 per local authority). However, if this work was integrated with that for special procedures the expectation is that savings could be made overall. The precise cost savings would depend upon the activity undertaken and are therefore currently unknown.

Courts

673. As noted above, the legislation is not expected to result in any more than three prosecutions per annum. There would therefore only be limited impact on the courts in Wales. A detailed costing framework has not yet been discussed between the Welsh Government and the Ministry of Justice, and so these costs are unknown at present.

Practitioners/Businesses

674. Practitioners/businesses may incur some costs from time spent helping to develop and familiarising themselves with the new requirements, and on implementing any changes to their processes to ensure young people do not have an intimate piercing. As failing to comply with the new legislation could lead to a prosecution, it is envisaged that a longer period would be required for this familiarisation work (three hours) than with Option 2. However, the other assumptions relating to this work outlined for Option 2 are considered to remain relevant: this would suggest a cost for this familiarisation work to practitioners/businesses of approximately £4,200 in 2016/17.

675. As with Option 2, the guidance would be updated every three years at which time practitioners/businesses may incur some costs from familiarising themselves with the revised guidance and in implementing any changes to ensure they are compliant with the legislation. As it is anticipated that only limited changes would be made to the guidance, these costs would be expected to be no more than half those experienced in 2016/17, at an estimated £2,100.

676. In addition, there may be some loss of income for the piercing industry in Wales if the legislation is successful in preventing intimate piercing of young people below the age of 16 years. This has been calculated to be between £600 and £76,700 per annum, applying the assumptions that:

- there are between 25 and 1,614 young people in this age group having such a procedure each year;
- the cost of an intimate piercing is between £25 and £50³⁷⁹; and
- there is a compliance rate of 95% with the legislation, as it is in line with good professional practice³⁸⁰.

677. As discussions with practitioners have suggested that a ban on intimate piercing of persons aged under 16 years would not involve any financial costs for them, the lower end of the above range would seem the more likely occurrence.

678. The expected high compliance rate with the legislation and the low number of breaches likely to be identified through complaints or test purchasing exercises suggests that few fines would be levied on piercing practitioners. It was estimated earlier that there would be no more than three prosecutions conducted by EHOs across Wales each year. As it is proposed that the offences of making arrangements to perform or performing an intimate piercing on a person who is under the age of 16 would be a Level 4 fine, the total cost of fines to practitioners could be up to £7,500 per year³⁸¹. In addition, prosecuted practitioners/businesses may be subject to legal fees, recovery of costs by local authorities and victim compensation. These costs would be highly variable and as such cannot be accurately assessed.

Table 7.35: Summary of additional costs associated with Option 3

Costs (£)	2016/17	2017/18	2018/19	2019/20	2020/21
Welsh Government					
Staff costs for the development of the guidance	4,600	0	0	0	0
Design and translation	600	0	0	0	0
Printing costs	400	0	0	0	0
Training	2,900	0	0	0	0
Review of guidance	0	0	0	1,200	0
Communication	10,000	0	0	0	0
Total costs for Welsh Government	18,500	0	0	1,200	0
Local authorities					

³⁷⁹ Based on an internet search of cosmetic piercing practitioners (January 2015)

³⁸⁰ Based on, for example, the Code of Practice and Ethics of the British Body Piercing Association

³⁸¹ As fines are set periodically by the Ministry of Justice we have not taken into account any increase in fines over time.

Staff costs to support retailers in complying with the legislation	76,000	76,000	38,000	38,000	38,000
Practitioners/businesses					
Staff costs to familiarise themselves with the new requirements	4,200	0	0	2,100	0
Cost of lost business	600 -76,700	600 - 76,700	600- 76,700	600 – 76,700	600 - 76,700
Cost of fines	0 - 7,500	0 - 7,500	0 -7,500	0 – 7,500	0 – 7,500
Total costs for practitioner/businesses	4,800- 88,400	600 – 84,200	600 - 84,200	2,700- 86,300	600 - 84,200
Total Cost	99,300- 182,900	76,600 – 160,200	38,600 – 122,200	41,900- 125,500	38,600 – 122,200

Benefits

NHS savings

679. The main quantifiable benefit from the proposed legislation would be savings for the NHS. An estimate of the costs to the NHS in Wales in treating health complications among persons aged under 16 years arising from intimate piercing was provided earlier in this section. Using these estimates, and assuming that the proposed legislation has a 95% compliance rate, the annual savings to the NHS are estimated at between £34 and £2,500.

680. It is recognised that these potential savings for the NHS might not fully materialise. One possible scenario is that under 16 year olds who are intent on having an intimate piercing would be driven underground, which would create a marketplace for disreputable businesses or lead to an increase in the number of young people piercing themselves or each other. Such practices may take place in un-hygienic environments, increasing the risk of health complications following intimate piercing, and creating additional demands on NHS services. The communications package outlined earlier would be important in making young people aware of the dangers of utilising practitioners/businesses that are not licensed to perform special procedures, and of piercing themselves or their friends.

Other savings

681. Beyond the potential savings for the NHS identified above, there would be a number of other benefits from the proposed legislation which are more difficult to quantify. First, placing a prohibition on the intimate piercing of a person under the age of 16 would bring clarity to the situation. Many of the practitioners who have been in contact with the Welsh Government

have indicated that they do not perform intimate piercings on young people, but because the law does not currently prohibit it, it is possible for an under 16 year old to have an intimate piercing. This option would reinforce the good practice of such practitioners, and raise awareness of the potential seriousness of intimate piercing for young people.

682. Secondly there would be benefits to young people. It is estimated above that there are currently between one and 77 under 16 year olds a year experiencing health complications following an intimate piercing which require help from a general practitioner. There may also be a number of people aged under 16 years undergoing intimate piercing who seek help with health complications from pharmacists and piercing practitioners, or in more severe cases from an A&E department, while others with health complications may seek no help at all. As health complications such as pain, discomfort and anxiety have costs to individuals as well as the NHS, their reduction from the prohibition of intimate piercing of persons aged under 16 years can be seen as beneficial, even though they cannot be quantified.

683. Thirdly, there would be benefits in terms of safeguarding children and young people who may be putting themselves in a vulnerable position in order to have an intimate piercing performed. By undergoing the procedure, young people are placing themselves in a situation in which their intimate areas are exposed to, touched and pierced by an adult who may previously be unknown to them.

684. Fourthly, given that the intimate piercing of persons under 16 years would be prohibited, if practitioners comply with the law they should no longer face complaints from parents in relation to this issue.

Summary and preferred option

685. Option 1 does not meet the policy objective. It continues the existing practice and would mean that children and young people would continue to have little or no protection from the risks associated with intimate piercing.

686. Option 2 may encourage practitioners/businesses to take action to strengthen their existing policies around intimate piercing of persons aged under 16 years, or for those who do not currently have a policy to develop one. There may also be increased awareness of the dangers of intimate piercing by young people and parents. However, as this option is based on voluntary action, the impact is not likely to be significant.

687. Option 3 is the preferred option. It utilises two reinforcing approaches to prohibit the intimate piercing of young people aged under 16 years. The combination of the two approaches – prohibiting the procedure through legislation and putting in place supporting communications activity with practitioners and young people – provides the best balance between cost and the likelihood of achieving the policy objective, and the resulting

tangible and intangible benefits for young people, the NHS and practitioners. This is because practitioners would have a greater interest and incentive in implementing the guidance produced by the Welsh Government than in Option 2, mainly due to the potential risk of them committing an offence and facing punishment.

Pharmaceutical services (Part 5)

688. Three options have been considered:-

- Option 1 - Do nothing;
- Option 2 - Replace the current system with needs based entry using pharmaceutical needs assessments (PNAs), and introduce an exit regime that allows effective action to be taken against under-performing providers or those in breach of terms of service. This is the preferred option; and
- Option 3 - Abolish 'control of entry' arrangements and allow a free market for the provision of NHS pharmaceutical services.

Option 1 – Do nothing

Description

689. Under this option, no policy changes would be made and it is anticipated that the incremental changes to pharmaceutical services provision seen in recent years would continue. The overall number of pharmacies in Wales would remain stable, as the current arrangements would continue to act as a barrier to market entry. There would be a very gradual increase in the numbers of pharmacies which provide additional services.

690. There would continue to be variation in the planning of pharmaceutical services by LHBs, and service commissioning would continue to be disparate. Those pharmacies which currently choose not to provide additional services would continue to resist requests to enhance their service offer, to the detriment of local populations. The high proportion of applications to provide NHS pharmaceutical services resulting in appeals to Welsh Ministers would persist.

Costs

Welsh Government

691. As this option proposes no change, the Welsh Ministers would continue to determine appeals made against the decisions of LHBs, both in relation to applications to provide NHS pharmaceutical services and breaches of terms of service. Costs would therefore be the same as they are now and would be related to the Welsh Ministers' duties to determine these appeals. The costs of an appeal to the NHS Litigation Authority under

arrangements in England, which at the time were analogous to the arrangements in Wales, have previously been estimated at approximately £6,000 per appeal³⁸² (at 2007/08 prices). Albeit infrequently, on occasion the decisions of the Welsh Ministers on appeal would be subject to challenge through judicial review.³⁸³ From experience of previous reviews the costs of a judicial review are estimated at £30,000.

Local Health Boards

692. LHBs would continue to determine applications made by persons wishing to provide NHS pharmaceutical services against the existing statutory tests, i.e. whether it is necessary or expedient to grant an application in order to secure the adequate provision of (dispensing) services. There were 22 such applications made in 2013-14³⁸⁴. LHBs would also continue to determine alleged breaches of terms of service when asked to do so by other LHBs. Costs would therefore be the same as they are now. In determining the fee to be paid by persons applying to be included in the pharmaceutical list, the NHS Wales Shared Services Partnership estimated the associated cost to NHS Wales to be £600 per application.

Persons applying to be included in the pharmaceutical list

693. Persons who wish to be included in the pharmaceutical list would continue to apply to their LHB. The decision about the location from which additional services will be provided would be made by the applicant.

694. As is the current situation, applicants would be required to pay a fee in relation to their application³⁸⁵ in order to defray the costs incurred by NHS Wales in reaching a decision. This fee is currently set at £600 for full applications to provide pharmaceutical services with a lower fee for changes of ownership, which are associated with less administrative work for LHBs. Whilst these fees may change over time they would continue to be set at a level which is proportionate to the work LHBs must undertake to determine each application.

Others

695. There would be no additional costs associated with this option for others such as existing pharmacy contractors, Local Pharmaceutical Committees, Local Medical Councils or Community Health Councils, all of which may make representations in relation to applications to be included in the pharmaceutical list. Neither would there be additional costs for patients. Any costs associated with the current system would continue.

³⁸² Department of Health (2008). *Impact assessment of proposals to reform 'market entry' based on pharmaceutical needs assessment*. DH. London.

³⁸³ There has been only one such judicial review in the last 4 years.

³⁸⁴ Welsh Government. (2014). *Community Pharmacy Services*. Welsh Government, Cardiff.

³⁸⁵ There were 22 applications made in 2013-14

Benefits

696. No additional benefits would accrue as a result of this option relative to the current position.

Option 2 – Replace the current system with needs based entry using pharmaceutical needs assessments (PNAs), and introduce an exit regime that allows effective action to be taken against under-performing providers or those in breach of terms of service

697. The assessment of this option has been structured in two parts. The costs and benefits of the needs based entry component are assessed first, followed by an assessment of the costs and benefits of the proposed exit regime.

Description

698. Under this option, the current 'control of entry' arrangements would be revoked and replaced by a new regime. Pharmacies wishing to be permitted to provide NHS services would be allowed to do so only if they are able to demonstrate that there is a particular unmet local need or service requirement that, in allowing them to provide pharmaceutical services, could be met.

699. In order to support this change LHBs would be required to robustly assess the pharmaceutical needs of their populations, and to publish a statement of those needs in the form of a PNA. The content and timing of PNAs would be determined by legislation.

700. The PNA would be a transparent document that gives contractors and potential new entrants greater clarity and certainty in respect of the health needs of local communities, and the standards against which applications will be assessed. The PNA would therefore enable new entrants to align their services with local needs, and enable existing providers to align and potentially extend their services. There would be no costs to contractors in relation to the needs based entry component.

Costs

Welsh Government

701. The Welsh Government would develop guidance to support LHBs in undertaking a PNA and overseeing market exit. This would include developing a standard template for a PNA. The guidance would be produced in 2017/18, following the development of and consultation on secondary legislation.

702. There would be costs to the Welsh Government associated with producing and issuing the guidance. Staffing costs to produce the guidance (based on 6,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £7,500. This is based on approximately five weeks of a FTE Higher Executive Officer (£4,600) to develop the guidance, and five weeks of a FTE Team Support for administration support (approximately £2,900).³⁸⁶
703. It is envisaged that a task and finish group would be established to oversee and develop the guidance. Due to the technical nature of the guidance it has been assumed that this would need to involve representatives of community health councils, community pharmacy contractors, GPs and representatives from Public Health Wales. It is estimated that three people from each group would be involved in attending up to five half-day meetings.
704. Costs for attending task and finish group meetings are estimated at the opportunity cost of time, i.e. forgone earnings, and uplifted by 30% for on-costs. Patient time is evaluated at UK median earnings (£25,000 per annum), GP time is evaluated at average GP salary (£106,100 per annum) as estimated by the Personal Social Services Research Unit (PSSRU, 2014), pharmacist time is evaluated at average pharmacist earnings (£38,735 per annum, from PSSRU, 2014) and Public Health Wales personnel's time has been estimated at the mid point of the Agenda for Change band 8d (£74,084 per annum) (Agenda for Change 2014/15). The task and finish group costs to develop guidance and the PNA template amount to £9,200 (based on £4,000 for GPs, £1,500 for pharmacists, £900 for patients and £2,800 for Public Health Wales representatives).
705. It is anticipated that design and typesetting would require one week of a 0.5 FTE Executive Officer, which would cost approximately £300. It is estimated that translation and proofreading would cost approximately £600.³⁸⁷
706. The guidance would be published in an electronic format only. There would therefore be no publishing costs.
707. Therefore, the total cost of developing guidance (including costs of the steering group) would be £17,600. The guidance would cover all aspects of undertaking a PNA and overseeing market exit and would be produced in 2017/18.

Local Health Boards

Cost of completing PNAs

708. It is assumed that completing a PNA would require input from one senior manager from an LHB for three months, and one administrative

³⁸⁶ Based on Welsh Government staff planning costs

³⁸⁷ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

support officer for one month. Their annual salaries are valued at the mid point of the Agenda for Change bands 8b and 4 at £52,235 and £20,983 (Agenda for Change 2014/15), uplifted by 30% to account for on-costs. It is assumed that three public meetings would be required to publicise each PNA at a cost each of £500, adding £1,500 to costs. The direct cost to each LHB to produce a PNA would therefore be £20,700. The first round of PNAs would be expected to be undertaken in 2017/18.

709. It is assumed that a PNA would need to be comprehensively reviewed every four years, and it is estimated that the costs outlined above would be repeated for this work. Additionally, it has been assumed that LHBs would make small scale updates to their PNA in the intervening years between the annual comprehensive reviews, taking one week of senior management time and one week of administrative support. The cost per update would therefore be approximately £1,800 per LHB.
710. There would be no formal requirement to do so, however due to the technical nature of the process it is envisaged that LHBs may wish to establish a group to oversee the completion of their PNAs. It has been assumed that each LHB would involve the community health council, community pharmacy contractors, GPs and representatives from the local public health team. It is estimated that three people from each group would be involved in attending up to five half day meetings in the first year, and every fourth year thereafter. In intervening years it is estimated that they would only meet twice.
711. Costs for attending local steering group meetings are estimated at the opportunity cost of time, i.e. forgone earnings, and uplifted by 30% for on-costs. Patient time is evaluated at UK median earnings (£25,000 per annum), GP time is evaluated at average GP salary (£106,100 per annum) as estimated by the Personal Social Services Research Unit (PSSRU, 2014), pharmacist time is evaluated at average pharmacist earnings (£38,735 per annum, from PSSRU) and local public health team personnel's time has been estimated at the mid point of the Agenda for Change bands 8a (£44,261 per annum). The costs of individuals' time in supporting each LHB in performing its PNA amount to £8,000 per LHB in the first year and in each year in which the PNA is comprehensively updated, and £3,000 per LHB in intervening years.
712. Each PNA would be published in an electronic format only. There would therefore be no publishing costs.
713. In addition to developing the PNA there would be associated translation costs. It is estimated that this would cost approximately £600 per LHB for each comprehensive update (based on 6,000 words), and £100 for each intervening year (based on 1,000 words)³⁸⁸.

³⁸⁸ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

714. Therefore, the total cost of PNAs for all LHBs (including costs of the steering group) is estimated at £205,100 every four years, and £34,300 for each intervening year. This equates to estimated costs per LHB of £29,300 every four years, and £4,900 for each intervening year.

Cost arising from commissioning additional services to meet pharmaceutical needs

715. The costs arising from commissioning additional services would be dependent on what, if any, unmet needs are identified in each LHB's PNA. If a PNA identifies no unmet pharmaceutical need, there would be no additional cost. The costs presented in this section are therefore illustrative.

716. Costs and later benefits have been estimated by constructing a hypothetical scenario based on variation in the delivery of Local Enhanced Services. To arrive at a conservative net benefit estimate, it has been assumed that the delivery of enhanced services, where necessary, will reflect the pharmaceutical needs of the local population. Thus, assuming that a robust PNA would lead to further commissioning of services to meet the needs of the local population, there would be costs to the LHBs to provide these services.

717. Under PNAs, LHBs would be able to influence the quality of service provision and patient access by commissioning services in locations of greatest need. Therefore, PNAs could result in LHBs commissioning more services from existing providers as well as from new entrants. There would be a cost to LHBs to provide these services.

718. Of the 714 pharmacies in Wales, in 2013/14 the following four local enhanced (public health) services were provided by:

- Emergency contraception – 542 pharmacies;
- Smoking cessation level 3 – 144 pharmacies;
- Syringe and needle exchange – 213 pharmacies; and
- Seasonal influenza vaccination – 236 pharmacies

This equates to 1.6 of these services provided per pharmacy on average.

719. Expenditure on these services was £1,454,759 in 2013/14. This is broken down as follows:

- Emergency contraception - £594,315
- Smoking cessation level 3 - £497,715
- Syringe and needle exchange - £243,083
- Seasonal influenza vaccination - £119,646

720. Published evidence³⁸⁹ suggests that there is considerable variation in the extent to which LHBs commission additional pharmaceutical services. Whilst there are likely to be a number of reasons for this, not least that some services will be being provided by providers other than pharmacies,

³⁸⁹ Welsh Government. (2014). *Community Pharmacy Services*. Welsh Government, Cardiff.

it is considered that at least in part some of the variation can be put down to institutional factors, including LHB commissioning decisions not being aligned to the pharmaceutical needs of their populations. This view is supported by evidence provided to the National Assembly for Wales' Health and Social Care Committee during its inquiry into the contribution of community pharmacy to health services in Wales³⁹⁰.

721. In the absence of PNAs there is no means by which to objectively quantify the extent to which needs are currently being met. Therefore, to ensure a conservative approach to estimating costs, it has been assumed that enhanced services commissioned by LHBs already address the vast majority of the pharmaceutical needs of their populations. This is estimated to be between 70% and 90% of the total need.

722. Under the new arrangements, therefore, between a 10% and 30% increase is expected in the provision of services, with costs increasing by the same proportion, from 2018/19. A range of potential scenarios representing the best, worst and most likely cases following the change are provided in the table below. The most likely scenario figure has been used in the summary costs table at the end of this option.

Table 7.36

Average number of enhanced services provided by pharmacies	1.6
Total cost of enhanced services provided (£)	£1,454,759
Increase in enhanced service provision (best case)	30%
Increase in enhanced service provision (worst case)	10%
Increase in enhanced service provision (most likely case)	20%
Increase in enhanced service costs (£ per annum) (best case)	£436,400
Increase in enhanced service costs (£ per annum) (worst case)	£145,500
Increase in enhanced service costs (£ per annum) (most likely case)	£291,000

Benefits

³⁹⁰ National Assembly for Wales (2012). *Inquiry into the contribution of community pharmacy to health services in Wales*. NAFW, Cardiff.

723. In the following section overall net benefit has been calculated by taking the difference between the discounted benefits and the discounted opportunity costs.

724. The benefit of reduced travel time and the health benefits of just one pharmacy service have been modelled. This makes the estimate of benefits highly conservative.

Health benefits arising from increased service provision

725. Whilst there are no data to prove conclusively that pharmaceutical needs are not being met presently in Wales, there is significant variation in service provision. There is scope to expand enhanced services in some LHB areas, with the local population likely to benefit from those services.

726. In order to arrive at a conservative net estimate of benefit, it has been assumed that the delivery of enhanced services will contribute to meeting the needs of the local population. Pharmacy smoking cessation services have been used to model the benefits to patients from increasing enhanced service coverage.

727. In order to present an illustrative example of potential additional costs, it is conservatively estimated that the most likely scenario under this option is for a 20% increase in service provision (in absolute terms) resulting from the introduction of PNAs and the tailoring of enhanced services to reflect the needs of local populations. Therefore it has been assumed that 80% of the potential benefit is already being achieved.

728. In 2013/14, 144 pharmacies provided a stop smoking level 3 service. The benefits in terms of health outcomes are extrapolated from the Quality Adjusted Life Years (QALY) benefits of people quitting smoking as a result of the service.

729. In 2013/14, 5,403 patients made an attempt to quit smoking through pharmacy stop smoking services and, of these, 2,016 were still not smoking at four weeks into their quit attempt.³⁹¹ The life time quit rate associated with stop smoking services is 7% (taking into account those who would have quit regardless of a stop smoking service), and it has been assumed that this is also the case for patients accessing pharmacy-led services.

730. The health benefits for people who stop smoking are significant. Individuals who quit smoking will gain both in terms of length and quality of life. The number of years of life gained by quitting smoking will vary depending on the age at which an individual quits. The University of

³⁹¹ Based on management information held by the Welsh Government

Birmingham³⁹² calculated the life years gained from quitting smoking by age groups as shown below:-

Table 7.37

Age at quitting (years)	Life years gained	QALY
<35	10	8.44
35-45	9	7.36
45-54	6	4.47
55-64	3	1.455

731. Data were not available on the age profile of pharmacy stop smoking service users. However, data were available for people quitting smoking in Wales through the national smoking cessation service provided by Stop Smoking Wales in 2012/13³⁹³. This is shown in the table below:-

Table 7.38

Age group	Number of quits	% of all quits
<18	14	0.53
18-34	414	15.80
35-59	1518	57.96
60+	664	25.35

732. In order to calculate the average QALY gain associated with stopping smoking, it has been assumed that the profile of people quitting in pharmacy would be the same as those using Stop Smoking Wales. Because the age groups reported by Stop Smoking Wales are not the same as those for which data for QALY gains are available, and to ensure a conservative estimate of benefits, QALY gains have been attributed to the age groups recorded by Stop Smoking Wales based on lower estimates. These are shown in the table below:-

Table 7.39

³⁹² Wang et al 2006. Cut Down to Quit with Nicotine Replacement Therapies (NRT) in Smoking Cessation: Systematic review of effectiveness and economic analysis. University of Birmingham.

³⁹³ Stop Smoking Wales. Stop Smoking Wales Annual Report 2012/13. Public Health Wales.

Age group	QALY gain	Discounted QALY gain ³⁹⁴
<18	8.44	2.22
18-34	8.44	2.22
35-59	4.47	2.14
60+	0	0

733. Applying these discounted QALY gains to the proportion of quits from each age group gives an average discounted QALY gain of 1.6 QALYs per quit.

734. Using the data on pharmacy stop smoking services from 2013/14 and the estimated growth in such services resulting from PNA, the effect on annual numbers of long term quits is shown in the table below:-

Table 7.40

Number of treated smokers per annum under current arrangements	5,403
Number of smokers quit at 4 weeks	2,016
Estimated number of long term quits (7% of 4 week quits)	141
Increase in number of long term quits (best case = 30% increase)	42
Increase in number of long term quits (worst case = 10% increase)	14
Increase in number of long term quits (most likely case = 20% increase)	28

735. At an average of 1.6 discounted QALYs gained per long term quit, the range of QALYs gained per annum as a result of a PNA is estimated to be between 22 (worst case) and 67 (best case), with 45 QALYs the most likely estimate.

³⁹⁴ *QALYs have been discounted at 3.5% in the Wang et al (2006) paper. Health benefits are usually discounted at 1.5%, so this provides a conservative estimate of the QALY gain.

736. Valuing a QALY at £60,000, the benefit from additional long term quits is therefore estimated to be between £1.32m and £4.02m, with the most likely estimate being £2.7m. This benefit is expected to accrue from 2018/19. This is likely to be a conservative estimate as it does not take into account other externalities that smoking causes (such as NHS or personal expenditure).

737. The potential benefits arising from the expected increase in other services that pharmacies provide have not directly been evaluated. Similar increases in provision and benefits would be expected; however these have not been quantified in order to ensure the net estimate of benefit is conservative.

Benefits arising from reductions in travel time

738. To calculate the benefits arising from reductions in travel time, the same method was utilised as adopted by the Office of Fair Trading (OFT) in its 2010 study *Evaluating the impact of the 2003 OFT study on the Control of Entry regulations in the retail pharmacies market*³⁹⁵. Whilst that study related to England it is considered reasonable to assume that the current community pharmacy market in Wales is similar to the market in England prior to the changes to 'control of entry' introduced in England in 2005. The travel time benefits as measured in the OFT report have been adapted to reflect the more conservative reduction in travel time that is considered would be achieved in Wales. In Wales it is envisaged that whilst the introduction of PNA would bring about small changes in the number of pharmacies (in contrast to the significant increase in pharmacy numbers seen in England), the majority of benefits would arise from an overall improved distribution of pharmacies (in contrast to the clustering of pharmacy premises seen in England).

739. In 2013/14 around 34.4m prescription forms were presented for dispensing at pharmacies in Wales. This represents 68.8m prescription related journeys, since people travel to and from the pharmacy. The OFT report referred to above estimated that approximately 14% of prescriptions are delivered rather than collected, reducing the number of prescription related journeys to 59.2m per annum. It has been assumed that the combination of market entry in areas of unmet need, combined with the better distribution of pharmacy services, results in a modest average reduction in travel distance to pharmacies. Assuming an average reduction of 10 metres and applying lower and upper average journey speed estimates of 5.85 and 8.78 km/h respectively on the 54/46 split of journeys by car and walking following the methodology adopted in the OFT report, this arrives at annual travel time savings of between 67,426 hours and 101,196 hours.

³⁹⁵ Office of Fair Trading. 2010. *Evaluating the impact of the 2003 OFT study on the Control of Entry regulations in the retail pharmacies market*. OFT. London.

740. Quantifying the impacts of travel time savings requires estimates of consumers' value of time (VOT). The Department for Transport (DfT) provides estimates of VOT for the purpose of routine transport project analysis. These differ substantially between working and non-working time (£26.73 and £4.46 per hour respectively at 2002 prices), reflecting whether or not there are opportunity costs in terms of labour output. The age and income profile of prescription users, and the fact that most prescriptions are repeat prescriptions, implies that the displacement of work time is likely to be very low.
741. According to the OFT consumer research, around 5% of pharmacy visits by prescription customers originate from work, and 87% of these occur during the working day, although it is envisaged that there are a significant number of lunch hour visits. On the other hand, some visits originating from home or the doctor's surgery will displace work time. In the absence of firm data the conservative assumption has been made that no more than 2% of incremental time travelling to and from a pharmacy displaces working time. This leads to an average VOT of £6.30 per hour for prescription customers once the values are adjusted for annual VOT growth since 2002, using the growth rates laid down by DfT in the same source.
742. Using the estimates of average VOT, the benefit of annual travel time savings associated with PNA would be between £424,800 and £637,600. Again, this annual benefit is expected to accrue from 2018-19. In order to provide a conservative estimate, and to adjust for possible overestimates in the number of journeys, the lower end of this range is included in the summary table at the end of this option.

Cost savings resulting from fewer applications

743. Currently a person wishing to provide NHS pharmaceutical services must make an application to the relevant LHB to do so. Prospective applicants must make their own judgement on the pharmaceutical needs of the population that would be served by the pharmacy they propose to open, and the adequacy of existing pharmaceutical services. Under this option, in the future applicants would be able to refer to the LHB's PNA when deciding whether or not to make an application. Given that over half of all applications (excluding those relating to minor relocations) made to LHBs are currently refused (59% in 2013/14), it is envisaged that a proportion of applications that would be made under the current system would not be made in future. This is because it would be immediately apparent from an LHB's PNA that additional pharmaceutical services are not needed.
744. Applicants currently pay a fee on each occasion they make an application to be included in an LHB's pharmaceutical list. The fee for a new inclusion is currently £600. It is expected that whilst the number of applications that are unlikely to succeed would reduce, this would be offset by an increase in applications which are not made currently but where a

need identified in the PNA prompts one. In order to ensure a conservative estimate of net benefits, and because the net reduction in applications is likely to be small, these cost savings have not been quantified. However, it is expected that some potential applicants would benefit relative to the current arrangements.

Cost savings arising from fewer appeals over entry

745. The decisions taken by LHBs in relation to the market entry of additional pharmaceutical service providers are frequently subject to appeal. Such appeals are made to the Welsh Ministers.
746. Greater consultation during the preparation of PNAs and more clarity over decisions resulting from applications being judged against explicit statements of pharmaceutical needs should result in a reduction in appeals to the Welsh Ministers. The numbers of appeals determined by the Welsh Ministers between 2009/10 and 2013/14 are shown below:-

Table 7.41

Year	2009/10	2010/11	2011/12	2012/13	2013/14	Total
Appeals determined	8	29	28	39	11	115

747. The number of appeals to the Welsh Ministers in any period is subject to significant variation. Appeals received in one year might be considered in the subsequent year and in some cases, such as those involving judicial review, appeal decisions may be delayed further. The average number of appeals determined by the Welsh Ministers is estimated to be 23 per annum.
748. The costs of an appeal to the NHS Litigation Authority under arrangements in England, which at the time were analogous to the arrangements in Wales, have previously been estimated at approximately £6,000 per appeal³⁹⁶. This would give a total annual cost of £156,000 to the Welsh Ministers in determining 23 appeals per annum (uprated from £138,000 at 2007/08 prices).
749. Whilst it is expected that the number of appeals against LHB decisions would reduce, there is significant uncertainty in estimating how many appeals would be made following the changes. This is because not only would LHB decisions be more transparent and better understood, but also because having a PNA in place is expected to lead to fewer speculative applications in the first place.

³⁹⁶ Department of Health (2008). *Impact assessment of proposals to reform 'market entry' based on pharmaceutical needs assessment*. DH. London.

750. For the purpose of this RIA a range of potential scenarios are provided in the table below, representing the best, worst and most likely case scenarios following the change. It is assumed that regulations for a new needs-based entry regime would come into force in 2017, and that all appeals outstanding under the existing regime would be dealt with during 2017/18.

Table 7.42

Year	2016/17	2017/18	2018/19	2019/20	2020/21
Appeals expected under current regime	23	23	23	23	23
Estimated cost of appeals (£ 000s)	156	156	156	156	156
Reduction in appeals under new regime (best case)	0%	0%	30%	30%	30%
Reduction in appeals under new regime (worst case)	0%	0%	5%	5%	5%
Reduction in appeals under new regime (most likely case)	0%	0%	20%	20%	20%
Estimated savings under new regime (£) (best case)	0	0	46,800	46,800	46,800
Estimated savings under new regime (£) (worst case)	0	0	7,800	7,800	7,800
Estimated savings under new regime (£) (most likely case)	0	0	31,200	31,200	31,200

751. Under the most likely case scenario, a 20% reduction in the number of appeals made to the Welsh Ministers would be expected. This would result in savings of £31,200 per annum from 2018/19.

Wider benefits

752. It is anticipated that this option also would bring about further indirect benefits. In particular it is envisaged that increasing these services may lead to a more efficient use of health services, freeing up GP time. Economic benefits to local communities would also be expected where

new pharmacies are established. Community pharmacies have been identified as one of the essential businesses that ensure economic prosperity in communities³⁹⁷. New entrants will therefore contribute to sustaining local communities, providing shopping access, local employment and building social capital. However, these benefits have not been quantified.

Disbenefits for pharmacy contractors resulting from market entry

753. It is not envisaged that there would be any net disbenefit for pharmacy contractors, since any disbenefits to existing contractors would be offset by equal benefits to the new entrants.

Exit regime

Description

754. Alongside the introduction of needs-based entry, an exit regime would also be introduced that would lead to effective graduated actions being taken to deal with those providers who fail to meet their terms of service obligations, and who are receiving NHS remuneration without fulfilling their contractual obligations to the NHS. Ultimately where a pharmacy persistently breaches its terms of service or where the breach is significant, an LHB could remove the pharmacy from its pharmaceutical list.

755. It was noted in the Public Health White Paper that the Welsh Government wished to ensure there were more effective sanctions to address poor performance. Introducing provisions directly related to quality would provide incentives for contractors to improve delivery, and give LHBs the power to de-commission services where there is already adequate service provision but the contractor does not meet minimum acceptable quality standards.

756. Alongside the existing powers in sections 82 and 83 of the NHS (Wales) Act 2006, additional powers are considered to be necessary to enable LHBs to remove contractors from the pharmaceutical list where they seriously or persistently breach their NHS terms of service.

757. This option would enable LHBs to take effective and proportionate action, including withdrawal of the right to provide pharmaceutical services, against those contractors operating below acceptable levels of quality. This is expected to have a direct benefit of reducing poor quality service provision by these providers, but would also provide incentives to all pharmacies to raise standards.

³⁹⁷ Department of Health. (1999) *Improving Shopping Access for People Living in Deprived Neighbourhoods – a paper for discussion*. DH. London.

Costs

758. LHBs would be expected to incur costs in administering these measures: in collecting and analysing information to identify poor quality contractors; in pursuing the action against them; and in managing appeals against their decisions.
759. Contractors would incur costs in gathering the information required by LHBs in order to administer this system. Contractors against whom action is taken would also sustain costs in conducting their defence. The ultimate impacts of the proposal will depend on the detail of regulations brought forward under the primary legislation. Therefore, illustrative costs and benefits have been calculated for representative scenarios that may result following implementation. Regulations would be subject to usual consultation procedures, and would be developed with due consideration of the consequent risks, costs and benefits.
760. Guidance regarding the exit regime would be provided by the Welsh Government and incorporated into the overall PNA guidance detailed earlier in the assessment of Option 2. There would be no additional costs beyond those outlined previously.

Cost to LHBs in undertaking performance management

761. LHBs already carry out performance management of pharmacy contractors as part of the current NHS pharmaceutical services contractual framework. It is assumed that no additional costs would be incurred in identifying those against which action should be considered.
762. Based on discussions with LHBs it is estimated that action might be taken against up to five pharmacy contractors each year. Each action would incur staff costs of assembling additional information, managing the disciplinary process and defending any appeals – which are assumed, as a worst-case scenario, to be made against all actions. It is assumed that this process would require a total of one senior manager and one administrative support officer from an LHB for up to 10 days; annual salaries are valued at the mid point of the Agenda for Change bands 8b and 4 at £52,235 and £20,983 (Agenda for Change 2014/15) uplifted at 30% for on-costs. Based on previous experience legal costs at an average of £3,900 per case are assumed. The total resulting annual cost to LHBs is therefore estimated at £34,500, incurred from 2018/19.

Contractor compliance cost

763. Contractors would be expected to incur costs in providing the information required for assessment by LHBs. It is expected that most contractors already undertake this work in order to fulfil their existing obligations for performance monitoring. However, it is assumed that a small number of contractors do not undertake this work, and these contractors would therefore incur additional costs. It is estimated that for

10% of contractors (approximately 70), this would represent additional workload and cost. The time taken to demonstrate compliance is estimated to be one week per year. If the work is carried out by a pharmacy technician, whose time costs £15 per hour (including on-costs)³⁹⁸, and there are 70 contractors to which this applies, the annual costs would be £39,000 per annum from 2018/19.

Contractor costs of defending actions

764. It is assumed that a contractor defending an action would incur the same costs as the LHB bringing the action. This results in annual costs of £34,500 from 2018/19.

Costs to existing contractors through lost profits

765. It is assumed that any profits lost by contractors no longer supplying the NHS would be directly offset by the profits gained by existing contractors or new entrants that replace them.

Benefits

766. Giving LHBs the power to take appropriate action against poor contractors is expected to improve service quality – both by improving the standards of poor and under-performing providers or withdrawing their right to provide NHS services, and by creating a universal incentive to raise standards.

767. It is not possible to forecast exactly the value of the patient benefit that can be expected to result from these measures. In order to evaluate whether the benefits outweigh the costs, it is therefore necessary to construct a credible, conservative scenario, which underestimates the likely net benefit of the measures. Accordingly the benefits associated with strengthened exit arrangements have not been quantified.

Table 7.43 - Summary of cost and benefits associated with Option 2

	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
	£	£	£	£	£	£
Costs						
Welsh Government						

³⁹⁸ Based on top of scale agenda for change band 4 plus 30% on cost

Costs for developing guidance	0	17,600	0	0	0	0
Total Cost to Welsh Government	0	17,600	0	0	0	0
Local Health Boards						
Costs associated with undertaking PNAs	-	205,100	34,300	34,300	34,300	205,100
Cost arising from commissioning additional services to meet pharmaceutical needs	-	-	291,000	291,000	291,000	291,000
Cost in undertaking performance management	-	-	34,500	34,500	34,500	34,500
Total Cost to LHBs		205,100	359,800	359,800	359,800	530,600
Contractors						
Contractor compliance cost	-	-	39,000	39,000	39,000	39,000
Contractor costs of defending actions	-	-	34,500	34,500	34,500	34,500
Total Cost to Contractors			73,500	73,500	73,500	73,500
Total costs	-	222,700	433,300	433,300	433,300	604,100
Benefits						

Health benefits	-	-	2.70m	2.70m	2.70m	2.70m
Reductions in travel time	-	-	424,800	424,800	424,800	424,800
Reduced appeals to the Welsh Ministers under new regime	-	-	31,200	31,200	31,200	31,200
Total benefits		-	3,156,000	3,156,000	3,156,000	3,156,000
Net benefits		- 222,700	2,722,700	2,722,700	2,722,700	2,551,900

Option 3 – Abolish ‘control of entry’ arrangements and allow a free market for the provision of NHS pharmaceutical services

Description

768. This option would enable market forces to determine the number, location and services offered by community pharmacies. It is likely that there would be considerable growth in numbers of pharmacies, with associated increases in costs. It is not possible to estimate how significant the growth in pharmacy numbers would be, although experience from England is that the introduction of limited exemptions to the ‘control of entry’ tests which came into force in 2005 resulted in an increase of 18% between 2005/06 and 2012/13³⁹⁹.

Costs and benefits

769. Abolition of ‘control of entry’ arrangements would likely bring some benefits in terms of improved access, choice and competition. However, this is most likely in areas of highest economic demand, which are already well served. This would lead to diminishing economic returns since each incremental new entrant would bring lower associated benefits but the same fixed costs.

770. A change to the legislation would be likely to lead to a high level of market disruption. New entrants and many existing pharmacies would look to secure the most advantageous trading positions in order to maximise dispensing revenue.

³⁹⁹ HSCIC (2013) General Pharmaceutical Services in England - 2003-04 to 2012-13

771. It is extremely difficult to make plausible assumptions regarding the cost and benefits of this option. It is highly unlikely that market forces would deliver the policy objectives in terms of aligning services with local needs, because most entrants would make the decision about where to locate on the basis of dispensing prescriptions, as this is the market data that is available, rather than providing public health services, which cannot currently be assessed. It is probable that some pharmacies would relocate from existing locations within communities to locations adjacent to large GP practices. In such situations access would diminish in some areas, and improve in others. This would particularly impact on rural communities. This option is therefore considered unsatisfactory and has not been quantified.

Summary and preferred option

772. The evidence demonstrates the benefits of changing the current 'control of entry' arrangements in Wales. The introduction of PNA and needs-based entry arrangements would address the current situation where pharmaceutical needs may not be routinely assessed, and where pharmaceutical service planning is not necessarily aligned to identified health needs. The changes would also strengthen the role of LHBs in determining where and by whom such services are provided, and provide performance management tools to improve the quality and consistency of service provision by pharmacy contractors.

773. Option 1 proposes no change to current arrangements, but responses to a previous consultation⁴⁰⁰ on 'control of entry' in Wales suggests there is a consensus that these arrangements are outdated and inadequate. In general, stakeholders recognise and support the need for change. Option 3 is not considered to deliver the key policy objective. There is evidence from England that deregulation leads to improved access through an increase in the number of pharmacies. However pharmacies tend to cluster close to one another generally in areas of low need⁴⁰¹. Option 2 is therefore the preferred option, as it addresses the need for better planning, improved decision making and performance management. The conservative analysis carried out suggests that the benefits of the change would outweigh the costs, resulting in a positive net present value of approximately £10,497,300 over the five year period.

Provision of toilets (Part 6)

774. Four options have been considered:-

⁴⁰⁰ Welsh Government (2011). Proposals to reform and modernise NHS Pharmaceutical Services in Wales

⁴⁰¹ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063460

- Option 1 - Do nothing;
- Option 2 - Re-hypothecate the Public Facilities Grant Scheme;
- Option 3 - Require each local authority to develop and publish a local toilets strategy. This is the preferred option; and
- Option 4 - Require local authorities to ensure adequate provision of toilets for public use.

Option 1 – Do Nothing

Description

775. This option proposes no change to the current position. There would be no additional legislation involved, and the provision of toilets for public use would continue to be at the discretion of each local authority.

776. The Public Facilities Grant Scheme was established in 2009/10 to increase the provision of free public access to toilet facilities in Wales. It sought to improve the quality and accessibility of these facilities, by encouraging local authorities to work in partnership with local businesses to allow public access to their facilities. All local authorities in Wales were invited to participate. The Scheme reimbursed local authorities (to a maximum of £17,500 per local authority each year) for payments of up to £500 made to local businesses, for allowing free public access to their toilet facilities.

777. In 2014/15 £200,000 was transferred to the Revenue Support Grant in a move to increase flexibility of funding to local authorities. It is now for each local authority to decide how this funding is utilised to deliver its range of services, in order to meet the needs and priorities of its communities.

Costs

Welsh Government

778. There would be no additional costs to the Welsh Government associated with this option. As noted above, £200,000 per annum is included in the Revenue Support Grant to improve public access to toilet facilities in Wales.

Local authorities

779. There would be no additional costs for local authorities under this option. Local authorities could continue to administer funds from within the Revenue Support Grant to businesses for the purpose of allowing free public access to their toilet facilities. It is estimated that local authority administration of the full £200,000 grant would equate to a total annual cost of £33,000. Information provided by local authorities indicates that

current spending on grants is at approximately 75% of the amount made available under the Public Facilities Grant Scheme. Assuming continued use of the grant scheme at current levels, approximately 75% of those administration costs would be incurred, a total of £24,800 each year. Further information on the level of grant spending is provided under Option 2. There is a risk that provision of toilets for public use would decline under this option.

Table 7.44: Summary of costs associated with Option 1

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government Costs					
Contribution to Revenue Support Grant	200,000	200,000	200,000	200,000	200,000
Local authority costs					
Staff time	24,800	24,800	24,800	24,800	24,800
Total Costs	224,800	224,800	224,800	224,800	224,800

Benefits

780. As this option proposes no change, there would be no additional benefits to the Welsh Government or local authorities.

781. There would continue to be funds available within the Revenue Support Grant for local authorities to provide public access to toilet facilities. However, given that these funds are not hypothecated there is a risk that due to financial pressures, local authorities could prioritise spending in areas other than toilet facilities. Whilst improvements in toilet provision could result in benefits to health, tourism and the economy, it is unlikely that there would be additional benefits to the general public under this option. Furthermore, there could be potential dis-benefits if the status quo is not maintained.

782. Businesses would continue to be able to apply to their local authority for funding to improve public access to toilet facilities. There would be no additional benefits to businesses. However, if the priority given by a local authority to this issue through its use of the Revenue Support Grant was reduced, there may be dis-benefits to the businesses currently receiving grants.

Option 2 – Re-hypothecate the Public Facilities Grant Scheme

Description

783. This option would involve the Welsh Government re-hypothecating the Public Facilities Grant Scheme by removing it from the Revenue Support Grant. The £200,000 annual funding would then be ring-fenced by the Welsh Government for improving provision of and access to toilets for public use across Wales.

784. During a short debate in the National Assembly for Wales⁴⁰² in 2013, the then Minister for Local Government and Government Business confirmed that (along with other funding) the Public Facilities Grant Scheme fund would be mainstreamed into the Revenue Support Grant. The Minister stressed the importance of local authority provision of public toilets and said she had made it clear that this move could not and should not be seen as an excuse to downgrade provision.

785. Information gathered by the Welsh Government from local authorities during 2014 indicates that since the change in funding mechanism, seven local authorities either have or are suspending the Public Facilities Grant Scheme in their area, or reviewed it during 2014/15. In addition, a further five local authorities have not taken part in the scheme. This means that there are 12 authorities where the scheme is inactive or was reviewed during 2014/15.

786. This option would involve the Welsh Government reviewing the implementation of the previous Public Facilities Grant Scheme, with a view to re-hypothecating it. All local authorities would be expected to take part and utilise their grant allocation.

Costs

Welsh Government

787. The Welsh Government would review the previous Public Facilities Grant Scheme, considering any previous evaluations, and would then implement any necessary changes. Completion of this review, including engaging local authorities, businesses and any other relevant representative groups, is anticipated to cost £10,600 (approximately six weeks of a FTE Senior Executive Officer, which would equate to £7,100, plus one and a half months of a FTE Team Support, equating to £3,500).⁴⁰³ These costs would be incurred in 2016/17. This review would negate the need for local authorities to carry out their own reviews of the scheme.

⁴⁰² <http://www.assembly.wales/en/bushome/pages/rop.aspx?meetingid=184&language=en&c=RecordofProceedings&startDt=13/11/2013&endDt=13/11/2013#110676>

⁴⁰³ Based on Welsh Government staff planning costs

788. There would be a further review of the scheme after three years, requiring the total Welsh Government costs of £10,600 to be repeated in 2019/20.

789. The £200,000 to fund a dedicated scheme would not be an additional annual cost, as it is currently provided to local authorities via the Revenue Support Grant. This amount would be re-hypothecated from that budget. The scheme would be managed in line with Welsh Government grant allocation guidance. It is anticipated that the management of the grant scheme would require 0.05 FTE Executive Officer, at an annual cost of £1,500. This would equate to approximately two hours per week for the management of the scheme.

Local authorities

790. The allocation of funding to individual local authorities would be dependent on the outcome of the review of the scheme. The grant provided to a local authority could only be spent on issuing funding as part of the renewed grant scheme.

791. This option would reduce each local authority's ability to direct funding from the Revenue Support Grant to other priority areas. In cases where local authorities are not currently spending the equivalent of their grant allocation on access to toilet facilities, the hypothecation of this funding could necessitate cuts to other services.

792. In 2013/14, 327 businesses were issued with a grant by local authorities for making their toilet facilities available to the public, totalling £147,910⁴⁰⁴. Assuming similar figures for 2014/15, it can be estimated that £52,090 has been provided to local authorities but spent on areas other than public toilet provision. If the Welsh Government required the full allocation of £200,000 to be spent on public toilet provision, it is likely that this £52,090 would be deducted from other services. However, as a number of local authorities have suspended or are reviewing the scheme (as noted above), it is feasible that the shortfall to other services could be greater than £52,090.

793. Local authority staff costs would also need to be considered. This would include engagement with the Welsh Government during the review of the Public Facilities Grant Scheme, and then the ongoing annual cost of administering the grant to businesses. It is anticipated that this would require ongoing administration from an 0.05 FTE Administrative Officer, an annual cost of £1,500 to each local authority.⁴⁰⁵ This would equate to approximately two hours per week. As this cost would be duplicated across all 22 local authorities, there would be a total cost of £33,000. Taking into consideration the £24,800 cost incurred for administration of

⁴⁰⁴ Welsh Government figures

⁴⁰⁵ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

the grant scheme in option 1, this would amount to an additional cost of £8,200.

794. A review of the Public Facilities Grant Scheme could result in changes to how the funds may be spent by local authorities in future. For example, costs for improving publicity and signage could potentially be financed from within the grant funds. The proportion of the overall funding which could be used for this purpose would vary dependent on local priorities and therefore cannot be assessed. However, the total funding available under a future revised Grant Scheme would remain at current levels.

Businesses

795. A reviewed version of the Public Facilities Grant Scheme could lead to an increase in publicity and signage, which would be intended to result in an increase in the use of toilets within those businesses receiving a grant. Although it is not possible to quantify, businesses could see an increase in the costs of maintenance, cleaning and disposables if their toilets are more frequently used. However, the grant of £500 is intended to cover these costs.

Table 7.45: Summary of costs associated with Option 2

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £
Welsh Government Costs					
Public Facilities Grant Scheme	200,000	200,000	200,000	200,000	200,000
Grant Management Staff Time	1,500	1,500	1,500	1,500	1,500
Review Staff Time	10,600	0	0	10,600	0
Total Welsh Government Costs	212,100	201,500	201,500	212,100	201,500
Local authority costs					
Staff time	33,000	33,000	33,000	33,000	33,000
Total Local Authority Costs	33,000	33,000	33,000	33,000	33,000
Total Costs	245,100	234,500	234,500	245,100	234,500
Additional Costs to Option 1	£20,300	£9,700	£9,700	£20,300	£9,700

Benefits

Welsh Government

796. The Welsh Government would have greater assurance that the scheme was being dealt with in a largely consistent manner across each local authority in Wales, and that a consistent sum would be dedicated to enhancing toilet provision. A review of the previous scheme, with engagement from key stakeholders, would seek to maximise the impact of the scheme overall.
797. Several local authorities have indicated that they have planned to review their administration of the Public Facilities Grant Scheme. A review led by the Welsh Government would allow for a consistent approach across Wales, rather than several different reviews being conducted using different methods.

Public

798. The general public could see an increase in the number of toilets and the range of places where toilets are available to them from this option. If each local authority spends its maximum allocation on issuing grants alone, then there could be approximately 18 business premises with toilets available to the public within each local authority area.
799. However, there would be a risk that local authorities would seek to reduce the impact of cuts to other services by transferring funds currently used for direct public toilet provision to competing priorities. This could counteract any increase in access to toilets for public use which may be achieved.

Businesses

800. Businesses would have an opportunity to improve the previous scheme by engaging with the Welsh Government as part of a review. Businesses may also see an increase in footfall if their toilet facilities are made available for use by the public. This could result in an increase in business turnover. It is not possible to quantify this and the other potential benefits.

Option 3 – Require local authorities to develop a local toilets strategy

Description

801. Under this option a duty would be placed on each local authority in Wales to prepare, consult upon and publish a local toilets strategy. The current legal position whereby local authorities may provide toilets for use by the public would also apply. The Welsh Government funding for

improving public access to toilet facilities would remain mainstreamed within the Revenue Support Grant.

Costs

Welsh Government

802. The Welsh Government would produce guidance to accompany a new duty. There would be costs to the Welsh Government associated with producing and issuing the guidance. Staffing costs to produce the guidance (based on 6,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £7,500. This is based on approximately five weeks of a FTE Higher Executive Officer (£4,600) to develop the guidance, and five weeks of a FTE Team Support for administration support (approximately £2,900).⁴⁰⁶

803. It is anticipated that design and typesetting would require one week of a 0.5 FTE Executive Officer, which would cost approximately £300. It is estimated that translation and proofreading would cost approximately £600.⁴⁰⁷ There would be no printing costs as it would only be produced electronically. The total cost for the development, design and translation of guidance would therefore be £8,400 and would be incurred in 2016/17.

804. The guidance would be updated every four to five years, to coincide with the cycle for preparation of the strategies by local authorities. It is anticipated that this would take approximately one week of a FTE Higher Executive Officer's time, which would equate to approximately £900. Design and translation costs would amount to half the original costs, a total of £500. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,400, incurred every four to five years. It is envisaged that the first review would take place in 2021/22.

805. The £200,000 contribution to the Revenue Support Grant each year would continue.

Local authorities

806. Local authorities would need to undertake an assessment of the need for toilets in their area to be available for use by the public and publish their local toilets strategy within a year of the first local government elections to be held following the provisions' coming into force. The needs assessment could involve analysing existing public toilet provision, engaging with local communities and stakeholders regarding their perception of need, and considering other factors such as appropriate methods for publicising facilities.

⁴⁰⁶ Based on Welsh Government staff planning costs

⁴⁰⁷ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

807. The strategies would include a statement setting out the steps that the local authorities propose to take to meet the needs they have identified. The assessment of need and development of the strategy is anticipated to require two thirds of a FTE officer for one month (equivalent to £2,300), with oversight from a FTE senior officer dedicating one third of their time for one month (equivalent to £2,000).⁴⁰⁸ These costs are based on the assumption that the local authority currently has no local toilets strategy in place, nor is one already in the process of development.

808. Assuming that the preparation of the strategy follows a best practice model, it would progress through a local authority's specific scrutiny process. A Task and Finish scrutiny inquiry and a pre-scrutiny review would be likely to take place prior to the strategy being approved and published by the local authority. Progress in implementing the strategy would also be likely to be routinely monitored by a scrutiny committee within the local authority, subject to work programmes. It is estimated that the above process would require one third of a FTE Grade 9 Scrutiny Officer's time over a three month period (equivalent to a cost of £3,900), and one month of a FTE Grade 8 Scrutiny Researcher (equivalent to a cost of £3,000).⁴⁰⁹

809. Prior to publication, local authorities would also be required to consult on their local toilets strategies. There would be a range of consultation options available to local authorities, with varying associated costs. This process would be likely to include questionnaires, drop in sessions, local media coverage and online engagement, at a cost of approximately £6,000.⁴¹⁰

810. There would therefore be an approximate total cost to each local authority for the initial development of the strategies of £17,200. Repeating these costs for all 22 local authorities would amount to £378,400. These costs would be incurred in 2017/18, following local government elections.

811. Each local authority would also be required to undertake a review of its local toilet strategy every four to five years, within a year of local government elections. If changes are needed, the strategies would need to be revised and consulted upon. As future reviews of the strategy are likely to be less resource intensive than the initial development, it is assumed that the staff time required to support this work would be reduced. However, it is anticipated that staff costs for scrutiny of the strategy would be replicated. If revised, consultation costs would also be repeated. A review of the strategy and associated scrutiny costs and a consultation exercise would therefore be estimated to cost a total of £331,100 (£15,050 for each local authority).

⁴⁰⁸ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

⁴⁰⁹ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

⁴¹⁰ According to figures provided by local authorities

812. Local authorities would continue to administer funds from within the Revenue Support Grant to businesses for the purpose of allowing free public access to their toilet facilities. It has been estimated that administration of the full £200,000 grant would equate to a total cost of £33,000. It is assumed that given the duty to prepare a local toilets strategy, local authorities would be more likely to utilise the full £200,000 for the purpose of grant allocations and administration costs would equate to £33,000 annually (£1,500 per local authority) from 2018/19.

Table 7.46: Summary of costs associated with Option 3

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £	2021/22 £
Welsh Government Costs						
Production of guidance	8,400	0	0	0	0	1,400
Addition to the Revenue Support Grant	200,000	200,000	200,000	200,000	200,000	200,000
Total Welsh Government Costs	208,400	200,000	200,000	200,000	200,000	201,400
Welsh Government costs additional to Option 1	8,400	0	0	0	0	1,400
Local authority costs						
Strategy development and consultation	0	378,400	0	0	0	331,100
Grant Management Staff Time	24,800	24,800	33,000	33,000	33,000	33,000
Total local authority costs	24,800	403,200	33,000	33,000	33,000	364,100
Total local authority costs additional to Option 1	0	378,400	8,200	8,200	8,200	339,300
Total Cost	233,200	603,200	233,000	233,000	233,000	565,500
Additional	8,400	378,400	8,200*	8,200*	8,200*	340,700

<u>Costs to Option 1</u>						
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* Additional costs in these years relate only to the increase in management costs to facilitate the full £200,000 spending on grants. Further additional costs would be determined by the development and implementation of the strategies. As these strategies are at the discretion of each local authority following an assessment of need in its area it is not possible to estimate the additional costs to increase provision levels. However, greater spending on the implementation of strategies is likely to result in a greater degree of the benefits discussed below being realised.

813. Local authority and Welsh Government staff costs incurred in 2020/21 would be repeated every four to five years, aligning with the review period for the strategies.

Benefits

Welsh Government

814. The Welsh Government would gain an assurance that each local authority across Wales has a local toilets strategy in place to meet the needs of its community for these facilities. This strategy could include information such as the location of toilets and details of how need would be met over the long term. An emphasis on the provision of better information and better forward planning processes could encourage a more strategic use of funding in relation to public toilets.

Local authorities

815. In developing their strategy, local authorities would undertake an assessment of the need for toilet facilities to be available for use by the public in their area, and would develop their strategy to meet that need. Given the flexibility afforded to local authorities in implementing their strategy, it is difficult to accurately quantify the benefits to be derived from any improvements in local toilets provision. An indication of the range of benefits is provided below.

Health

816. An improvement in the quality and quantity of provision of toilets for public use can have positive impacts on health. A National Assembly for Wales Health and Social Care Committee inquiry⁴¹¹ into public toilet facilities heard from Age Cymru and the Welsh Senate of Older People, who described the lengths people take to avoid needing to use the toilet when away from home. This includes not taking essential medication that might exacerbate the need to urinate frequently, or limiting fluid intake which results in dehydration and associated health problems. These behaviours could lead to a requirement for further treatment.

⁴¹¹ <http://www.senedd.assembly.wales/mglIssueHistoryHome.aspx?lId=2572> Page 14.

817. 23% of people surveyed in a public facilities report from Guernsey⁴¹² said they plan or sometimes plan their journeys around toilet provision, with the main reasons given being medical conditions such as bladder and bowel disorders, diuretic medication and dependant relatives/ children.

818. The National Assembly for Wales' Health and Social Care Committee inquiry⁴¹³ into public toilet facilities heard evidence that many people with bladder or bowel conditions do not go out in case they cannot access a toilet, and this can lead to individuals becoming more immobile, isolated, ill and/or depressed, leading to a possible need for further treatment. For example, research provided to the Committee estimated that within the 600,000 population of the Aneurin Bevan Health Board area, approximately 22,000 people would suffer with bladder or bowel incontinence and could be affected by a lack of toilet provision.

819. Another potential benefit is a reduction in street fouling, which could decrease the cost of street cleaning for local authorities. *"Street fouling is an increasing issue as the number of toilets decrease and the night time economy brings drinkers into town and city centres, this has public health implications as well as raising costs of street cleaning. A survey of local authorities by ENCAMS showed that over 30% of cities and almost 20% of towns said that human fluids on their streets were a major problem."*⁴¹⁴

Tourism

820. An improvement in the quality and quantity of provision may result in a positive impact on tourism in Wales. An ENCAMS survey⁴¹⁵ found 60% of visitors considered public toilets as an important factor when deciding on location of a beach visit.

Economy

821. Members of the public can be less inclined to spend time shopping in town centres if they know that there is a lack of adequate toilet provision. The survey above also found that 38% of women will either choose not to visit an area or spend less time there if there is inadequate toilet provision. This could significantly impact on local businesses.

Option 4 – Local authorities to ensure adequate provision of toilets for public use

Description

⁴¹² McDermott, P & Kernohan, W. The adequacy and public perception of the public toilet provision on Guernsey. Page 63.

⁴¹³ <http://www.senedd.assembly.wales/mglIssueHistoryHome.aspx?lId=2572> Page 13

⁴¹⁴ ENCAMS (Environmental Campaigns) policy statement on public toilets. Available at:

<http://kb.keepbritaintidy.org/toilets/background.html>

⁴¹⁵ <http://kb.keepbritaintidy.org/toilets/background.html>

822. Under this option, each local authority in Wales would be under a statutory duty to ensure adequate provision of toilets for public use. There would be a requirement to complete a needs assessment to determine the quantity, location and type of facilities required for adequate provision. Local authorities would be under a duty to prepare a strategy and ensure this provision was then secured.

823. In ensuring adequate provision of toilets for public use, a range of options would be available to local authorities. This would include those toilets provided to the public via schemes similar to the Public Facilities Grant Scheme, public toilets in places like shopping centres and public buildings (such as museums, sports centres), as well as providing local authority maintained facilities. This option is therefore similar to Option 3, but accompanied by a further duty to ensure adequate provision of toilets for public use.

Costs

Welsh Government

824. The costs to Welsh Government would be the same as under Option 3.

Local authorities

825. The costs to local authorities associated with the development of a local toilets strategy would be the same as under Option 3.

826. Once a local authority has developed a local toilets strategy, there would then be a further duty to implement that strategy in order to ensure adequate provision of toilets for public use. The range of approaches local authorities could take to secure access is too broad to accurately cost. However, in order to provide an estimate of the potential costs associated with this option, it has been assumed that local authorities would meet half the need for extra provision by building new facilities (“directly provided toilets”, and the remaining half through the expansion of a scheme similar to the Public Facilities Grant Scheme. It is accepted that local authorities would vary greatly in their approach, but the approach outlined below is considered to provide a reasonable approximation.

827. A company specialising in the provision of public toilets has provided costs for blocks of four toilets (a unit of one accessible toilet plus three other cubicles). Only one company was contacted for prices for illustrative purposes. The cost for a block of four toilets was £107,500⁴¹⁶. It is anticipated that local authorities would spread the cost of building new toilet facilities over three years, from 2018/19 to 2020/21, ahead of a review on the implementation of its strategy.

⁴¹⁶ Based on prices provided by a public toilet provider

828. An increase in such directly provided toilets would also carry further cleaning, maintenance and cost implications for local authorities. Whilst it is difficult to estimate these costs as each local authority would handle the matter differently, figures provided by a specialist public toilet provider indicated annual costs of £10,500 per unit. Total spend of £20,500 would cover all costs, including revenue management, consumables, parts, utilities, rates, repairing vandalism, cleaning and maintenance. These costs could potentially be offset by placing a charge for the public to use the toilet facilities. Average revenue, based on a usage fee of 20p is estimated to be approximately £10,000 per unit annually. The net annual ongoing cost is therefore assumed to be £10,500 per unit annually.
829. It has been assumed that any scheme similar to the Public Facilities Grant Scheme would continue to provide grants of £500 per year to businesses. It has also been assumed that each business receiving a grant provides four toilet cubicles for public use.
830. Current levels of toilet provision vary across local authorities. Current British Toilet Association recommendations provide suggested ratios for the number of toilets required for a given population. However these figures have not been applied in this estimate; an assessment of need would be determined at a local level, based on factors such as localised footfall, alternative provision and population demographic.
831. Based on figures provided by local authorities to the Welsh Government during 2014, there are approximately 950 public toilet facilities across Wales. This includes directly provided local authority facilities, community council facilities and those provided through the grant scheme. It is assumed that there is an average of four cubicles per toilet facility. As the level of unmet need that would be identified by local authority assessments of needs is unknown, an illustrative range of options have been calculated. These options consider the costs of increasing the levels of toilet provision across Wales by applying varying rates of increasing provision. It is anticipated that a conservative assessment of need could identify the need to increase provision by 50%. A higher estimate could identify the need to double toilet provision across Wales. The cost of a 75% increase has also been provided as a further illustrative example.
832. The following tables illustrate the estimated costs of increasing provision by 50%, 75% and 100%. These costs are based on the following assumptions:-
- There are approximately 950 local authority public toilet facilities across Wales.
 - Each local authority would meet identified additional need on the basis of half of the extra provision being met through directly provided toilet facilities, and the other half being met through allocation of grants;

- Creation of an additional directly provided toilet facility would have a capital cost of £107,500;
- The building of additional directly provided toilet facilities would be spread evenly over three years, from 2018/19 to 2020/21;
- Any additional directly provided toilet facility would have annual ongoing maintenance costs of £10,500;
- Any additional toilet facility secured through the allocation of grants would have ongoing annual costs of £500; and
- There is an annual usage fee cost to the public of £10,000 per unit which will contribute towards the maintenance of additional directly provided facilities.

Table 7.47

Option	Increase in provision	Additional units required	Total capital cost of direct provision £	Annual ongoing cost of direct provision £	Annual cost of grant allocation (in addition to current £200,000 funding) £	Total annual cost £
4a	50%	475	25,531,300	2,493,800	118,800	2,612,600
4b	75%	712.5	38,296,900	3,740,600	178,100	3,918,700
4c	100%	950	51,062,500	4,987,500	237,500	5,225,000

Table 7.48: Summary of costs associated with Option 4a

Option 4a – 50% increase in provision

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £	2021/22 £
Welsh Government costs						
Staff time	8,400		0	0	0	1,400
Public Facilities Grant Scheme	200,000	200,000	200,000	200,000	200,000	200,000
Local authorities						
Strategy development		378,400	0	0	0	331,100

and consultation						
Grant management staff time	24,800	24,800	43,400	43,400	43,400	43,400
Capital investment		0	8,510,400	8,510,400	8,510,400	0
Annual maintenance		0	831,300	1,662,500	2,493,800	2,493,800
Additional Grant scheme annual cost		0	118,800	118,800	118,800	118,800
Cost to the public						
Usage fees	0	0	791,700	1,588,300	2,375,000	2,375,000
Total Cost	233,200	603,200	10,495,600	12,123,400	13,741,400	5,563,500
Additional Costs to Option 1	8,400	378,400	10,270,800	11,898,600	13,516,600	5,338,700

Table 7.49: Summary of costs associated with Option 4b

Option 4b – 75% increase in provision

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £	2021/22 £
Welsh Government costs						
Staff time	10,300		0	0	0	2,400
Public Facilities Grant Scheme	200,000	200,000	200,000	200,000	200,000	200,000
Local authorities						
Strategy development and consultation		378,400	0	0	0	331,100
Grant management staff time	24,800	24,800	49,600	49,600	49,600	49,600
Capital investment		0	12,765,600	12,765,600	12,765,600	0

Annual Maintenance		0	1,246,900	2,493,700	3,740,600	3,740,600
Grant scheme annual cost		0	178,100	178,100	178,100	178,100
Cost to the public						
Usage fees	0	0	1,187,500	2,375,000	3,562,500	3,562,500
Total Cost	233,200	603,200	15,627,700	18,062,000	20,496,400	8,063,300
Additional Costs to Option 1	8,400	378,400	15,402,900	17,837,200	20,271,600	7,838,500

Table 7.50: Summary of costs associated with Option 4c

Option 4c – 100% increase in provision

	2016/17 £	2017/18 £	2018/19 £	2019/20 £	2020/21 £	2021/22 £
Welsh Government costs						
Staff time	8,400		0	0	0	2,400
Public Facilities Grant Scheme	200,000	200,000	200,000	200,000	200,000	200,000
Local authorities						
Strategy development and consultation		378,400	0	0	0	331,100
Grant management staff time	24,800	24,800	62,000	62,000	62,000	62,000
Capital investment		0	17,020,800	17,020,800	17,020,800	0
Annual Maintenance		0	1,662,500	3,325,000	4,987,500	4,987,500
Grant scheme annual cost		0	237,500	237,500	237,500	237,500
Cost to the public						
Usage fees	0	0	1,583,300	3,166,700	4,750,000	4,750,000

Total Cost	233,200	603,200	20,766,100	24,012,000	27,257,800	10,570,500
Additional Costs	8,400	378,400	20,541,300	23,787,200	27,033,000	10,344,700

833. The local authority and Welsh Government staff time costs incurred in 2020/21 would be repeated every four to five years, in line with the review mechanism.

834. There would be significant costs associated with the building of new directly provided toilet facilities. It is anticipated that this cost would reduce with each iterative cycle of local authority strategies, as the gap between identified need and current provision should narrow as a result of the implementation of previous strategies.

Benefits

835. The benefits for this option are the same as those identified under Option 3. Again, it is not possible to quantify the extent to which these benefits would be achieved. However, it can be assumed that this option would achieve the benefits to a greater extent, as the level of access to adequate toilet provision would be assessed and local authorities would be legally required to ensure that any identified shortfall was addressed.

Summary and preferred option

836. Option 1 does not meet the policy objective. It continues existing practice and would not encourage the improvement of local toilet provision. There is an added risk that access to public toilet facilities would decline under this option.

837. Option 2 may encourage local authorities to increase their spending on the provision of public toilets. However, re-hypothecation of the funding could necessitate cuts in other areas, and would not support the Welsh Government's general policy of affording flexibility to individual local authorities.

838. Option 3 is the preferred option. This approach places a duty on local authorities to produce a local toilets strategy, for which they are accountable. The strategy must take into account the needs of the local population. Local authorities would then be able to optimally implement the strategy, in line with any budgetary pressures. Local authorities should develop a better understanding of their community's needs through this approach, and seek effective means of meeting that need.

839. Whilst Option 4 would meet the policy objective, it would entail potentially prohibitive costs for local authorities at a time when budgets are already constrained. There is a lack of consensus on the levels of toilet

provision required to be considered adequate. Dependent on the level of need identified during the development of the strategy, the duty within Option 4 could become overly onerous on local authorities.

8. Competition Assessment and Specific Impacts

Competition Assessment

840. Due to the varied issues covered by the Public Health (Wales) Bill, the extent to which provisions impact on competition vary. Separate competition filter tests have therefore been completed and are presented below.

Tobacco and Nicotine Products

i) Restrictions on the use of tobacco and e-cigarettes in enclosed and substantially enclosed public and work places

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	Yes
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

ii) Register of retailers of tobacco and nicotine products

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes*
Q2: In the market(s) affected by the new regulation,	Yes*

The competition filter test	
Question	Answer yes or no
does any firm have more than 20% market share?	
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	Yes*
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

*As there are no data available on the market share of retailers for tobacco and/or nicotine products, the market share of grocery sales has been used

Handing over tobacco etc to persons under 18

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes*
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	Yes*
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	Yes*
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	Yes

The competition filter test	
Question	Answer yes or no
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

*As there are no data available on the market share of retailers for tobacco and/or nicotine products, the market share of grocery sales has been used

Special procedures

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

Intimate piercing

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation,	No

The competition filter test	
Question	Answer yes or no
do the largest three firms together have at least 50% market share?	
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

Pharmaceutical services

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	Yes
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	Yes (but no more than is currently the

The competition filter test	
Question	Answer yes or no
	case)

Provision of toilets

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

Specific Impacts

841. A series of impact assessments on the policy areas contained within the Public Health (Wales) Bill ('the Bill') have been completed as part of the Regulatory Impact Assessment. The impacts varied in a number of policy areas but were largely positive. Examples of the main impacts are summarised in the following paragraphs.

Equality Impact Assessment

842. The Welsh Government is bound by the Equality Act 2010, and the Wales-Specific Equalities Duties Regulations, the Human Rights Act 1998 and the European Convention on Human Rights (ECHR). Assessments on the different components of the Bill found largely positive impacts for

vulnerable and protected groups. Whilst the proposals are intended to benefit the health and well-being of the population of Wales as a whole, the process also identified specific impacts for protected groups. To avoid duplication the specific impacts on children and young people are summarised separately, at the United Nations Convention on the Rights of the Child (UNCRC) section.

843. The changes in relation to **pharmaceutical services** are relatively technical in nature, but significant in terms of equality. Community pharmacies are easily accessible and provide a convenient, less formal environment for those who cannot or do not wish to visit other kinds of health services. The changes to the way in which decisions about local pharmaceutical services are made, towards a system which is more alert and responsive to the pharmaceutical needs of local communities, will improve the planning and delivery of public health services and have a range of benefits. These will include better access to emergency hormonal contraception, increased access to seasonal flu vaccinations for those at increased risk, improved understanding of the pharmaceutical needs of minority groups, and timely access to the right services for pregnant or new mothers, older people and those with physical disabilities. Continuing to develop the public health role of community pharmacies could also widen access to services for people who are less likely to be registered with a local GP, for example travellers and people seeking asylum.
844. Similarly, the changes to the planning of **provision of toilets** will have positive impacts for a number of specific groups. Some of these can be disproportionately affected by poor provision. Poor provision is known to have particular negative impacts on older people, including effects on their independence, community participation and social isolation. Improving provision will also be beneficial for other groups, such as women, young families, those with certain medical conditions and homeless people. Each local authority's assessment of the needs of its community will also help ensure provision responds appropriately to the needs of their communities, including those of people with disabilities.
845. The creation of the **special procedures** licensing scheme will have a generally positive impact for all those who elect to have one of the defined special procedures, including people within protected or vulnerable groups. The requirements will help to drive up standards in a consistent way across Wales, and ensure individuals are better informed about the health risks associated with particular procedures, and are able to identify providers who they know have achieved the requirements for licensing. It is intended that regulations will require pre-and post-consultation consultations with customers to be conducted, which should lead to better understanding about how to look after wounds and avoid infections. This will be beneficial to all but will have particular benefits for certain groups such as people with learning disabilities.

Human rights

846. A number of the policy areas contained in the Bill are relevant to human rights. For example, a number of the provisions involve placing restrictions on certain activities or behaviours, or on the use of certain products in defined circumstances.

847. As such it is conceivable that an individual may seek to challenge aspects of the proposals on the basis that there is a breach of Article 1 of the First Protocol (“A1P1”) to the ECHR, for example in provisions relating to the **register of retailers of tobacco products and nicotine products; restrictions on the use of tobacco and e-cigarettes in enclosed public places; pharmaceutical services; special procedures** and **intimate piercing** cause a loss of earnings to businesses or practitioners. A1P1 provides that:-

“Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.”

848. The ECHR does recognise that a public authority can justify a breach of this right if the “law says that it can interfere with, deprive or restrict the use of a person’s possessions.” The European Court of Human Rights has found that a Member State may enact and enforce laws as it deems necessary to control the use of property and that Member States have a wide margin of discretion particularly in relation to matters controlling public health and control.

849. Similarly, it is conceivable that an individual may seek to challenge aspects of the Bill on the basis of interference with Article 8 ECHR (the concept of “private and family life”). However, such interference is permissible if pursuing a legitimate public policy aim, including the “protection of health or morals.” In addition, whilst provisions such as those dealing with **handing over tobacco to persons under 18** and **intimate piercing** arguably discriminate on the basis of age, and to that extent engage Article 14 ECHR, the proposals have an objective and reasonable justification for doing so, given the alignment of provisions with other relevant restrictions for purchasing tobacco, with the default ages of consent in sexual and medical matters, and the aim of protecting children and young people from potential harm.

850. A number of the proposals actively progress human rights principles. For example, the proposals relating to **provision of toilets** may reduce the possibility of a person being subject to degrading treatment (Article 3 ECHR).

United Nations Convention on the Rights of the Child (UNCRC)

851. The Rights of Children and Young Persons (Wales) Measure 2011 places a duty on all the Welsh Ministers to have due regard to the substantive rights and obligations within UNCRC and its optional protocols when exercising any of their Ministerial functions. This means that they need to consider all the issues which are relevant to the decision they are making and do everything possible to ensure it furthers children's rights.
852. Through its combination of provisions the Bill supports several of the articles of the Convention, including:-
- **Article 3** – All organisations concerned with children should work towards what is best for each child;
 - **Article 6** – All children have the right of life. Governments should ensure that children survive and develop healthily;
 - **Article 12** – Children have the right to say what they think should happen when adults are making decisions that affect them, and have their opinion taken into account;
 - **Article 23** – Children who have any kind of disability should have special care and support so that they can lead full and independent lives;
 - **Article 24** – Children should have the right to good quality healthcare;
 - **Article 31** – All children have the right to relax and play, and join in a range of activities; and
 - **Article 36** – Children should be protected from any activities that could harm their development.
853. The importance of protecting the health of children, and preventing future health harms, is a common theme across many of the Bill's provisions. Articles 3 and 36 are particularly relevant to the provisions dealing with tobacco and nicotine products. Preventing access to tobacco products by children and young people is a crucial part of protecting them from the health harms caused by smoking, and is a key aim of both the **register of retailers of tobacco and nicotine products** and the provisions addressing **handing over tobacco to persons under 18**. Reducing the visibility and normalisation of smoking behaviours is another key aim of the Bill. The provisions placing **restrictions on the use of tobacco and e-cigarettes in enclosed public places** provide an example of this principle, with a particular focus on the impacts on young people. In relation to e-cigarettes specifically, the provisions also seek to address concerns of a possible gateway effect for children and young people towards smoking tobacco.
854. The proposals relating to **intimate piercing** also have the need to protect children and young people from avoidable harm at their core. These provisions are consistent with the Welsh Ministers' duty to act in children's best interests, and to protect them from harm and exploitation.

855. The provisions addressing **pharmaceutical services** will support Article 24 as these aim to ensure that the planning and delivery of these services appropriately meet the needs of local communities. This has the potential to have a range of positive benefits on the health and well-being of children and young people. Improving assessments of local pharmaceutical needs may lead to more pharmacies providing ‘Enhanced Services’, which may include medication for the treatment of minor ailments which are common in children, such as constipation, earache, diarrhoea, hay fever, head lice, mild eczema, nappy rash and teething. At the other end of the age range, young people approaching or within the 16-18 age bracket may benefit from improved provision of emergency hormonal contraception and smoking cessation services.
856. Article 24 also promotes a right of access to information that will assist children and young people in safeguarding their health. This is supported by the provisions addressing **special procedures**. The intended requirements for pre and post-procedure consultations and public access to a register of licensed businesses will help young people to become better informed when considering a defined procedure.
857. Improving the planning of **provision of toilets** will support Articles 23 and 31 of the Convention. This may benefit children and young families who often rely on the availability of toilet and baby changing facilities when away from home, and provide greater opportunities for young people, particularly those who have a disability or certain medical conditions, to participate in a wide range of activities outside the home.
858. The **provision of toilets** part of the Bill will also support Article 12 as there will be an expectation for local authorities to assess the needs of their communities for toilet facilities, including those of children and young people, and to engage with them appropriately in assessing local needs. Similarly, in relation to **pharmaceutical services**, the pharmaceutical needs assessments prepared by LHBs will be subject to public consultation. These provisions will therefore help support the rights of young people to express their views on matters which affect them.

Impact on the Welsh language

859. The Welsh Government’s Welsh Language Scheme requires that an assessment of the impacts of proposed primary legislation on the Welsh language be carried out and a set of impact assessments for each individual policy area in the Bill has been carried out. The Welsh Government has also published its “*laith Fyw; laith Byw*” strategy for the Welsh language for the period 2012-17, which aims to see an increase in the number of people who speak and use the language. In relation to health specifically, the “*More than just words*” strategy aims to strengthen Welsh language services among frontline health and social care services.
860. The issues dealt with in the Bill primarily relate to discrete public health issues, rather than the provision and accessibility of general health

services. As such there are limited direct impacts on the Welsh language, either positive or negative. However, there are a number of more indirect impacts, and the Bill's provisions indirectly support a number of the aims of "*laith Fyw; laith Byw*." Of these, the most relevant is the aim of strengthening the position of the Welsh language within the community, particularly in the context of developing community health assets.

861. The Bill has potential to positively impact on the Welsh language in varying ways. For example, the proposals relating to **provision of toilets** and **pharmaceutical services** involve assessing the needs of local communities for services and facilities, in a way which includes meaningful engagement with local citizens. In assessing local needs, the expectation will be that the engagement process will be inclusive of the spectrum of people in their communities, including Welsh speaking members. This will therefore have potential to increase the visibility of the Welsh language in community settings, and encourage community participation through the medium of Welsh in the process of planning and shaping local services and facilities.

862. A number of the Bill provisions will also require the provision of information to the public, in a variety of forms. In a number of policy areas contained in the Bill this could involve the production of bilingual signage as well as the production and dissemination of bilingual documentation and guidance, and opportunities for training through the medium of Welsh. The production of documentation will take place in accordance with the Welsh language schemes / Welsh language standards or policies of the relevant organisation.

Sustainable development

863. As part of the policy impact screening for the Bill, consideration has been given to the five headline indicators in the Welsh Government's Sustainable Development Scheme. These are as follows:-

- Sustainable Resource Use;
- Sustaining the Environment;
- A Sustainable Economy;
- A Sustainable Society; and
- The Well-being of Wales.

864. The provisions contained within the Bill make an important contribution to a broader agenda focused on preventing avoidable harms to health and well-being. Such a focus on preventative principles is an intrinsic component of sustainable development, as it aims to achieve sustainable benefits for both individuals and society over the long term.

865. Due to the nature of the issues included in the Bill, a number of the supporting indicators for the Sustainable Development Scheme are not directly affected either positively or negatively by the provisions. For example, there are no direct impacts in terms of the supporting indicators for Sustainable Resource Use or Sustaining the Environment, including no

impacts on biodiversity or Wales' ecological footprint, with the exception of potential reductions in travel time resulting from the changes to **pharmaceutical services**. However, the indicators for a Sustainable Economy, a Sustainable Society and the Well-being of Wales are more directly relevant.

A Sustainable Economy

866. The provisions relating to **pharmaceutical services** in particular support a sustainable economy through improving the planning and delivery of important community assets. Community pharmacies have been identified as one of the essential businesses that ensure economic prosperity within communities. Improving the planning and delivery of the services they provide will therefore contribute to sustaining local communities, providing shopping access, local employment and helping to build social capital.

867. Improving the planning of the **provision of toilets** will help people (for example older people and those with specific medical conditions) to become more confident in playing a full and active role within their communities, and therefore help promote local facilities and the wider local economy. It may also be the case that, as local authorities will need to consider a full range of available opportunities for providing access to local toilets, this could lead to increased foot-fall for certain premises/businesses within the surrounding area. This could, for example, lead to more people accessing other services at the same premises, or encourage repeat visits.

868. Conversely, the impact assessments for the **register of retailers of tobacco products and nicotine products** recognised the potential negative effect that refusal of entry to a register, or suspension from it, may have on some local businesses. There may also be similar potential effects in relation to **special procedures** if a licence or approval application is refused or revoked. In both cases this will be mitigated by enforcement officers being able to provide advice and guidance on the steps that can be taken to ensure compliance with the relevant requirements. Furthermore, in relation to special procedures, if provisions within the Bill lead to fewer people contracting infections or suffering avoidable adverse effects (either through improved practice or better understanding of any after-care required), then other local businesses may benefit from fewer working hours lost due to illness.

A Sustainable Society

869. The provisions relating to **pharmaceutical services** aim to improve the planning and delivery of these services, by better aligning them with the needs of local communities. Similarly, improved **provision of toilets** will help encourage people who may need regular access and who are affected by poor provision, to take more exercise and stay more physically active, thereby helping to address health inequalities. Furthermore, the

provisions relating to **tobacco** have the potential to contribute to a further reduction in smoking rates, which generally tend to be higher in more deprived areas and amongst people in lower socio-economic groups.

The Well-being of Wales

870. The provisions in the Bill as a whole have a primary purpose of supporting and improving the overall Well-being of Wales, by seeking to address a series of specific public health concerns. The provisions relating to **tobacco and nicotine products** collectively aim to reduce the visibility of smoking behaviours, and prevent young people from accessing these products. They therefore seek to protect future health and well-being from the risks of smoking-related disease and addiction to nicotine.

871. The contribution which improving the **provision of toilets** and access to **pharmaceutical services** will make to overall well-being in Wales is clearly set out in earlier paragraphs. In addition, the **special procedures** provisions and the prohibition of **intimate piercing** of persons aged under 16 years will also protect future health and well-being by helping to avoid preventable health harms.

Rural Proofing

872. The proposed changes within the Bill will impact on both urban and rural areas, and will apply equally to all parts of Wales. The rural proofing screening assessments found that a number of the policy areas will also have considerations which are particularly relevant to rural areas.

873. The existing challenges regarding the **provision of toilets** have particularly acute impacts in rural areas and communities. The general issue of toilet provision and access has commonly been raised in the context of rural areas, where poor provision is understood to have a disproportionately large impact due to the greater distances between available facilities. Improving planning and access will therefore have particular benefits for those living in rural areas, and will contribute to sustaining rural communities. The requirements to consult on the strategies will help ensure that appropriate engagement takes place which reflects the make-up of local populations, including the particular needs of rural communities. There may also be indirect benefits for rural businesses if improved provision encourages greater community participation and repeated visits to an area.

874. Improving the planning and delivery of **pharmaceutical services** will have positive impacts for rural areas. People in rural areas may rely more heavily on the services provided by community pharmacies if these are more accessible to them than other services. If gaps in services are identified in rural communities through pharmaceutical needs assessments, this should lead to steps being taken to ensure adequate provision.

875. The **register of retailers of tobacco and nicotine products** will apply equally across Wales. However, the impact screening identified the potential for greater impact in rural areas of any retailers being prevented from selling these products if they fail to comply with the requirements. There may be fewer customers to help sustain small, independent shops if they lose income from selling these products. Customers may also have to travel further to purchase these products if there are fewer alternative options available locally. This potential impact will be mitigated by the role of local authority enforcement officers in providing advice and support to retailers to help them avoid breaches of the requirements. There could be similar impacts associated with the **special procedures** provisions, which will be mitigated in the same way.

876. It is anticipated that there will be no differences in costs for registration solely by virtue of being in rural areas. However, there may be potential for some rural areas to be more affected by the need to pay fees, for example if an area has a higher proportion of small businesses or sole traders. This potential impact is mitigated by the setting of fees at a level which is not considered prohibitive for sole practitioners or small retailers.

877. In general, the enforcement mechanisms for the changes provided for in the Bill will make use of existing local systems. This will ensure that local knowledge and expertise held by enforcement and inspection officers is harnessed, including experience of operating within a rural context.

Health and Well-being

878. Improving and protecting the health and well-being of the Welsh population is the overall purpose of the Bill. It seeks to put in place a series of practical and preventative legal measures, each designed to help address a specific public health challenge. Taken together, the proposals aim to have a cumulative, positive impact on overall health and well-being. The provisions also make a positive contribution in relation to health inequality, as the issues addressed by the Bill can disproportionately affect the most disadvantaged individuals, families and communities.

879. The Bill combines a number of approaches for influencing the social and community influences on health. The provisions dealing with **tobacco and nicotine products** continue the strong tradition of legislating to address important lifestyle issues, and seek to further strengthen the extensive legal framework in these areas.

880. In a similar way, the provisions relating to **special procedures** and **intimate piercing** seek to avoid and minimise the risk of potential harms to health. In relation to special procedures in particular, ensuring practitioners and their premises meet and maintain specified standards will have a positive effect on the conditions affecting the health of customers and employees.

881. The provisions dealing with **pharmaceutical services** and the **provision of toilets** focus on particular local services and facilities which have an important public health role. All community pharmacies are contracted to help promote healthy lifestyles including the provision of healthy eating advice. Where pharmacies are accredited to provide enhanced services (such as smoking cessation services), this also supports healthier lifestyles. The local toilet strategies provided for by the Bill aim to reduce social isolation, particularly amongst vulnerable groups. Ensuring adequate provision therefore aims to improve community infrastructure and amenities in a way which supports good health and well-being.

Impact on Privacy

882. The privacy impact screenings indicated that a number of areas of the Bill will involve the handling and processing of personal information. Where this is the case the data controller will need to ensure its processing complies with the Data Protection Act 1998. The most directly relevant areas of the Bill are the proposed schemes for **retailers of tobacco and nicotine products**, and **special procedures**. These will involve the handling of personal information about retailers, practitioners and their premises. Data on the register of retailers of tobacco and nicotine products will be maintained centrally, with access being available to local authorities for enforcement purposes. More limited information (for example a retailer's name and business address) will be available to the public. In the case of special procedures, data on licence holders will be held by local authorities and will be available to the public. Practitioners will also be expected to maintain appropriate customer records.

883. In submitting this type of personal information, individuals will be doing so due to their role within the business. The relevant data controllers and data processors for the registers will need to comply with appropriate data protection principles and legislation. Providing appropriate fair processing will be key to this, so individuals and/or the businesses they represent, are aware of how the personal data will be used – especially where the provision of personal data is not optional. The same principles will apply to the personal information held by special procedures practitioners on their customers.

884. The changes to the planning of the **provision of toilets** include requirements to undertake local engagement and consultation. Some handling of personal information is likely to be involved in the administration of such exercises. The relevant data controllers will be responsible for ensuring that any personal data is processed in accordance with the Data Protection Act 1998. In the case of local authorities, for example, they will have established procedures in place for conducting consultations, including relating to the handling of any personal information. Furthermore, it will be the choice of each individual as to whether they wish to respond to a consultation exercise or to have their response anonymised.

885. In respect of **pharmaceutical services**, each LHB already has its own pharmaceutical list and so will already have data protection protocols in place in order to comply with their statutory duties. Data collected through the new pharmaceutical needs assessments are unlikely to contain any sensitive personal information, or will have any relevant details anonymised.

886. Although expected only in minimal circumstances, there is potential for some individuals to be subject to prosecutions resulting from the legal changes made by the Bill. In such eventualities any personal information will be processed by the relevant authorities in accordance with established procedures and legislation. This will be of particular importance in some circumstances, for example where sensitive personal information may be held as part of any prosecution in relation to the intimate piercing of a person aged under 16 years. In such cases, the relevant authorities will be deemed the data controller and the onus will be on them to ensure compliance with the Data Protection Act 1998.

Impact on the voluntary sector

887. A range of voluntary sector organisations engage in the public health agenda, often with particular interests in certain issues. Whilst the provisions in the Bill do not directly affect voluntary sector organisations, organisations representing particular sectors or groups within the population will have a keen interest in the implementation of the Bill.

888. Voluntary sector organisations are also likely to participate in engagement and consultation processes involved in implementing different areas of the Bill. The sector will also be likely to input into monitoring of the legislation and contributing to post-implementation reviews.

Impact on the judicial system

889. A number of new offences will be created under different parts of the Bill, for example relating to the provisions on **tobacco and nicotine products, special procedures** and **intimate piercing**. There will also be appeal mechanisms in place in relation to the various provisions included in the Bill. Applying previous experience from similar areas, it is envisaged that the legislation will attract generally high levels of compliance, with an anticipated minimal number of court cases. The overall impact on the courts and judicial system in Wales is therefore anticipated to be low. Where potential impacts have been identified, these have been referenced at the appropriate points within the Regulatory Impact Assessment.

9. Post implementation review

890. The Public Health (Wales) Bill is multi-faceted and designed to provide a legislative basis for action in discrete subjects, in order to prevent avoidable health harms. The review, monitoring and evaluation arrangements must reflect this overall context.

891. A programme of monitoring and evaluation activity will be developed to correspond with key activities and dates. Various research and evaluation methods will be considered, depending on the nature of the data required. The monitoring and evaluation arrangements will comprise a coherent set of components, some of which will be common to two or more elements of the Bill while others, because of the specific nature of certain parts, will be bespoke. For some elements it will be necessary for a reasonable period of time to have elapsed before the outcome of the provisions can be assessed, and the ability to demonstrate change may be constrained by the use of modelled or estimated baseline measures in some areas.

892. The proposed monitoring and evaluation arrangements can be grouped into three broad categories. Taken together, these will encompass a blend of monitoring routine health data and statistics, administrative data and independent review. In addition, consideration will be given to commissioning specific research into the implementation of certain parts of the Bill as and when a need for such research is identified.

Health data and statistics

893. Activity to monitor the implementation of the Bill will wherever possible be aligned to other relevant work. Data provided in surveys routinely undertaken by the Welsh Government (and partners) will therefore provide an important source of data to aid in the monitoring of the legislation. At the same time, consideration may need to be given to new data collections as necessary.

894. Whilst routine health data will provide an essential information source, it must be noted that a number of the issues addressed in the Bill are also being addressed by other forms of action. It will therefore be difficult to fully attribute certain population level trends (as may be identified through this type of data) to the effects of the Bill. For example, the Bill's provisions relating to tobacco and nicotine products seek to make a general contribution towards reducing smoking rates amongst children and young people, by further restricting access and visibility of certain products. However, it would not be possible for such a trend to be attributed solely to the Bill, particularly given other relevant developments in legislation such as proposals to introduce standardised packaging for tobacco, and to introduce age restrictions on the sale of nicotine products, alongside other societal influences.

Administrative data

895. Similarly, best use will be made of the most relevant administrative information already collected. Importantly, this will include a range of data collected by local authorities in respect of the topics covered in the Bill. This will include:

- data on inspections undertaken;
- enforcement information, including data on written warnings, fixed penalty notices and prosecutions; and
- data on complaints/enquiries received by trading standards and environmental health departments.

Independent review

896. The third component of the overall review arrangements will provide for a formal process of periodic independent review. It is envisaged that this will involve the formal input of key stakeholders through established expert groups. Due to the varying issues addressed by the Bill, it is anticipated that this role would most appropriately be fulfilled by different groups. Groups who could potentially undertake such a function across the Bill's different components could include the Welsh Health Protection Committee, the Welsh Pharmaceutical Committee and the Tobacco Control Delivery Board, although other Groups or Panels could be considered or established as appropriate.

897. Each expert group allocated with this type of responsibility would formally be tasked with undertaking a review of the Bill (or part of the Bill), potentially following a three-year cycle. Each group would then report back to the Welsh Government in the first instance. This strand of review would not be mutually exclusive from the others, as routine data and administrative data would help inform the judgements of such expert groups.

898. A practical illustration of how the legislation will be monitored can be provided by reference to the provisions restricting the use of tobacco and e-cigarettes in public and work places. Compliance with the restrictions will be monitored by local authority enforcement teams. It is anticipated this will require completion of a quarterly return to the Welsh Government by each local authority, using a form no more than one side of A4 in size. Local authorities will be asked to provide details on: the number of FPNs issued in relation to the smoke- and e-cigarette-free offences, the number of FPNs paid and the number of court hearings and prosecutions.

899. Monitoring of the impact of the restrictions on the use of tobacco and e-cigarettes in public and work places will be through existing mechanisms to track rates of exposure to and use of tobacco and e-cigarettes among children and adults in Wales. Important sources for this work will include the Health Behaviours in School-aged Children Survey (HBSC) and the Welsh Health Survey⁴¹⁷.

⁴¹⁷ From 2016-17, the Welsh Health Survey will be amalgamated with the National Survey, the Arts in Wales Survey and the Welsh Outdoor Recreation Survey into a single survey.

Annex A – Explanatory Notes

PUBLIC HEALTH (WALES) BILL

EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes relate to the Public Health (Wales) Bill as laid before the National Assembly for Wales on 8 June 2015.
2. They have been prepared by the Welsh Government's Department for Health and Social Services in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by the National Assembly for Wales.
3. The Explanatory Notes should be read in conjunction with the Bill. They are not meant to be a comprehensive description of the Bill. Where an individual section of the Bill does not seem to require any explanation or comment, none is given.

POLICY BACKGROUND

4. The health and well-being of the population of Wales is continuing to improve. In general, people are living longer and enjoy better health than ever before. However, Wales still faces a number of specific and significant health challenges. These range from overarching demographic challenges such as an ageing population and continuing inequalities in health, to more discrete ones posed by lifestyle choices and contemporary developments within society.
5. Legislation has historically played an important role in improving and protecting health. Legislation in areas as varied as the ban on smoking in enclosed public places and wearing seat-belts has been seen to make significant contributions to health and well-being.
6. This Bill has been developed following consultation on a Public Health White Paper, which included a series of legislative proposals to address a number of public health issues in Wales. The focus of the Bill is on shaping social conditions that are conducive to good health, and where possible, avoiding health harms that can be averted.

GENERAL OVERVIEW OF THE BILL

7. The Bill includes provisions in a number of discrete policy areas, all of which pose challenges to health and well-being in Wales.
8. The Bill is comprised of 102 sections (within 7 Parts) and 4 Schedules.
 - Part 1 – Overview
 - Part 2 - Tobacco and Nicotine Products
 - Chapter 1: Restricts smoking and the use of nicotine inhaling devices in smoke-free premises and vehicles;
 - Chapter 2: Establishes a national register of retailers of tobacco and nicotine products;
 - Chapter 3: Provides the Welsh Ministers with a regulation making power to add to the offences which contribute to a Restricted Premises Order (RPO) in Wales;;
 - Chapter 4: Prohibits the handing over of tobacco or nicotine products (when delivered or collected in connection with their sale) to a person under the age of 18;
 - Part 3 provides for the creation of a mandatory licensing scheme for businesses/practitioners offering specified ‘Special Procedures’, namely acupuncture, body piercing, electrolysis and tattooing;
 - Part 4 introduces a prohibition on the intimate piercing of persons under the age of 16 years;
 - Part 5 changes the arrangements for determining applications for entry onto a Local Health Board’s pharmaceutical list, to a system based on the assessed needs of local communities;
 - Part 6 requires local authorities to prepare a local toilets strategy in order to plan how they will meet the needs of their communities for access to public toilets; and
 - Part 7 contains a number of general provisions, including in relation to regulations, interpretation, powers to make consequential and transitional provisions, and coming into force arrangements.

COMMENTARY ON SECTIONS

PART 1 OVERVIEW

9. Section 1 provides an overview of the main provisions of the Bill. It summarises the subjects covered in each subsequent Part.

PART 2

TOBACCO AND NICOTINE PRODUCTS

CHAPTER 1: SMOKING AND USE OF NICOTINE INHALING DEVICES

10. This Chapter contains provisions that make enclosed and substantially enclosed public premises and shared workplaces smoke-free. These are referred to as ‘smoke-free premises’. For the purpose of this Chapter, ‘smoke-free’ means that smoking and the use of nicotine inhaling devices (commonly known as ‘electronic cigarettes’) is not permitted, unless the premises are exempted by regulations made under section 10 of the Bill.
11. Regulations can also provide for additional premises to be smoke-free in certain circumstances. These additional smoke-free premises need not be enclosed or substantially enclosed. Vehicles may also be smoke-free; such vehicles are referred to as ‘smoke-free vehicles’ in this Chapter.
12. This Chapter restates Part 1 of Chapter 1 of the Health Act 2006 on “Smoke-Free Premises, Places and Vehicles” in relation to Wales. This restatement makes no substantive changes in relation to smoking in smoke-free premises. The purpose of the restatement is to enable the Welsh Ministers to bring the use of nicotine inhaling devices into the smoke-free regime in one piece of legislation for ease of access and to assist with enforcement.
13. Nicotine inhaling devices are a relatively new phenomenon. The Bill treats smoking and the use of nicotine inhaling devices in the same way in order to prevent the renormalisation of smoking behaviours, particularly in young people, and to aid the enforcement of the current smoking ban. Restricting the use of nicotine inhaling devices in public places will work alongside other legislation, including the Nicotine Inhaling Products (Age of Sale) Regulations 2015, which, subject to specific exceptions, make it an offence in England and Wales to sell nicotine inhaling devices to, or buy them for, persons under the age of 18.

Section 2: Smoking and nicotine inhaling devices

14. This section provides the definitions of “smoking” and a “nicotine inhaling device” for Chapter 1 of Part 2 of the Bill. The definition of “smoking” covers the smoking of cigarettes, pipes, cigars, herbal cigarettes and waterpipes (often known as hookah or shisha pipes) etc. The definition of a “nicotine inhaling device” includes all types of devices that can be used for the inhalation of nicotine via a mouthpiece, but does not include devices that may be used for the inhalation of lit tobacco.
15. The Welsh Ministers may make regulations to exempt devices that would otherwise be covered by the definition of a nicotine inhaling device.

Section 3: Extension to other devices

16. This section gives power to the Welsh Ministers to make regulations that provide for further devices enabling the inhalation of a substance to be covered by this Chapter where they are satisfied that this is likely to contribute towards the promotion of the health of the people of Wales. Such additional devices may or may not enable nicotine to be inhaled. The Welsh Ministers could, for example, use these powers should it become apparent that other devices are undermining enforcement of the smoke-free requirements and/or are contributing to the renormalisation of smoking behaviours, and are therefore having a negative impact on the health of the people of Wales.

Section 4: Offence of smoking or using a nicotine inhaling device in smoke-free premises or vehicle

17. This section makes it a criminal offence to smoke or use a nicotine inhaling device in smoke-free premises or in a smoke-free vehicle. The offence may only be tried in the magistrates' court and is punishable on conviction by a fine not exceeding level 1 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982. A fixed penalty notice may be issued by an authorised officer instead of prosecution. Section 19 contains more details on fixed penalty notices.

Section 5: Offence of failing to prevent smoking or use of a nicotine inhaling device in smoke-free premises

18. This section requires managers of smoke-free workplaces and public premises to take reasonable steps to prevent smoking or the use of nicotine inhaling devices in those places. The Welsh Ministers may make regulations to place corresponding duties in respect of smoke-free vehicles and any additional smoke-free premises designated by the Welsh Ministers under section 8. Any person who fails to comply with these duties is committing an offence. The offence may only be tried in the magistrates' court and is punishable on conviction by a fine not exceeding level 4 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

Section 6: Workplaces

19. This section details what is meant by "workplaces" in the context of this Chapter. A "workplace" is a place that is used as a place of work by more than one person (irrespective of whether such people work there at the same time) or is a place of work for one person but is somewhere that the public may have access to. Where only parts of the premises are used as a place of work, only those parts are smoke-free. In all cases, only those areas that are enclosed or substantially enclosed are smoke-free. All workplaces are smoke-free all of the time, except that a dwelling used as a workplace is smoke-free only when being used as such.

20. The Welsh Ministers may make regulations to define what is meant by ‘enclosed’ and ‘substantially enclosed’ for the purposes of workplaces and premises that are open to the public. The current definitions of ‘enclosed’ and ‘substantially enclosed’, for the purposes of smoke-free premises under the Health Act 2006, are set out at regulation 2 of the Smoke-free Premises etc. (Wales) Regulations 2007.

Section 7: Premises that are open to the public

21. This section details what is meant by “premises that are open to the public” in the context of this Chapter. It includes all premises that are open to the public (irrespective of whether this is by invitation or not, or whether there is a charge for entry or not). Where only parts of the premises are open to the public, only those parts are smoke-free. All such premises are smoke-free only when open to the public and only in those areas that are enclosed or substantially enclosed.

Section 8: Additional smoke-free premises

22. This section gives power to the Welsh Ministers to make regulations to designate additional smoke-free premises. These need not be enclosed or substantially enclosed (i.e. they may be open spaces such as playgrounds, school grounds, hospital grounds, etc.). The Welsh Ministers can only designate additional smoke-free premises where they are satisfied that designating those premises as smoke-free is likely to contribute towards the promotion of the health of the people of Wales. These powers differ to those under section 4 of the Health Act 2006, whereby the Welsh Ministers may designate an additional smoke-free place in Wales only if, in their opinion, there is significant risk that, without designation, persons present in the place would be exposed to significant quantities of smoke.
23. The Welsh Ministers’ regulations may also provide for exemptions to the smoke-free status of any additional smoke-free premises. The regulations may, for example, allow the person in charge of the additional smoke-free premises to designate areas in which smoking or use of a nicotine inhaling device is to be permitted. The designation would have to be in accordance with any conditions set out in the regulations.
24. Dwellings, unless they are a workplace or open to the public (within the meaning of this Chapter), may not be designated as smoke-free premises under this section.

Section 9: Vehicles

25. This section gives power to the Welsh Ministers to make regulations providing for vehicles to be smoke-free. These regulations may make provision about the types of vehicles that are to be smoke-free, the circumstances in which they are smoke-free, for the vehicle to be smoke-free when located in specific areas and for exemptions to any of these requirements. For example, the regulations may designate as smoke-free

vehicles used for public transport (e.g. buses), vehicles that are workplaces (e.g. taxis), and private vehicles carrying persons under the age of 18.

26. The Welsh Ministers can only designate a vehicle as being smoke-free where they are satisfied that designating that vehicle is likely to contribute towards the promotion of the health of the people of Wales.

Section 10: Exempt premises

27. This section gives power to the Welsh Ministers to make regulations to exempt premises or places in Wales from the requirement to be smoke-free. These regulations may exempt defined premises or specific areas within defined premises. Exemptions from the smoke-free requirements may be in respect of both smoking and use of nicotine inhaling devices, smoking only, or the use of nicotine inhaling devices only.

28. An equivalent power to exempt premises, for the purposes of smoke-free premises under the Health Act 2006, is included at section 3 of that Act. Regulation 3 of the Smoke-free Premises etc. (Wales) Regulations 2007, made in exercise of the power at section 3 of the Health Act 2006, sets out the premises within which managers may designate smoking rooms (i.e. may designate rooms as being exempt from the smoke-free requirements of the Health Act 2006). Exemptions currently apply to specific rooms within care homes, adult hospices, mental health units, research or testing facilities, hotels, guesthouses, inns, hostels and members' clubs.

Section 11: Signs

29. This section requires a person who occupies or manages smoke-free public premises or workplace to display smoke-free signs. Such signs must meet the specification for smoke-free signs as set out in regulations by Welsh Ministers. Requirements for smoke-free signs may include specifications regarding the dimensions of the sign, the minimum text size and font, any graphic or symbol that must be included and any mandatory warning message. The Welsh Ministers may make regulations that place a corresponding duty on those who occupy or manage additional smoke-free premises (section 8) and smoke-free vehicles (section 9).

30. Failure to comply with these requirements is an offence. The offence may only be tried in the magistrates' court and is punishable on conviction by a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982. A fixed penalty notice may be issued by an authorised officer instead of prosecution. Section 19 contains more details on fixed penalty notices.

Section 12: Enforcement authorities

31. This section places a duty on enforcement authorities to enforce the smoke-free provisions in this Chapter. The relevant enforcement authorities will be designated in regulations made by the Welsh Ministers. County and

county borough councils in Wales are currently designated to enforce the smoke-free provisions of the Health Act 2006.

32. Enforcement authorities may arrange to transfer a particular case to another enforcement authority, for example, where those enforcement authorities are investigating the same person for offences relating to smoke-free premises and vehicles.
33. In this Chapter, an authorised officer is any person authorised by the enforcement authority to carry out their enforcement functions. An authorised officer may or may not be an officer of the enforcement authority.

Section 13: Powers of entry

34. This section confers powers on an authorised officer to enter any premises in Wales, excluding premises used wholly or mainly as a dwelling at any reasonable time if they consider it necessary in relation to an offence in this Chapter. The section applies to a vehicle as if it were premises.
35. Authorised officers must not use force to enter premises or vehicles when exercising their power under this section. If they are asked to do so, authorised officers must present evidence of their authority before entering any premises or vehicles. Section 67(9) of the Police and Criminal Evidence Act 1984 provides that, while acting in the course of their enforcement functions, authorised officers of the enforcement authority must have regard to the relevant code of practice made under that Act. Therefore, authorised officers must have regard to PACE Code of Practice B in the exercise of their enforcement functions.

Section 14: Warrant to enter dwelling

36. This section provides that a justice of the peace may issue a warrant to enable an authorised officer to enter a premises used wholly or mainly as a dwelling. A warrant may be issued only where the justice of the peace is satisfied that there are reasonable grounds to believe that an offence has been committed at the premises and that it is necessary to enter into the premises for the purpose of establishing whether such an offence has been committed. Entry may be obtained by force if need be. This section applies to a vehicle as if it were premises.

Section 15: Warrant to enter other premises

37. This section provides that a justice of the peace may issue a warrant to enable an authorised officer to enter any premises, including vehicles, in Wales. This excludes premises used wholly or mainly as dwellings which are dealt with in section 14. The section sets out the circumstances in which a warrant may be issued. Entry may be obtained by force if need be.

Section 17: Powers of inspection, etc.

38. This section confers power on authorised officers to carry out inspection of premises and vehicles. Officers may request items, inspect them, take samples from them and/or take the item(s) and/or samples from the premises. For example, officers may wish to review CCTV footage of the premises, test inhaling devices for nicotine content or retain smoking debris for evidence purposes. They may also request information and help from any person but that person is not required to answer any questions or produce any document which they would be entitled to refuse in the course of court proceedings in England and Wales. The authorised officer may analyse any samples taken. The authorised officer must leave a statement detailing any items that have been taken. Officers may also take copies of any documents.

Section 18: Obstruction etc. of officers

39. This section provides that any person who intentionally obstructs an authorised officer from carrying out their function under this Chapter is committing an offence. Any person who fails to help the officer carry out their function without reasonable cause is committing an offence but that person is not required to answer any questions or produce any document which they would be entitled to refuse in the course of court proceedings in England and Wales. The offence may only be tried in the magistrates' court and is punishable on conviction by a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out at section 37 of the Criminal Justice Act 1982.

Section 19: Fixed penalty notices

40. This section allows authorised officers to issue fixed penalty notices (FPNs) to persons believed to have committed certain offences under this Chapter. A fixed penalty can be issued for the following offences:
- smoking in smoke-free premises or vehicles;
 - using a nicotine inhaling device in smoke-free premises or vehicles;
 - failing to comply with signage requirements.
41. FPNs may be issued to a partnership or an unincorporated association where the authorised officer believes it appropriate. Payment of the FPN discharges the person believed to have committed an offence from being convicted for the offence in court. The section also introduces Schedule 1 on fixed penalties (for commentary on this, see Schedule 1 below).

CHAPTER 2: RETAILERS OF TOBACCO AND NICOTINE PRODUCTS

42. This Chapter contains provisions which will create a national register of retailers of tobacco and nicotine products. All retailers who sell either tobacco products, nicotine products or both from a premises to the general public in Wales will be required to register in order to sell tobacco and/or nicotine products.

Section 22: Duty to maintain register of retailers of tobacco and nicotine products

43. This section establishes a register of retailers of tobacco and nicotine products in Wales. The register will contain details of persons carrying on a business selling tobacco or nicotine products in Wales. The section places a duty on the registration authority to maintain the register. Regulations made by the Welsh Ministers will specify a body, for example a local authority, to act as the registration authority.
44. The register may include other appropriate information.

Sections 23 and 24: Application for entry in the register and grant of application

45. Section 23 allows retailers to apply to be on the Register of Retailers of Tobacco and Nicotine Products. The registration authority can only refuse an application if the applicant is subject to a Restricted Sales Order under section 12B of the Children and Young Person's Act 1933. Premises cannot be added to the register if they are currently subject to a Restricted Premises Order under section 12A of the Children and Young Persons Act 1933. If the application contains multiple premises then only the premises not subject to a Restricted Premises Order will be added to the register.
46. A Restricted Premises Order is an order made by a magistrates' court that prohibits retail premises from selling tobacco products for a period of up to 12 months. This prevents any sale of tobacco products, including cigarette papers, from within those premises until the Restricted Premises Order ceases to have effect. From 1 October 2015 the prohibition will also apply to the sale of nicotine products. A court can only issue a Restricted Premises Order if it is satisfied that a person convicted of a tobacco offence on the premises in question has also committed other tobacco offences on at least 2 previous occasions within a period of two years. A tobacco offence is defined in section 12D of the Children and Young Persons Act 1933 and includes selling tobacco to a person under the age of 18. From 1 October 2015 the definition of tobacco offence is amended to include an offence under section 92 of the Children and Families Act 2014 (prohibition of sale of nicotine products to persons under 18).
47. A Restricted Sales Order prohibits a named person who has been convicted of a tobacco offence from selling tobacco products for a period up to 12 months. As with a Restricted Premises Order, a magistrates' court can only make a Restricted Sales Order if it is satisfied that the named person has also committed other tobacco offences on at least 2 previous occasions within a period of two years.
48. The Welsh Ministers may, through regulations, require additional information to be provided when submitting an application for inclusion in the register, and may make provisions for a fee to be paid when submitting an application.

Section 25: Duty to give notice of certain changes

49. This section places a duty on retailers to inform the registration authority within 28 days of changes to an entry contained in the register, for example if they no longer sell tobacco products from the premises included on the register.

Section 26: Duty to revise the register

50. This section outlines the process the registration authority must follow when making changes to the register. It also sets out the circumstances when the registration authority must make changes to the register.
51. The Welsh Ministers may, by regulations, allow the registration authority to charge a fee for revising the register.

Section 27: Access to the register

52. Under this section the registration authority must publish a list of all those persons and premises on the Register of Retailers of Tobacco and Nicotine Products. Where the business is carried on from a vehicle, stall, tent or other moveable structure, the list must indicate the local authorities in which it operates.

Section 28: Moveable structures, etc.

53. This section provides a regulation making power to the Welsh Ministers to require additional information to be provided when submitting an application for inclusion in the register, in relation to premises which consist of a vehicle, stall, tent or moveable structure.

Section 29: Offences

54. This section creates offences in relation to the register. Subsections (6) and (7) set out the different levels of penalty for the offences. The fine for carrying on a tobacco or nicotine business without being registered is not limited by any levels on the standard scale, so its amount will be determined by the magistrates' court. The other offences are punishable by a fine not exceeding level 2 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982. A fixed penalty notice may be issued by an authorised officer in place of a fine. Section 38 contains more details on fixed penalty notices.

Section 30: Authorised officers

55. This section clarifies that any references to authorised officers in this Chapter are to an officer authorised by a local authority, whether or not they are an officer of the local authority.

Section 31: Powers of entry

56. This section outlines under what circumstances an authorised officer may enter premises in Wales for the purpose of enforcing provisions relating to the retail register.
57. Authorised officers must not use force to enter premises when exercising their power under this section. If they are asked to do so, authorised officers must present evidence of their authority before entering any premises.

Sections 32 and 33: Warrant to enter dwelling and Warrant to enter other premises

58. These sections set out the circumstances in which a justice of the peace may issue a warrant to enter domestic premises or business premises in Wales for the purpose of enforcing provisions relating to the retail register. The warrant remains in force for 28 days commencing on the date the justice of the peace signed the warrant.

Section 35: Powers of inspection, etc.

59. This section allows for authorised officers to carry out inspections on premises. Officers may request and inspect items, take samples from them and/or take the item(s) from the premises. They may also request information and help from any person that may help them carry out their function. The authorised officer may analyse any samples taken. The authorised officer must leave a statement detailing any items that have been taken. Officers may also take copies of any documents.

Section 36: Obstruction etc. of officers

60. This section states that any person who intentionally obstructs an authorised officer from carrying out their function under this Chapter is committing an offence. Any person who fails to help the officer carry out their function, fails to give information without reasonable cause, or gives a false or misleading statement is also committing an offence. The offence is punishable by a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

Section 37: Power to make test purchases

61. An authorised officer may make purchases and secure the provision of services if the officer considers it necessary for the purpose of enforcement in relation to this Chapter.

Section 38: Fixed penalty notices

62. This section provides details about when an authorised officer can issue a fixed penalty notice in respect of an offence associated with the retail register. A fixed penalty can be issued for the following offences:-

- A registered person carrying on a tobacco or nicotine business in premises other than those noted in the person's entry on the register;
- A registered person carrying on a tobacco business at premises consisting of a moveable structure, such as a stall or vehicle, in a local authority area other than the ones noted in the person's entry on the register; and
- A registered person who fails to comply with section 25 (duty to give notice of certain changes).

CHAPTER 3: PROHIBITION ON SALE OF TOBACCO AND NICOTINE PRODUCTS

Section 40: Restricted premises orders: tobacco or nicotine offence

63. This section amends section 12D of the Children and Young Persons Act 1933. That section sets out a number of offences that are a "tobacco or nicotine offence" for the purposes of sections 12A and 12B. Restricted premises orders and restricted sales orders may be made in respect of persons who have been convicted of tobacco or nicotine offences. The amendment provides the Welsh Ministers with a regulation making power to add new offences, conviction of which may be used to support an application to make a restricted premises order.

CHAPTER 4: HANDING OVER OF TOBACCO ETC TO PERSONS UNDER 18

Sections 41 and 42: Offence of handing over tobacco etc to persons under 18 and Arrangements in connection with handing over tobacco etc.

64. Section 41 makes it an offence to knowingly hand over tobacco, cigarette papers or nicotine products during the course of a delivery of goods, to a person who is under the age of 18, unless they are accompanied by someone who is aged 18 or older.

65. In order to avoid committing the offence, where tobacco, cigarette papers or nicotine products are included in a purchase of goods (whether on their own or as part of a larger purchase), the person delivering the goods might, for example, need to remove any tobacco, cigarette papers or nicotine products from the delivery if not satisfied the person receiving the goods is aged 18 or over.

66. The offence also covers any tobacco, cigarette papers or nicotine products which have been purchased remotely (for example by telephone or

via the internet) for collection from premises in Wales (often referred to as “click and collect”).

67. No offence is committed if the tobacco, cigarette papers or nicotine products are wrapped and sealed. For example they could be sealed in an envelope, or wrapped in brown paper and sealed with tape. The parcel must also have on it the name and address of the person to whom the parcel should be delivered.

Section 43: Enforcement

68. Section 5 of the Children and Young Persons (Protection from Tobacco) Act 1991 requires local authorities to consider, at least once a year, whether it is appropriate for them to carry out a programme of enforcement action relating to various tobacco related offences. A programme of enforcement involves bringing prosecutions, investigating complaints and taking measures to reduce offences.
69. Section 43 amends section 5 of the 1991 Act to make the offence of knowingly handing over tobacco, cigarette papers or nicotine products to a person under the age of 18, as detailed in section 41, one of the offences in respect of which a local authority in Wales must consider a programme of enforcement.

Section 44: Interpretation of this Chapter

70. Section 44 contains definitions relating to chapter 4. “Nicotine product” is defined by reference to regulations under section 92 of the Children and Families Act 2014. That section allows the Secretary of State to make regulations prohibiting the sale of nicotine products to persons under 18 in England and Wales. The offence under section 41 applies to nicotine products that, in accordance with those regulations, are prohibited for sale to those under 18.
71. Regulations under section 92 of the 2014 Act may make different provision in respect of certain nicotine products. For example, some nicotine products may be prohibited for sale to those under 16 only. Defining “nicotine product” by reference to regulations under section 92 means that the offence under section 41 is committed only if the nicotine product in question is prohibited for sale to the person under 18 in question to whom it is handed over.

PART 3 SPECIAL PROCEDURES

Section 46: What is a special procedure?

72. This section lists those procedures that are considered to be a special procedure for the purposes of this Part. These are acupuncture, body

piercing, electrolysis and tattooing. Each of the procedures is defined in section 77(1). The meaning of special procedure may be amended by regulations, as provided by section 76.

Section 47: Requirement for individual performing special procedure to be licensed

73. Section 47(2) provides that a person performing a special procedure in Wales on someone else in the course of a business must be licensed unless they are an exempted practitioner. The requirement also applies to those persons designated in respect of a special procedure under section 50. This licensing requirement applies only to individuals.
74. The requirement to be licensed does not however extend to a person who is treated via section 49 as being an exempted from the requirement to be licensed in respect of that special procedure.

Section 48: General provision about special procedure licences

75. This section provides that a special procedures licence is issued by a local authority. The special procedure licence authorises the performance, by the licence holder, of the special procedure (or those special procedures) specified in the licence.
76. A special procedure licence does not, however, authorise a person to carry out a special procedure at premises or in a vehicle either occupied by, or managed or controlled by, the licence holder unless the premises or a vehicle from which the special procedure will be performed has been approved (as required by section 59). It also requires that the approved premises or vehicle from which a special procedure will be performed by the licence holder is identified on the special procedure licence. This requirement will ensure that the licence holder's terms of practice are clear to both clients and enforcement officers.
77. The requirement on the licence holder to only practice special procedures from an approved premises or vehicle does not apply if the premises or vehicle has been specified in regulations made under section 58(6). These regulations will therefore enable certain premises or vehicles to be exempt from the approval requirements and the requirement for identification on the licence.
78. A special procedures licence authorises that a special procedure may be carried out for the period specified on the licence. This period must either be no more than 7 days (to take account of temporary exhibitions, entertainment or other events), or three years. Once the licence has expired, an application to the local authority must be made for a replacement licence.
79. The procedure for applying for a special procedure licence, including the process for varying, reviewing or revoking a licence is provided for in Schedule 3.

80. Section 48(8) sets out the meaning of three key terms (“licence period”; “licence holder” and “temporary licence”) which are referred to in the Part.

Section 49: Exempted individuals

81. This section provides the circumstances in which an individual is an exempt from the requirement to obtain a special procedure licence in order to perform the special procedure. Subsection (1) provides that an individual who is a member of a profession mentioned in paragraphs (a) to (ga) of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 is exempt, unless regulations specify that a licence is required in relation to a specific special procedure. These professions include doctors, dentists and nurses.
82. Subsection (3) provides the Welsh Ministers with a regulation making to enable individuals who are members of a profession (but not those specified in paragraphs (a) to (ga) of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002) or are workers of a description specified in regulations, to be exempt if they are registered with a qualifying register. A qualifying register is defined in subsection (4) as one maintained by the Health and Care Professions Council or a voluntary register accredited by the Professional Standards Authority for Health and Social Care.
83. These regulation making powers provide the Welsh Ministers with the discretion to exempt qualifying professions from the requirement to obtain a special procedure licence.

Section 50: Designation of individual for the purposes of section 47(3)

84. If the local authority is satisfied that the condition in subsection (2) is met, this section enables the local authority to give notice to an individual thereby designating them as a person requiring a special procedure licence if they intend to perform a specified special procedure.
85. The condition at subsection (2) is that the person is likely to perform the specified procedure on someone else in Wales, that the performance presents or could present significant risk of harm to human health, and in order to remove or reduce that risk it is appropriate to designate the person. The local authority’s ability to designate the person does not rely on the special procedure being performed in the course of a business; therefore a person performing a special procedure in any circumstances and for any purpose (such as from home and not for remuneration) can be designated.
86. The notice provided to the individual must specify why the authority has decided to designate the individual, the date upon which the designation will take effect (which may be the date of the notice or a subsequent date), and prohibit the individual from performing the specified special procedure, unless it is under the authority of a special procedure licence. The notice

must also state that the person may appeal the designation and the timescale within which an appeal may be brought.

87. Once served the designation notice will be in place until the local authority withdraws it, thereby preventing the designated individual from performing the specified special procedure unless it is under the authority of a special procedure licence. If the local authority withdraws the designation, the local authority must give notice to the individual. The notice must contain the reasons for the withdrawal and the date upon which the withdrawal is to take effect. Once the designation is withdrawn the prohibition on the performance of the special procedure will cease to have effect.

Section 51: Licensing criteria

88. This section requires the Welsh Ministers to make regulations that set out the licensing criteria. The licensing criteria may, amongst other things, relate to an individual's eligibility for a licence; the premises or vehicle from which a special procedure is to be performed and the equipment used in (or in connection with) the performance of a special procedure. The licensing criteria will set out all the requirements that must be met in order for the application for a special procedure licence to be granted.
89. The licensing criteria may also cover such things as standards of competence to perform a special procedure. This may include the applicable training undertaken by the applicant or their knowledge of the special procedure.
90. Regulations made under this section may also require that the local authority undertakes an inspection of the premises or vehicle identified in the application before a licence is issued or renewed. This is to enable the local authority to determine the premises' or vehicle's compliance with the licensing criteria. The regulations may also make different provision for different descriptions of premises and vehicles; for different special procedures; and for the different circumstances in which a special procedure is performed. These circumstances may include the frequency, regularity or period during which a procedure is performed. The licensing criteria may also address the basis upon which the special procedure will be performed, and specify the requirements in relation to each practice.
91. The basis upon which a special procedure is performed are: on a peripatetic basis (i.e. the applicant plans to practice a special procedure in various different premises, for example clients' homes); on a fixed site basis; on a mobile basis (if the special procedure is performed in a vehicle) or on a temporary basis (if the special procedure will be performed in the course of an entertainment, exhibition or other event that does not exceed seven days). The regulations will therefore set out the criteria that must be met in relation to the practice of all special procedures, in all settings.

Section 52: Mandatory licensing conditions

92. Section 52 requires the Welsh Ministers to make regulations that set out the mandatory licensing conditions. The mandatory licensing conditions will detail the requirements that the holder of a special procedure licence must adhere to. The mandatory licensing conditions may differ depending on the procedure being performed and the basis on which it is being performed i.e. peripatetically or from a fixed location. Subsection (2) sets out the elements that the mandatory licensing conditions may relate to. These include the condition (such as cleanliness, maintenance and standards of hygiene) of the premises or vehicle from which a special procedure is performed or where the equipment or material is stored or prepared; how the licence holder must maintain their records; and how they must display their licence.
93. The mandatory licence conditions may also specify the way in which a special procedure is to be performed. This will include the equipment that should be used, how the procedure should be performed and the requirements in relation to the protective clothing worn by the licence holder. The provision of information by the licence holder to clients both before and after a special procedure is carried out may also be specified in the conditions.
94. The regulations may provide that different mandatory licensing conditions apply in relation to different purposes. For example there may be different mandatory licensing conditions for different premises and vehicles, for different special procedures and to take account of the different circumstances in which a special procedure is practiced.

Section 53: Consultation about licensing criteria and mandatory licensing conditions

95. Before regulations under sections 51 or 52 are made, this section requires the Welsh Ministers to consider whether there are persons who appear to represent the interests of those likely to be affected by them, and as appropriate consult with them. This will ensure that those who are affected by the regulations are consulted and have their views considered.

Section 54: Mandatory grant or refusal of application for special procedure licence

96. This section outlines the circumstances under which the local authority must grant or refuse an application for a special procedure licence. The detail of how a licence application must be made is set out in Schedule 3. The local authority must grant the special procedure licence application if they are satisfied that all the applicable licensing criteria are met in respect of the special procedure, thereby authorising the performance of the procedure on the basis specified in the application.
97. If the local authority is not satisfied that all the applicable licensing criteria are met, it must give notice to the applicant that the application has been refused. The process the local authority must follow in relation to

providing notice and communicating with the applicant (including the process available to them for making representations) is provided in Schedule 3. The licensing committee of the authority (or one of its sub-committees) will consider the application and make a decision. The applicant may appeal against the local authority's decision to the magistrates' court.

Section 55: Discretion to grant application for special procedure licence

98. The requirement on the local authority to grant the application does not apply in the case of an applicant who has been convicted of a relevant offence. The relevant offences are provided under subsection (3). If the applicant has been convicted of a relevant offence, the local authority retains the discretion to grant a special procedures licence, if it thinks fit. Alternatively, the local authority may decide not to issue a licence, in which case it must provide notice to the applicant that the application has been refused. A conviction for a relevant offence is to be disregarded by the local authority if it is spent for the purposes of the Rehabilitation of Offenders Act 1974 (c.53).

Section 56: Grant or refusal of application for renewal

99. Sections 54 and 55 apply for the purposes of an application to renew a special procedure licence in the same way as if the application was for the issue of a licence.

Section 57: Revocation of special procedure licence

100. This section provides discretion for the local authority to revoke a special procedure licence (or revoke the licence in so far as it relates to the performance of a particular special procedure), if it is satisfied that two conditions are met. The conditions are (a) that the licence holder has failed to comply with an applicable mandatory licensing condition; and (b) that the non-compliance presents or could present significant risk of harm to human health.
101. The revocation will have effect following the expiry of the period for bringing an appeal or further appeal, or the withdrawal of any appeal or further appeal, in respect of the revocation. Further detail on the procedure for revocations is provided in Schedule 3.

Section 58: Performance of special procedure in course of business: approval requirements

102. Section 58 establishes that a person carrying on a business, in the course of which a special procedure is performed, must comply with two requirements. These requirements also apply to designated individuals as they are treated as carrying on a business for the purposes of this section and section 59.

103. The first requirement is that the procedure is performed at premises or in a vehicle that has been approved by the local authority under section 59. The second requirement ensures that once approved, a premises or vehicle complies with the mandatory approval conditions (provided at section 59(3)). The approval requirements will also apply to a person who organises an exhibition, entertainment or other event to which members of the public have access, and at which a special procedure is performed by a person in the course of business.

104. Subsection (6) provides the Welsh Ministers with a regulation making power to exempt certain premises or vehicles from the approval requirements. The premises or vehicle may be described in the regulations by way of reference to the persons by whom they are managed or controlled; the nature of activities carried on at or in them; the different circumstances in which a special procedure is performed at or in them; or the numbers of individuals performing special procedures. This will enable specific premises or vehicles to be exempt from the approval requirements. For example, the premises from which a special procedure is performed by an exempted individual may be exempt.

Section 59: Approval of premises and vehicles in respect of performance of special procedure

105. This section enables a local authority to approve a premises or vehicle so that a special procedure (or special procedures) may be performed at or inside it. The approval of a premises or vehicle will last for either a maximum of seven days (if it relates to procedures carried out on a temporary basis (i.e. in the course of an entertainment, exhibition or other event), or three years. The premises must be in the local authority's area and the vehicle must be considered to be driven, used or kept in the area of the local authority, in order for the local authority to approve it.

106. Subsection (3) requires the Welsh Ministers to make regulations in relation to the approval of premises and vehicles. These regulations must cover the criteria to be met in order for the application to be granted, the circumstances in which an application for approval is to be granted, and the process for an applicant to appeal against a refusal of an application. In addition, the regulations will specify the conditions (the "mandatory approval conditions") which must be complied with in order for the approval to be retained. These conditions may include the facilities available at the premises or vehicle, such as suitable hand cleansing facilities.

107. The regulations may also make provision about the way in which an application for approval is made and is dealt with (including the payment of a fee), the circumstances in which an application for approval must not be granted, or may be granted at the local authority's discretion, and the process that will apply to the renewal of an approval.

108. The regulations may also make different provision for different descriptions of premises and vehicles; for different special procedures; and for the different circumstances in which a special procedure is performed.

Section 60: Revocation of approval

109. This section provides the local authority with the ability to revoke a premises or vehicle approval if it is satisfied that both the conditions in subsection (2) are met. These conditions are that the mandatory approval conditions that apply to the premises or vehicle (as required by section 59(3)) have not been complied with, and that this non compliance presents or could present, significant risk of harm to human health.
110. In order to revoke the approval, the local authority must serve a notice on the person who applied for the approval.
111. Schedule 3 outlines the process for the revocation of the approval. This process is the same as that for revocation of a special procedures licence (as provided by section 57) and provides that the person may appeal against the local authority's decision to the magistrates' court.

Section 61: Duty to maintain register of special procedure licences and approved premises and vehicles

112. As part of the local authority's requirements under this Part, section 61 requires a local authority to maintain a register containing details of all valid special procedures licences issued by it, as well as details of all those premises and vehicles currently approved by it. This register must be accessible to members of the public. This is to allow members of the public to view the details of licence holders and/or approved premises or vehicles in their area, for example on the local authority's website. The purpose of this provision is to improve transparency in relation to the practice of special procedures, and aims to provide consumer confidence.
113. Subsections (2) and (3) specify the information that must be provided in the register in relation to licences and approvals.
114. In respect of licences, subsection (2) requires that the register must record information including the name of the licence holder, the date the licence was issued, the special procedure authorised by the licence and the period that the licence is valid for (i.e. 7 days or 3 years). If the licence relates to the performance of a special procedure in a specific premises or vehicle, the register must contain relevant information relating to the approval. For premises and vehicle approvals, subsection (3) requires that the register contains information such as the name of the person holding the approval, the date the approval was issued and its period of validity, as well as the special procedure authorised to be performed on those premises or vehicle. Specific information such as the premises address or the vehicle's registration number will also be required.

115. Subsection (4) provides that the local authority maintaining the register may include such other information as it considers appropriate.

116. Although each local authority will be required by this section to maintain its own register, subsection (6) enables the Welsh Ministers to arrange for a central register to be kept by one appointed local authority. As the Welsh Ministers may require all local authorities in Wales to participate in and provide their information to the central register, this would contain information on all currently valid licences and approvals in Wales. The Welsh Ministers may also require all local authorities to contribute towards the costs of such a central register.

117. A central register would aim to assist local authorities with their enforcement functions in relation to special procedures, as well as provide a single source of information for the public to access.

Section 62: Stop notices

118. If the local authority is aware of an individual performing a special procedure in their area without a licence (this includes individuals who are designated as always requiring a licence under section 50), or carrying on a business from a premises or vehicle that has not been approved, the local authority may issue that individual or person with a stop notice. The aim of the stop notice is to prohibit the carrying out of the special procedure specified in the notice.

119. Breach of the stop notice is an offence (as provided by section 67(4)) and is punishable by a fine not exceeding level 3 fine on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

120. The stop notice must be provided to the person concerned and contain the information required in subsections (4) and (5). This includes the reason for the stop notice, details of the prohibition and notifying the person subject to the notice of their right to appeal against its issue. The stop notice can apply to an area of Wales (for example the local authority's area) or extend to all of Wales. The stop notice will be effective until the person obtains the relevant licence or approval.

Section 63: Special procedure licences: licence holder remedial action notices

121. If a local authority becomes aware that a licence holder is breaching an applicable mandatory licensing condition, and that the breach presents or could present, significant risk of harm to human health, it may issue the licence holder with a remedial action notice. The remedial action notice must, amongst the other things provided by subsection (4), specify the matters giving rise to the breach and the steps that the licence holder must take to secure compliance with the applicable mandatory licensing conditions. The notice may also prohibit the performance of a special procedure until the

steps specified in the notice have been taken. The prohibition may relate to the performance of the special procedure in an area of Wales (for example the local authority's area) or may extend to all of Wales.

122. The notice must specify the compliance period (which must not be less than 14 days) within which the licence holder should take the steps specified in the remedial action notice. If the local authority is satisfied that the steps specified in the notice have been taken, it must issue the licence holder with a completion certificate to discharge the notice, as required by section 65.
123. The remedial action notice must also provide details of the licence holder's right to appeal to the magistrates' court against the local authority's decision.
124. Whilst contravention of the remedial notice is an offence (as provided by section 67(5)) and is punishable by a fine not exceeding level 3 on the standard scale, the local authority must not begin proceedings against the licence holder until the compliance period has expired. If the licence holder takes the steps specified in the remedial action notice within the compliance period, no proceedings for an offence will be taken by the local authority. The local authority will, however, be able to undertake proceedings if the licence holder continues to practice a special procedure, despite the prohibition placed upon their practice. In addition to the remedial action notice, the local authority may also revoke a special procedures licence if the licence holder fails to comply with an applicable mandatory licensing condition.

Section 64: Approved premises and vehicles: premises remedial action notices

125. Similar to the provisions set out in section 63, section 64 provides the local authority with the ability to issue a remedial action notice to a person in respect of an approved premises or vehicle. The notice may be issued if the local authority is satisfied that the person is breaching an applicable mandatory condition of approval. The remedial action notice must, amongst the other things provided by subsection (4), specify the reason(s) for the breach and the steps that the licence holder must take to secure compliance. The notice may also prohibit the performance of the special procedure at the premises or in the vehicle, until the steps specified in the notice have been taken.
126. The notice must specify the compliance period (which must not be less than 14 days) within which the licence holder should take the steps specified in the remedial action notice. If the local authority is satisfied that the steps specified in the notice have been taken, it must issue the licence holder with a completion certificate to discharge the notice, as required by section 65.
127. The notice must also provide details of the person's right to appeal to the magistrates' court against the local authority's decision to issue a remedial action notice. Contravention of the notice is an offence (as provided for by section 67(6)) and is punishable by a fine not exceeding level 3 on the

standard scale. However, the local authority must not begin proceedings until the compliance period has expired.

128. If the person takes the steps specified in the remedial notice within the compliance period, no proceedings for an offence will be taken by the local authority. The local authority will, however, be able to undertake proceedings if the person continues to practice the special procedure from the premises or vehicle specified in the notice, despite the prohibition. In addition to the remedial action notice, the local authority may also revoke a premises or vehicle approval if the person fails to comply with a mandatory approval condition.

Section 65: Completion certificate

129. In relation to a remedial action notice issued by the local authority under section 63 or 64, if the local authority is satisfied that the steps specified in the notice have been taken, it must provide the person with a certificate (a “completion certificate”) discharging the notice. This to ensure that both the person who was subject to the notice and the local authority are aware that the remedial action notice has been complied with, and have a record of the steps which have been taken.

130. The person subject to the notice may apply to the local authority for a completion certificate at any time. The application process and the information required will be specified by the local authority. If the local authority refuses the application, it must give notice to the person that the application has been refused. In addition, the reasons for the refusal and information on the appeals process must be provided to the person.

Section 66: Appeals

131. This section provides a person with a right to appeal to the magistrates’ court against a local authority’s decision under sections 62, 63 or 64. An appeal against the local authority’s decision to refuse an application for a completion certificate (section 65) may also be made. The magistrates’ court may take any of the actions specified in subsection (5); these include confirming the notice or refusal, quashing or varying the notice, or referring the case to the local authority to dispose of in accordance with directions given by the court.

132. If the local authority’s decision is varied or quashed, the magistrates’ court may order the local authority to compensate the person for loss suffered as a result of the notice. For example, the person could be compensated for a loss of income due to the local authority’s decision to prevent them from working.

Section 67: Offences

133. Section 67 sets out the offences which apply in relation to the Part. Amongst others, offences will be committed if a person fails to comply with

the licensing or approval conditions, or fails to comply with enforcement action ordered by a local authority such as a stop notice or a remedial action notice. There is also an offence for making a false or misleading statement (including if the person knows or are reckless as to whether it is false or misleading) when applying for a licence or approval of a premises or vehicle.

134. Upon conviction, a person found guilty of an offence under this section is liable for a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

Section 68: Authorised officers

135. This section clarifies that any reference to authorised officers in sections 69 to 75 are to any person authorised to exercise functions of a local authority, whether or not they are an officer of the local authority.

Section 69: Powers of entry, etc.

136. Section 69 enables an authorised officer to enter, at any reasonable time, premises (excluding premises used wholly or mainly as a dwelling) if the officer has reason to believe that a special procedure has been, is being, or is likely to be performed at the premises, or that material or equipment relating to a special procedure is stored or prepared at the premises. The power to enter premises does not enable the authorised officer to enter by force. If required, an authorised officer must, before entering the premises, show evidence of their authorisation. The power of entry also applies to a vehicle.

137. Section 67(9) of the Police and Criminal Evidence Act 1984 provides that, while acting in the course of their enforcement functions, authorised officers of the enforcement authority must have regard to the relevant code of practice made under that Act. Therefore, authorised officers must have regard to PACE Code of Practice B in the exercise of their enforcement functions.

Section 70: Warrant to enter dwelling

138. If access to premises which are wholly or mainly used as a dwelling is necessary a written application must be made by the local authority to a justice of the peace. Section 70 enables a justice of the peace to sign a warrant, thereby authorising an authorised officer to enter the dwelling, if needs be by force. Any such warrant will be in force for the period of 28 days beginning on the date it was signed by the justice of the peace. This section also applies to a vehicle.

Section 71: Warrant to enter other premises

139. If access to premises that are not only used wholly or mainly as a dwelling is necessary section 71 enables a justice of the peace to sign a warrant authorising any authorised officer to enter the premises, if needs be

by force. The warrant can be obtained by making a written application to a justice of the peace. The premises to which entry is being sought must be used for business purposes, or for both business and as a dwelling. In the case of premises used wholly or mainly as a dwelling a warrant must be sought under section 70. This section also applies to a vehicle.

140. In order for a warrant to be signed, one or more of the requirements set out in subsections (2) to (5) must be met. These include that a request to enter the premises has been, or is likely to be, refused; an application for admission, or the giving of notice of an intention to apply for a warrant is likely to defeat the purpose of the entry; the premises are unoccupied; or the occupier is temporarily absent, and awaiting their return is likely to defeat the purpose of the entry. Once the warrant is signed, it will be in force for the period of 28 days beginning on the date it was signed by the justice of the peace.

Section 72: Supplementary provision about powers of entry

141. This section enables an authorised officer entering premises under sections 69, 70 or 71 to take with them any other persons or equipment as the officer considers appropriate. It also requires that if the premises are unoccupied or the occupier is temporarily absent, the authorised officer must leave the premises as effectively secured against unauthorised entry as the officer found them. The provisions in this section also apply to a vehicle.

Section 73: Powers of inspection, etc.

142. Once an authorised officer has gained entry to premises, they may undertake inspections and examinations for the purposes of the local authority's functions in relation to special procedures. This may include inspecting and examining the premises, viewing and retaining closed-circuit television records and obtaining copies of documents, such as procedure records and consent documents. The authorised officer may also require the production of or take possession of anything and retain it for as long as the officer considers necessary for the purpose of exercising the authority's functions. In this instance, however, the officer must leave at the premises a statement containing the particulars of what has been taken.

143. The authorised officer may also require any person to provide them with information, or afford facilities and assistance with respect to matters within the person's control. However a person is not required to answer any question or produce any document which they would be entitled to refuse to answer or produce during proceedings in a court in England and Wales. This section also applies to a vehicle.

Section 74: Obstruction etc. of officers

144. This section provides that a person commits an offence if they intentionally obstruct an authorised officer from exercising their functions under sections 69 to 73.

145. A person commits an offence if, without reasonable cause, they fail to provide an authorised officer with facilities that are reasonably required under section 73(1) or they fail to comply with a requirement under section 73(1)(b) or (d) such as producing CCTV footage, or provide information.

146. A person found guilty of an offence under this section is liable on summary conviction to a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

Section 75: Power to make test purchases

147. An authorised officer may make purchases and arrangements, and secure the provision of services if the officer considers it necessary for the purpose of enforcement of the local authority's functions in relation to special procedures. This includes enlisting the assistance of a person to ascertain if a special procedure is being performed from a premises or vehicle in contravention of the requirements in this Part.

Section 76: Powers to add or remove special procedures

148. This section enables the Welsh Ministers to amend, via regulations, the list of special procedures contained in section 46. The amendment may add or remove a type or description of procedure to or from the list, or may vary the description of a procedure already contained in the list. The procedure may be described by reference to (amongst other things) the individual who carries out the procedure, or the individual on whom it is carried out. In order for the procedure to be added to the list, the Welsh Ministers must consider that the procedure is performed for aesthetic or therapeutic purposes and the performance of the procedure is capable of causing harm to human health. Harm to human health is defined in section 77(4) and includes harm to an individual's physical or mental health.

149. This provision enables the list of special procedures to remain up to date, thereby ensuring the requirements in the Part take account of changing practices and trends.

Section 77: Interpretation of this Part

150. This section sets out the meaning of the key terms used in this Part including the meaning of acupuncture, body piercing, electrolysis and tattooing. The definition of tattooing includes micro pigmentation.

151. Subsection (3) provides details on the meaning of the different basis (i.e. fixed site basis, mobile basis, peripatetic basis and temporary basis) referred to in the Part in relation to the practice of a special procedure. For example, different licensing criteria may be applied to these different bases by virtue of the regulations provided under section 51(4).

152. Subsection (4) provides the definition of the term “harm to human health”. This includes (amongst other things) harm to an individual’s physical health arising through physical injury or exposure to an infection, and harm to an individual’s mental health. Any procedure considered for addition to the list of special procedures (and therefore captured by the provisions in this Part) must be capable of causing harm to human health. For example, a procedure may be considered for inclusion in the list if it is capable of causing physical injury.

PART 4

INTIMATE PIERCING

Section 78: Offence of performing or making arrangements to perform an intimate piercing on a child

153. This section makes it an offence for a person who is in Wales to perform an intimate piercing on a child in Wales. It also makes it an offence for a person in Wales to make arrangements to perform an intimate piercing on a child in Wales. A child in this Part is any person who is under the age of 16. A person convicted of either offence is liable on summary conviction to a fine not exceeding level 4 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982. A person charged with either offence may put forward a defence that they took reasonable precautions and exercised due diligence to avoid committing the offence.

154. For the purposes of this section, “Wales” has the meaning provided in section 158(1) of the Government of Wales Act 2006 (c.32).

Section 79: What is an intimate piercing?

155. An intimate piercing is defined as the perforation of the skin or mucous membranes of a listed intimate body part, with a view to enabling the attachment or implantation of jewellery or another object to that body part. For the purposes of this Part, the definition of “jewellery” is provided in section 77(2) and includes (among other things) a bead, bar, rod or plug of any shape or material. The objects included in the definition may be prescribed in regulations under section 77(1) but may include objects such as ribs or stars.

156. The intimate body parts are listed in subsection (2) and include the breast (including the nipple and areola), buttocks and genitals. The list captures parts of both the male and female anatomy. Mucous membranes are included in the definition as the surface of intimate body parts such as the vulva may comprise skin or mucous membranes.

157. The offences created by this section do not apply to intimate piercings of a person under the age of 16 if they occur in the course of a medical procedure carried out by a registered medical practitioner, a registered nurse

or a registered midwife. Medical procedure is defined as any procedure carried out for the purposes of or in connection with the diagnosis, prevention, monitoring, treatment or alleviation of disease, ill-health, disability or other physical or mental abnormality or birth control.

Section 80: Enforcement action by local authorities

158. This section enables a local authority to undertake enforcement action in relation to this Part. A local authority may:

- bring prosecutions in respect of offences under section 78;
- investigate of complaints in relation to alleged offences under section 78;
- take other steps with a view to reducing the incidence of offences in its area. These may include actions such as communicating with and educating body piercing practitioners, or undertaking test purchasing inspections to assess compliance.

159. Subsection (2) requires a local authority to consider at least once every 12 months a programme of enforcement action aimed at preventing the commission of the intimate piercing offences set out in section 78. A local authority must also, to the extent that it considers it appropriate to do so, carry out such a programme of enforcement action. This enforcement action may involve any or all of the steps referred to in subsection (1).

160. In undertaking its enforcement action, a local authority must carry out such consultation as it considers appropriate with the police.

Section 81: Authorised officers

161. The section clarifies that any reference to authorised officers in this Part is to any person authorised by a local authority, whether not they are an officer of the local authority.

Section 82: Powers of entry

162. This section enables a constable or an authorised officer to enter, at any reasonable time, premises (excluding premises used wholly or mainly as a dwelling) because there are reasonable grounds to believe that an offence under section 78 has been committed and entry is necessary to ascertain whether or not an offence has taken place. This power to enter premises does not enable the constable or authorised officer to enter by force. If required, an authorised officer must, before entering the premises, show evidence of their authorisation by the local authority. The power to enter premises (as provided by sections 83 to 86) includes any place and any vehicle (other than aircraft and hovercraft), stall or movable structure of entry.

163. Section 67(9) of the Police and Criminal Evidence Act 1984 provides that, while acting in the course of their enforcement functions, authorised officers of the enforcement authority must have regard to the relevant code of

practice made under that Act. Therefore, authorised officers must have regard to PACE Code of Practice B in the exercise of their enforcement functions.

Section 83: Warrant to enter dwelling

164. If access to a premises that is used wholly or mainly as a dwelling is necessary, because there are reasonable grounds to believe that an offence under section 78 has been committed and entry is required to ascertain whether or not an offence under section 78 has taken place, a written application must be made to a justice of the peace. This section enables a justice of the peace to sign a warrant authorising a constable or authorised officer to enter the dwelling, if needs be by force. Any such warrant will be in force for the period of 28 days beginning on the date it was signed by the justice of the peace.

Section 84: Warrant to enter other premises

165. If access to premises that are not used wholly or mainly as a dwelling is required to because there are reasonable grounds to believe that an offence under section 78 has been committed and entry is necessary to ascertain whether or not an offence under section 78 has taken place, section 84 enables a justice of the peace to sign a warrant authorising a constable or authorised officer to enter such premises, if needs be by force. The warrant can be obtained by making an application to a justice of the peace. The premises to which entry is being sought under this section must be used for business purposes, or for both business and as a dwelling. In the case of premises used wholly or mainly as a dwelling, a warrant must be sought under section 83.

166. In order for a warrant to be signed, one or more of the requirements set out in subsections (2) to (5) must be met. These include that a request to enter the premises has been, or is likely to be, refused; requesting to enter, or the giving of notice of intention to apply for a warrant, is likely to defeat the purpose of the entry; the premises are unoccupied; or the occupier is temporarily absent, and awaiting the occupier's return is likely to defeat the object of the entry. Once the warrant is signed, it will be in force for the period of 28 days beginning on the date it was signed by the justice of the peace.

Section 85: Supplementary provision about powers of entry

167. This section enables authorised officers or constables entering premises under sections 82, 83 and 84, to take with them any other persons or equipment as appropriate to ascertain whether an offence under section 78 has been committed. The section also requires that if the premises are unoccupied or the occupier is temporarily absent, those authorised to enter the premises must leave it as effectively secured against unauthorised entry as the person found them.

Section 86: Powers of inspection, etc.

168. Once a constable or an authorised officer has gained entry to premises, they may undertake inspections and examinations to ascertain whether an offence under section 78 has been committed. This may include inspecting and examining the premises, viewing closed-circuit television records and obtaining copies of documents, such as procedure records and consent documents. The constable or authorised officer may also take possession of anything on the premises, and retain it for as long as necessary or require any person to provide them with information, or afford facilities and assistance within their control. This may include providing an account of events, or supplying information that is stored on a computer or other device. If a constable or authorised officer takes possession of anything, they must leave at the premises a statement containing the particulars of what has been taken. However a person is not required to answer any question or produce any document which they would be entitled to refuse to answer or produce during proceedings in a court in England and Wales.

Section 87 : Obstruction etc. of constable or officer

169. This section provides that a person commits an offence if they intentionally obstruct a constable or an authorised officer from entering premises when the constable or authorised officer is authorised to do so.

170. A person commits an offence if, without reasonable cause, they fail to provide facilities or comply with any requirements required of them under section 86(1) (i.e. to provide a constable or an authorised officer with anything on the premises or with facilities, assistance or information (for example access to electronic records) that the constable or authorised officer reasonably requires).

171. A person found guilty of an offence under this section is liable on summary conviction to a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

Section 88: Power to make test purchases

172. An authorised officer may make purchases and arrangements, and secure the provision of services if the officer considers it necessary for the purpose of enforcement of the offences. This includes enlisting the assistance of a young person to ascertain if a person is offering and making arrangements to intimately pierce those under the age of 16.

PART 5

PHARMACEUTICAL SERVICES

173. This Part introduces changes to the way in which Local Health Boards (LHBs) determine applications to provide NHS pharmaceutical services. The

principal changes require LHBs to prepare and publish a pharmaceutical needs assessment for their area, and to determine applications for entry onto the pharmaceutical list (or applications to amend entries on the pharmaceutical list) by reference to whether or not the application meets a need for a service or services identified in the assessment. Each LHB maintains a pharmaceutical list which includes details of the persons whose applications to provide NHS pharmaceutical services have been approved and the location from which they provide those services.

174. This new “control of entry test” replaces the existing test in section 83 of the National Health Service (Wales) Act 2006 (‘the 2006 Act’), which requires LHBs to determine whether it is “necessary or expedient” to grant the application in question. Further changes authorise LHBs to remove a person from its pharmaceutical list for very serious or persistent breaches of terms and conditions of service.

Section 89: Pharmaceutical needs assessments

175. This section inserts section 82A into the 2006 Act which makes provision for a new duty for LHBs in Wales to prepare and publish an assessment of need for pharmaceutical services.

176. Section 82A(2) places a duty upon each LHB to keep its most recently published assessment under review and revise it as and when it is appropriate to do so.

177. Section 82A(3) requires regulations to make provision for:

- the date by which a LHB must publish its first assessment of pharmaceutical needs. This is to ensure that all LHBs have an assessment prepared and published by a set date so that there will be a smooth transition from the current arrangements to the new arrangements for determining applications;
- the circumstances in which a LHB is to revise its assessment. Regulations could, for example, require a LHB to review, and if appropriate revise, its assessment if there are significant changes to the demographics of an area which could have an impact upon the need for pharmaceutical services. Regulations could also stipulate that a LHB is required to revise its assessment every, for example, three years in order to ensure that the information in the assessment remains up to date; and
- the way in which an assessment is to be published. This could, for example, include a requirement to place a copy of the assessment on the LHB’s website as well as making hard copies available in NHS pharmacies and GP surgeries so that the assessment is accessible to persons living in the LHB’s area.

178. Regulations may make provision about the preparation, publication, review and revision of an assessment under subsection (1) including, but not limited to:

- the information to be contained in an assessment. For example, regulations could specify that an assessment must contain information on the demography of the people in its area, any seasonal trends and age profiles;
- the extent to which an assessment is to take account of likely future needs and of other matters. For example, regulations could specify that an assessment must consider the impact of planned housing or commercial developments;
- the consultation to be carried out in connection with an assessment. For example, regulations may require LHBs to consult specified persons about specified matters when preparing their assessment. LHBs may, for example, be required to consult with local authorities, patient and community groups and local professional representative committees; and
- procedural requirements.

Section 90: Pharmaceutical lists

179. This section amends sections 83 and 84 of the 2006 Act. Section 83 of that Act sets out the principal regulation making powers governing the provision of NHS pharmaceutical services in Wales, whilst section 84 provides for rights of appeal resulting from decisions made under section 83.

180. Section 83(2)(c) of the 2006 Act sets out the legislative criteria which a LHB must apply when considering applications to be included on a LHB's pharmaceutical list and applications for changes to the list. These criteria are often referred to as the "control of entry" test.

181. Subsections (2) and (3) modify the "control of entry test" that LHBs are required to apply when considering applications to join their pharmaceutical list. Subsection (2) removes the requirement for LHBs to consider whether it is "necessary or expedient" to grant the application in order to secure "adequate" provision of pharmaceutical services within the neighbourhood.

182. In its place, subsection (3) inserts the new subsection (2B) into the 2006 Act which provides that a LHB may grant an application where it is satisfied, having regard to its most recently published pharmaceutical needs assessment, and any matters that are specified in regulations, that to grant the application would meet the need/s identified within its assessment. This amendment means that the "control of entry test" will be clearly based on meeting assessed local pharmaceutical needs.

183. Section 90(3) also inserts a new subsection (2A) into section 83 of the 2006 Act which permits the Welsh Ministers to specify, in regulations, persons, or the description of persons, who are not to be included within a pharmaceutical list.
184. Section 90(3) also inserts a new subsection (2C) into the 2006 Act which makes additional provision in cases where a LHB is satisfied that an application meets the criteria for grant of the application required under (2B). First, new subsection (2C) provides that the regulations may set out the procedure which the LHB must follow when determining an application for inclusion in a pharmaceutical list. For example, the regulations may provide that a LHB must seek representations from local patient representative bodies and other key interested parties. Secondly, new subsection (2C) provides that the regulations may stipulate certain matters which a LHB must or must not take into consideration when deciding whether or not to grant an application under (2B).
185. Subsections (4), (5) and (6) modify the existing provisions which enable regulations to specify the circumstances in which two or more applications are considered together by a LHB.
186. Subsection (4) inserts a new subsection (3A) into the NHS (Wales) Act 2006 to provide that the regulations may prescribe the circumstances in which two or more such applications may be considered together by a LHB. Subsection (5) amends section 83(4) of the NHS (Wales) Act 2006 to create a general power to make provision for the case where two or more applications, taken individually, meet the test under the new subsection (2B), but, taken together, do not.
187. Section 90(7) inserts a new subsection (6)(za) into section 83 of the 2006 Act, which permits the regulations to prescribe the circumstances in which LHBs may invite applications for inclusion in their pharmaceutical list. This will enable a LHB, if it is not receiving applications to provide the pharmaceutical services which are required to meet needs identified in their pharmaceutical needs assessment, to actively seek applications that will fulfil those needs.
188. Section 90(7)(b) makes amendments to section 83(6)(g) of the NHS (Wales) Act 2006 so that regulations under section 83 may provide grounds for removal of a person from the pharmaceutical list that are not connected with a person's fitness to practise. It is intended to use this power to enable LHBs to remove pharmacists from the pharmaceutical list for serious and/or persistent breaches to their terms and conditions of service. Before removing a person from the pharmaceutical list for persistent breaches of terms of service an LHB must first issue the person with a notice describing the alleged breach (a so called "breach notice") and any action required by the person to rectify it. A person may only be removed from the pharmaceutical list where, having been issued a breach notice, fails to comply with the requirements stipulated therein. Appeals against removal will be to the Welsh Ministers.

189. Section 90(8) inserts (10A) which requires LHBs to provide reasons for their decisions as to any matters covered within section 83.
190. The remaining subsections amend section 84 of the 2006 Act, which deals with appeals against decisions made by LHBs under the regulations provided for in section 83.
191. Section 90(9) amends section 84 of the 2006 Act so as to ensure that appeals against a LHB's determination of an application for inclusion in a pharmaceutical list are heard by the First Tier Tribunal only if they are on fitness to practise grounds. The amendment removes the requirement relating to redetermination so that the First Tier Tribunal is not limited in the way it determines the appeal, for example, it could remit the matter back to the LHB. Appeals on other grounds are to be made to the Welsh Ministers – including appeals against a removal from the list for breaches of terms and conditions of service.
192. Section 90(10) provides that if regulations made under section 83 of the 2006 Act include provision for removal of a person or an entry in respect of premises from a pharmaceutical list, the regulations must require LHBs to give a pharmacist notice of their intention to remove him from the list, together with their reasons for the intended removal. The regulations will also need to set out the rights that a pharmacist will have to make representations prior to a LHB taking a decision to remove. It is intended that regulations will require the LHB to give a pharmacist written notice of his right to make representations orally and/or in writing before a substantive decision is made.
193. Section 90(11) removes text relating to section 83(6)(d) of the National Health Service (Wales) Act 2006 from the table in Schedule 6 (repeals and revocations of the Health Act 2009).

PART 6

PROVISION OF TOILETS

Section 91: Local toilets strategies: preparation and review

194. This section places a duty on each local authority (i.e. each county and county borough council) in Wales to prepare and publish a local toilets strategy for its area. The strategy will include an assessment of the need for toilets, including changing facilities for babies and changing places facilities for disabled persons, in the local authority's area to be available for use by the public. The strategy will also set out how the local authority plans to meet those needs. The strategy may also include any other information which the local authority considers appropriate.
195. A local authority's first strategy must be published no later than 12 months following the first ordinary local authority election held in the area after the commencement of this section. Following the publication of the first

strategy, the local authority may review its strategy at any time, and in any case must review its strategy no later than 12 months after each subsequent ordinary election.

196. When a local authority undertakes a review, it must publish a statement of the steps it has taken in accordance with the strategy during the period that the strategy has been in place. If during the review of the strategy, the local authority considers a change is needed, it must revise and publish the revised strategy.

197. The Welsh Ministers may issue guidance to local authorities about the matters which they should take into consideration when preparing, reviewing or publishing a local toilets strategy. Such matters could include suggested consultees that are likely to be interested in the provision of local toilets and the methods by which the local authority could publicise the toilets that are available in their area for use by the public.

Section 92: Local toilets strategies: consultation

198. This section sets out what a local authority must do with regard to consultation before publishing its local toilets strategy or its revised strategy. The local authority must consult with any person it considers is likely to be interested in the provision of toilets available locally for use by the public. The local authority must make the draft strategy available to consultees.

199. The section does not specify the categories of persons with whom the local authority should consult. Instead, it will be for the local authority to decide who, in their opinion, is likely to be interested in the provision of local toilets. Similarly, neither the timescale for the consultation nor the consultation methods to be used are specified in the section. It will be for the local authority to decide the timescale for an effective consultation and the appropriate consultation method it should use to engage with those interested in the provision of local toilets.

Section 93: Local authority power to provide public toilets

200. This section provides that local authorities and community councils in Wales may provide public toilets in any part of their areas. When providing toilets, the local authority and community council must have regard to the relevant local toilets strategy that is in place for its area. A local authority or community council may charge fees for the use of those toilets that it provides.

201. If the toilets are to be on or under land adjoining, or in the vicinity of, a highway or proposed highway, including bridges and tunnels, the relevant highway authority must consent to the provision of the toilets. In some cases, the local authority will be the highway authority, so no consent will be required where the local authority is proposing to provide the toilets.

Section 94: Power to make byelaws in relation to toilets

202. Subsection (1) enables a local authority or community council to make byelaws relating to the conduct of persons using or entering the toilets that they provide. If a community council makes such byelaws, any byelaws made by a local authority under section 2 of the Local Government Byelaws (Wales) Act 2012 (anaw.2) in relation to the community council's toilets will not apply for as long as the relevant community council byelaws remain in force

Section 95: Consequential amendments

203. This section gives effect to Schedule 4, which makes consequential amendments in relation to the provision of toilets.

PART 7 GENERAL

Sections 96 and 97: Offences by bodies corporate etc. and Offences committed by partnerships and other unincorporated associations

204. These sections make provision in connection with offences under the Bill that may be committed by a body corporate; a partnership; or other unincorporated organisation. It describes how offences may be attributed to a senior officer of the body corporate etc., or any person acting in that capacity, as well as, the body corporate etc. itself. Sections 96(3), 96(4) and 96(5) describe what is meant by the terms “senior officer”, “director” and “partnership” under this Part.

Section 98: Regulations

205. This section explains how powers to make regulations under this Bill are to be exercised and sets out the procedure to be followed in making regulations under different sections of the Bill.

Section 100: Power to make consequential and transitional etc. provision

206. This section permits the Welsh Ministers to make supplementary, incidental, consequential, transitional, transitory or saving provision in regulations. Such provision must be in consequence of other provisions of the Bill or in order to give full effect to them. For example, transitional arrangements may be needed to allow appropriate time for a practitioner of a special procedure to comply with the new requirements introduced by the Bill.

Section 101: Coming into force

207. This section sets out the provisions that will come into effect on the date of Royal Assent; and those that will come into force by Commencement Orders made by the Welsh Ministers.

Section 102: Short title

208. This provides that the short title of the Act will be the Public Health (Wales) Act 2016.

[End of Bill]

Schedule 1: Fixed penalties

209. Schedule 1 contains provisions relating to fixed penalties and fixed penalty notices. These include the contents of the penalty notice form, powers for the Welsh Ministers to make regulations to set the penalty and discounted amounts, and the periods for payment of the penalty and discounted amounts. Paragraphs 15 and 16 enable a person to request to be tried for the offence in court instead of paying the fixed penalty. Paragraph 17 permits authorised officers of the issuing authority to withdraw a fixed penalty notice.

Schedule 2: Smoking and nicotine inhaling devices: consequential amendments

210. Schedule 2 makes consequential amendments in relation to smoking and the use of nicotine inhaling devices. These amendments:
- Disapply Chapter 1 of Part 1 of the Health Act 2006 in relation to Wales because Chapter 1 of Part 2 of the Public Health (Wales) Bill restates the provisions of Chapter 1 of Part 1 of the Health Act 2006 in relation to Wales. Chapter 1 of the Health Act 2006 remains in force in relation to England; and
 - Amend section 91 of the Children and Families Act 2014, which modifies section 9 of, and Schedule 1 to, the Health Act 2006. The amendment inserts a new paragraph at subsection (5)(c) of section 91 of the Children and Families Act 2014. The amendment maintains the Welsh Ministers' powers to make regulations to specify the form of fixed penalty notices in relation to an offence under that section (in relation to the offence of buying or attempting to buy tobacco for a person aged under 18).

Schedule 3: Further provision in connection with special procedure licences

211. Paragraphs 1-4 set out the process that an applicant for a special procedures licence must follow, including the information that they must provide to the local authority to obtain a licence. In the application, the applicant must specify the special procedure/s to which the application relates and provide details on the basis that the procedure is to be performed (i.e. peripatetic basis (i.e. the applicant plans to practice a special procedure in various different premises, for example clients' homes), fixed site basis,

mobile basis, temporary basis, or otherwise). If the procedure is intended to be performed at set premises or vehicle, details of that premises or vehicle must be provided in the application. The application must also include the details of the applicant (including their full name, date of birth and contact details) as well as the fee required by the authority. In considering the application, the local authority may require further information to be provided by the applicant including information necessary to verify their identity. Paragraph 4(4) provides the Welsh Ministers with a regulation making power to make further provision about the procedure for dealing with applications.

212. Paragraph 5 specifies the content of a special procedures licence. The licence must, amongst other things, state the name of the licence holder, name the authority by which the licence is issued and state the special procedure that is authorised by the licence. The period that the licence is valid for must also be included on the licence; in the case of a temporary licence that is valid for no more than seven days, this must be specified on the licence. If required by section 48, the licence must also include the details of the approved premises or vehicle from which the licence holder is authorised to perform special procedures. Paragraph 5(3) provides the Welsh Ministers with a regulation making power to make further provision about the form and contents of special procedure licences. These regulations may include, amongst other things, information about the applicable mandatory licensing conditions that the holder of the special procedure licence must adhere to. These mandatory licensing conditions may relate to the condition (i.e. cleanliness, maintenance and standards of hygiene) of the premises or vehicle from which the special procedure is performed or where the equipment or material is stored or prepared.

213. Paragraphs 6 and 7 enable the licence holder to apply to the local authority for a copy of their licence if their licence is mislaid, stolen or damaged. As the mandatory licensing conditions may require the licence to be displayed, the licence holder may require a copy of the licence in order to comply with the requirement. The application must be made in any way the local authority requires and must be accompanied by whatever fee has been set by the authority. If the local authority is satisfied that the licence has been mislaid, stolen or damaged, the local authority must grant the application and issue a copy of the licence to the applicant as soon as practicable. In the case of a mislaid or stolen licence, the local authority must also be satisfied that the loss or theft has been reported to the police. The copy of the licence must be certified by the local authority as a true copy and will be treated as being the original licence.

214. Paragraph 8(1) provides details of the circumstances under which a licence expires. These circumstances include the end of the licence period, the voluntary termination of a licence or the date that the revocation by the local authority (as provided by section 57) of the licence takes effect. A licence will also expire once withdrawal of an individual's designation under section 50 takes effect.

215. Paragraph 9 enables a licence holder to apply to a local authority for the renewal of their special procedures licence. The application must be submitted to the local authority that granted the original licence and must be made in whatever way and contain whatever information is required by the local authority. The application must also include the fee set by the local authority.
216. Paragraph 10 provides that a licence does not expire during the time that the local authority is considering the application for the renewal of a licence, during the appeal period available in respect of an application for renewal or whilst an appeal is pending in respect of an application for renewal.
217. Paragraphs 11, 12 and 13 enable a special procedures licence to be varied upon application from the licence holder. For example, the variation may be applied for because the licence holder wishes to add, amend or remove a description of special procedure from their licence. The variation may also be required to add reference to an approved premises or vehicle from which the licence holder intends to perform special procedures or to remove a premises or vehicle previously identified on the licence. If the licence holder is applying to add a special procedure to their licence, the licence holder must specify the special procedure they wish to be added to their licence and meet the licensing criteria (as provided by section 51) in relation to that procedure. The variation cannot however transfer the licence from the licence holder to another individual or extend the licence period. The application must be made in whatever way is required by the local authority and be accompanied by whatever fee is set by the local authority.
218. If a licence holder intends to terminate their licence, paragraph 14 enables the licence holder to give notice to the local authority of voluntary termination of the licence. In giving notice, the licence holder must state the date with which the licence is to cease to have effect. Subject to any earlier expiry under paragraph 8(1) (a), (b) or (d), the licence will cease to have effect on the date specified in the notice.
219. Paragraph 15 provides that where a local authority proposes to give notice to an applicant, licence holder or individual (referred to as "A"), A has the right to make representations to the local authority licensing committee. The notice may relate to:
- the refusal of an application for a licence under sections 54(2) or 55(2)(b) (including under any of those provisions as applying in respect of the application by virtue of section 56 or paragraph 13);
 - the intention to revoke a licence (section 57); or
 - the designation of an individual under section 50(1), requiring them to have a licence.
220. Before a decision is taken by the local authority, the local authority must provide a warning notice to A that sets out what the local authority intends to do and why. The warning notice must state that within the period specified (which must not be less than 14 days) A may either make

representations or inform the local authority that he wishes to make representations about the proposal. If A wishes to, the local authority must enable A to make representations (including oral representations if A or his representative wishes to do so) and it must consider those representations. If A does not wish to make representations, or does not inform the local authority that he wishes to make representations within the specified period, the local authority may take the steps specified in the warning notice.

221. Having complied with the requirements in paragraph 15, paragraph 16 enables the local authority to take the action set out in the warning notice and to issue a notice of decision. The notice of decision must set out the local authority's reasons for giving it. It must also state that A may appeal the decision and provide details of the period within which an appeal may be brought. In the case of a revocation under section 57, the notice of decision must also state the date on which (in the absence of an appeal) the revocation will take effect.
222. Paragraph 17 provides that an applicant, licence holder or individual may appeal to a magistrates' court against the local authority's decision (as taken under paragraph 16). The appeal must be made within 21 days of the local authority's notice of decision. On hearing the appeal, the magistrates' court may confirm, quash or vary the decision made by the local authority; alternatively, the magistrates' court could remit the case to be considered by the local authority in accordance with directions given by the magistrates' court. The magistrates' court may also make an order for costs incurred to be paid. These may be the costs incurred by the applicant or the local authority in defending their decision.
223. Paragraph 18 provides that an appeal against the decision of the magistrates' court under paragraph 17 may be brought to the Crown Court. The Crown Court may confirm, vary or reverse the magistrates' court's decision or require that the case is considered by the magistrates' court or the local authority in accordance with the directions given by the Crown Court.
224. If on appeal under paragraphs 17 and 18, the local authority's decision is varied or reversed, the magistrates' court or the Crown Court may order the local authority to compensate the applicant, licence holder or person subject to designation under section 50, for loss suffered as a result of the decision. For example, the person could be compensated for a loss of income due to the local authority's decision to prevent them from working whilst the appeal was ongoing.
225. During the time that an appeal under paragraphs 17 and 18 is taking place, the decision made or the notice given by the local authority continues to have effect. Therefore, if it is the local authority's decision is revoke a licence under section 57, the decision will remain in force until the court makes their determination.
226. Paragraph 20 delegates the specified functions of a local authority to the licensing committee of the local authority. This allows the licensing committee to make the decisions in relation to those functions listed under

paragraph 20 (1). Whilst the functions remain functions of the local authority requiring the licensing committee (or one of its sub-committees) to take the decision provides a level of oversight. Committees and their members have experience in taking licensing decisions which may affect people's livelihood. In taking a decision, the licensing committee will be required to hear any representations provided by 'A' following the issuing of a warning notice by the local authority under paragraph 15. The functions of the licensing committee are provided to it by section 6 of the Licensing Act 2003. In addition to enabling the licensing committee to take decisions in relation to specific areas, these functions enable the licensing committee to refer specified decisions to the local authority and to sub-delegate decision making.

227. Paragraph 20(4) provides the Welsh Ministers with a regulation making power to make provision about the procedures applicable to licensing committees and their sub-committees for the purpose of the exercise of the delegated functions under this paragraph, including public access and the availability of records. Subject to any regulations made by the Welsh Ministers, paragraph 20(5) enables each licensing committee and its sub-committees to regulate its own procedure.

Schedule 4: Provision of toilets: Consequential amendments

228. Schedule 4 makes consequential amendments in relation to the provision of toilets. These amendments:

- i. Disapply section 87 of the Public Health Act 1936 in relation to Wales because section 93 of the [Public Health (Wales) Bill] restates the powers previously conferred by section 87 in relation to:
 - the provision of public toilets by county or county borough councils and community councils;
 - a community council's power to make byelaws as to the conduct of persons using or entering the toilets that they provide; and
 - county or county borough councils and community councils' power to charge for the use of the toilets that they provide.

Section 87 of the Public Health Act 1936 remains in force in relation to England.

- ii. Inserts reference to section 95 of the Bill in the tables in Parts 1 and 2 of Schedule 1 to the Local Government Byelaws (Wales) Act 2012 (anaw.2), so that the byelaws council councils, county borough councils and community councils may make in exercise of their power under section 95 are not subject to confirmation by the Welsh Ministers, and may make provision about fixed penalty offences.

Annex B – Summary of Costs of Legislation

This section outlines a summary of the anticipated additional costs of the provisions within the Public Health (Wales) Bill. All costs are additional to maintaining the status quo, as set out in the “do nothing” option for each proposal. This section must be read in conjunction with the relevant sections within the main RIA to provide the context and associated detail for the figures.

The figures used are a mid point when calculated from a range within the RIA.

The figures in the tables derive from the costs of the preferred option for each subject as set out in the main RIA.

Where there are likely to be cost savings, the net cost of the preferred option has been included.

The tables set out the annual costs over 5 years across Wales for each subject.

Annual Costs

Restrictions on the use of tobacco and electronic cigarettes in enclosed public places

	2016-17 (£)	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)
Welsh Government	300,000	0	0	0	0
Local authorities	20,500	0	0	1,400	0
Public and work places	3,704,700	1,294,400	1,274,400	1,271,900	1,271,900
E-cigarette industry	269,600	269,600	269,600	269,600	269,600
Public	5,100	6,000	6,200	2,600	2,600
Total Cost	4,299,900	1,570,000	1,550,200	1,545,500	1,544,100
Net Cost	4,298,700	1,568,500	774,900	769,800	768,000

Register of retailers of tobacco and nicotine products

	2016-17 (£)	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)
Welsh Government	26,500	8,700	0	0	0
Local authorities	6,500	- 116,800*	15,000	16,400	15,000
Retailers	0	246,000	11,100	11,100	26,100
Total Net Cost	33,000	137,900	26,100	27,500	26,100

* Local authorities will retain registration fees amounting to £148,100 in this year, amounting to a net saving of £116,800.

Handing over tobacco etc to persons under 18

	2016-17 (£)	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)
Welsh Government	15,900	0	0	1,400	0
Local authorities	125,700	72,000	72,000	72,000	72,000
Retail sector	80,300	2,000	2,000	41,200	2,000
Total Cost	221,900	74,000	74,000	114,600	74,000

Special procedures

	2016-17 (£)	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)
Welsh Government	61,500	-2,500	-2,500	3,100	-2,500
Local authorities*	61,000	234,000	178,400	162,500	143,200
Practitioners /businesses	0	387,700	37,600	36,600	264,400
Unregistered Practitioners	0	10,000	9,000	8,100	7,300
Total cost	122,500	629,200	222,500	210,300	412,400

* Local authorities will retain registration fees from businesses and practitioners to off-set the costs incurred in administering the license scheme. An amount equal to the anticipated registration fee total has therefore not been included in the total local authority costs.

Intimate piercing

	2016-17 (£)	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)
Welsh Government	18,500	0	0	1,200	0
Local authorities	76,000	76,000	38,000	38,000	38,000
Practitioners/ businesses	46,600	42,400	42,400	44,500	42,400
Total Cost	141,100	118,400	80,400	83,700	80,400

Pharmaceutical services

	2016-17 (£)	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)
Welsh Government	0	17,600	0	0	0
Local Health Boards	0	205,100	359,800	359,800	359,800
Contractors	0	0	73,500	73,500	73,500
Total Cost	0	222,700	433,300	433,300	433,300

Net Cost		222,700	-	-	-
			2,722,700	2,722,700	2,722,700

Provision of toilets

	2016-17 (£)	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)
Welsh Government	8,400	0	0	0	0
Local authorities	0	378,400	8,200	8,200	8,200
Total Cost	8,400	378,400	8,200*	8,200*	8,200*

* Additional costs in these years relate only to the increase in management costs to facilitate the full £200,000 spending on grants. Further additional costs would be determined by the development and implementation of the strategies. As these strategies are at the discretion of each local authority following an assessment of need in its area it is not possible to estimate the additional costs to increase provision levels. However, greater spending on the implementation of strategies is likely to result in a greater degree of the benefits discussed below being realised.

Total Bill costs summary

Each part of the Bill is expected to impose additional costs on the Welsh Government. Each part of the Bill, with the exception of pharmaceutical services, is expected to impose additional costs on local authorities. The total impact of the Bill on these organisations over the five year period is shown in the table below. The net cost has been used where there are likely to be savings to Welsh Government or local authorities. Other parties are impacted by individual parts of the Bill, as identified in the tables above.

	2016-17 (£)	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	Total (£)
Welsh Government	430,800	23,800	-2,500	5,700	-2,500	455,300
Local authorities	289,700	643,600	311,600	298,500	276,400	1,819,800

Annex C – Table of derivations

The table below is intended to provide information on the derivation of the provisions of the Public Health (Wales) Bill. The table does not provide definitive or exhaustive guidance and should be read in conjunction with the Bill and Explanatory Notes.

Derivations are only relevant to Parts 2 and 6 of the Bill (Tobacco and Nicotine Products, and Provision of Toilets). Accordingly, the other Parts are not referenced in the following table.

ABBREVIATIONS:

HA: Health Act 2006
SF: The Smoke-Free Premises etc. (Wales) Regulations 2007
PHA: Public Health Act 1936

TABLE OF DERIVATIONS		
SECTION /PARAGRAPH	CORRESPONDING REFERENCE IN EXISTING LEGISLATION	SUBSTANTIVE CHANGE?
PART 2: TOBACCO AND NICOTINE PRODUCTS		
CHAPTER 1: SMOKING AND USE OF NICOTINE INHALING DEVICES		
2(1)	Section 1(2) HA	No
2(2)-(3)	New	
3	New	
4(1)	Section 7(2) HA	No
4(2)	New	
4(5)-(7)	Section 7(4)-(6) HA	No
5(1)(a)	Section 8(1) HA	No
5(1)(b)	New	
5(2)-(6)	Section 8(3)-(4), 8(5)(b) and (c), 8(6)-(7) HA	No
6(1)-(7)	Section 2(1)-(5), 2(8) HA	Yes. A private dwelling that is a workplace is smoke-free only when used as a place of work.
7(1)-(5)	Section 2(1), 2(3)-(4), 2(7) HA	No
8(1)-(4)	Section 4(1)-(4) HA	No
8(5)-(6)	New	
9(1)	Section 5(1) HA	No
9(2)	New	
9(3)-(6)	Section 5(2)-(3)(a), 5(5) HA	No
10(1)-(4)	Section 3(1), 3(6)-(7) HA	No
10(5)-(6)	New	
11	Section 6(1)-6(8) HA	No
12(1)-(5)	Section 10(1)-(3), 10(5) HA	No

13(1)	Schedule 2: 2(a) HA	No
13(2)	Schedule 2: 2(a) HA	Yes
13(3)	New	
13(4)	Schedule 2: 2 HA	No
13(5)	Schedule 2: 1 HA	No
14	New	
15(1)-(6)	Schedule 2: 1, 6(1)-(4) HA	No
16(1)-(2)	Schedule 2: 1, 7 HA	No
17(1)	Schedule 2: 2(b)-(e) HA	No
17(2)-(3)	Schedule 2: 3, 9 HA	No
17(4)-(5)	New	
17(6)-(7)	Schedule 2: 1, 5 HA	No
18	Section 11(1)-(2), 11(4) HA	Yes
19(1)-(3)	Section 9(1)-(2) HA	No
19(4)-(5)	Regulation 1(3) SF	No
19(6)-(7)	New	
19(8)	Section 9(3) HA	No
Schedule 1: 2-17	Schedule 1: 1-16 HA	
Schedule 1: 18	New	
PART 6: PROVISION OF TOILETS		
93(1)	Section 87(1) PHA	No
93(4)	Section 87(2) PHA	No
93(5)	Section 87(3)(c) PHA	No
94(1)	Section 87(3)(a) PHA	No

Annex D – Summary table of existing and planned tobacco / e-cigarette control measures in Wales

Date	Tobacco/e-cigarette control measure	Applicable UK country
2003		
January	Requirements for large textual health warnings on cigarette packs came into force.	UK wide
January	Bilingual primary school resource – Smoke Signals – distributed with training to all primary schools in Wales	Wales
February	First phase of the Tobacco Advertising and Promotion Act ⁴¹⁸ came into force, bringing to an end tobacco advertising on billboards and in the print media, and bans direct mail, internet advertising and new promotions.	UK wide
April	National smoking cessation service established (now Stop Smoking Wales)	Wales
June	UK signs WHO Framework Convention on Tobacco Control (FCTC.)	UK wide
November	EU-supported Smokefree Class Competition (SFC) starts with pupils aged 11-13, and runs for 6-months. The SFC ran every year from 1998-2011	Wales
2004		
Feb 2004-Dec 2005	Co-ordination of EU-supported youth smoking cessation programme as part of ENYPAT Framework programme	Wales
December	Tobacco advertising point of sale regulations are upheld after court challenge by tobacco industry and came into force. The only permitted tobacco advertising allowed is one single A5 sized advertisement, with one third of the surface area taken up by a health warning.	UK wide
2005		
March	Entry into force of WHO FCTC in the UK.	UK wide
June	The Corporate Health Standard (CHS) which is the Welsh Government's national quality mark for workplace health and well-being, was re-launched in 2005 with additional criteria in preparation for proposed smoke-free legislation. It reinforces the need for employers to meet the requirements of legislation and encourages them to support staff to give up smoking through	Wales

⁴¹⁸ Tobacco Advertising and Promotion Act 2002 c.36 - <http://www.legislation.gov.uk/ukpga/2002/36/contents>

	signposting to smoking cessation services, and implementing support systems, for instance via peer support networks.	
July	Final part of the Tobacco Advertising and Promotion Act 2002, banning tobacco sponsorship of global sports such as Formula One motor racing, came into force.	England, Wales Northern Ireland
July	European Directive banning cross-border tobacco advertising and sponsorship came into force.	UK wide
2006		
September	ASSIST peer support programme on smoking prevention starts to be rolled out to secondary schools in the most deprived areas. 50-60 schools are targeted each year.	Wales
2007		
April	Smokefree legislation came into force in Wales, covering virtually all enclosed work and public places.	Wales
July	VAT on stop smoking aids reduced to the lowest level possible (5% instead of 17.5%) coinciding with the implementation of smokefree legislation to maximise quitting.	UK wide
July	NICE technology appraisal published: <i>Varenicline for smoking cessation</i> ⁴¹⁹ .	England and Wales
October	Age of sale for tobacco increased from 16 to 18 years.	England and Wales
2008		
April	Significant new sanctions and the introduction of Restricted Premises Orders ("banning orders") introduced in England to deal with retailers who persistently sell tobacco to children.	England and Wales
June	UK Centre for Tobacco Control Studies established, bringing together a network of universities in the UK to focuses on research, policy development, advocacy and teaching and training in the field of tobacco control studies.	UK wide
October	Picture warnings requirements introduced for all tobacco products.	UK wide
November	Government published <i>Tackling Tobacco Smuggling Together</i> , a strategy to reduce illicit tobacco ⁴²⁰ .	UK wide
2009		
2010		
March	The Medicines and Healthcare Regulatory	UK wide

⁴¹⁹ National Institute of Clinical Excellence. Final appraisal determination: Varenicline for smoking cessation Issued: July 2007. <https://www.nice.org.uk/guidance/ta123>

⁴²⁰ Tackling Tobacco Smuggling Together. An integrated strategy for HM Revenue & Customs and the UK Border Agency. London. 2008

	Authority holds a consultation on the regulation of nicotine containing products, such as e-cigarettes.	
July	Welsh Network of Healthy School Schemes (WNHSS) National Quality Award ⁴²¹ introduced – schools are independently assessed for this after nine years' involvement in WNHSS. Section on substance misuse requires evidence of a whole-school approach to tobacco control.	Wales
November	Guidelines for implementation of Article 14 (Demand reduction measures concerning tobacco dependence and cessation) agreed at the FCTC's fourth Conference of the Parties in Uruguay.	UK wide
2011		
February	Consultation launched on draft Tobacco Control Action Plan for Wales	Wales
April	Government published <i>Tackling Tobacco Smuggling: Building on our success</i> ⁴²² , a renewed strategy to reduce illicit tobacco. Plan announced that the number of cigarettes holidaymakers may bring back from mainland Europe is to be cut by more than two-thirds.	UK wide
September	National Award criteria issued for Healthy and Sustainable Pre-School Scheme ⁴²³ , together with funding to support 500 pre-school settings. Criteria include the need for policies and procedures in relation to smoking.	Wales
November	New cigarette safety standards came into force. All cigarettes sold in the EU must now meet a reduced ignition propensity (RIP) requirement	UK wide
2012		
February	Sale of tobacco from vending machines is banned in Wales	Wales
February	Tobacco Control Action Plan for Wales, and associated Tobacco Control Delivery Plan, published; and Tobacco Control Delivery Board established. The plan has a vision of a smokefree Wales, and targets to reduce the proportion of the population that smoke to 20% by 2016 and 16% by 2020.	Wales
February	Fresh Start Wales publicity campaign on smoking in cars carrying children launched. This included extensive TV and radio advertising, outdoor events and outdoor advertising. It ran until March	Wales

⁴²¹ <http://wales.gov.uk/topics/health/improvement/index/quality/?lang=en>

⁴²² Tackling Tobacco Smuggling – building on our success. A renewed strategy for HM Revenue & Customs and the UK Border Agency. London. 2011.

⁴²³ <http://wales.gov.uk/topics/health/publications/health/guidance/scheme/?lang=en>

	2014.	
March	Tobacco tax increased by 5% above inflation.	UK wide
April	Regulations prohibiting the display of tobacco in large stores under the Health Act 2009 came into force ⁴²⁴ , ⁴²⁵ , ⁴²⁶ . All other shops have until April 2015 to comply with the legislation.	England and Wales
	Published first consultation on standardised packaging of tobacco products.	UK wide
August	Quit packs launched to support Fresh Start Wales campaign	Wales
2013		
March	Tobacco tax increased by 2% above inflation.	UK wide
April	New requirement added to Welsh Network of Healthy School Schemes National Quality Award: School grounds to be smoke-free.	Wales
April	Local Health Boards are set Tier 1 target on smoking cessation - to treat 5% of their smoking population with 40% carbon-monoxide-validated as quit at four weeks.	Wales
October	Stoptober runs in England for the second year, and in Wales for the first time.	England and Wales
November	Health Ministers asked eminent paediatrician Sir Cyril Chantler to undertake an independent review of the public health evidence on standardised packaging of tobacco products.	N/A
2014		
January	New requirement added to the Welsh Network of Healthy School Schemes National Quality Award: Policies in place which preclude the use of e-cigarettes on school premises and grounds.	Wales
March	The Children and Families Act 2014 is granted Royal Assent. The Act is the primary legislation making it an offence for an adult to buy cigarettes for anyone under 18 (proxy purchasing) (England and Wales) and giving the Government powers to introduce regulations	See column to the left

⁴²⁴ The Tobacco Advertising and Promotion (Display) (Wales) Regulations 2012 (S.I.2012No. 1285(W.163))

<http://www.legislation.gov.uk/wsi/2012/1285/contents/made>

⁴²⁵ The Tobacco Advertising and Promotion (Display of Prices) (Wales) Regulations 2012 (S.I.2012No. 1911(W.233))

<http://www.legislation.gov.uk/wsi/2012/1911/contents/made>

⁴²⁶ The Tobacco Advertising and Promotion (Specialist Tobacconists) (Wales) Regulations 2012 (S.I.2012No. 1287(W.164))

<http://www.legislation.gov.uk/wsi/2012/1287/contents/made>

	relating to: <ul style="list-style-type: none"> • standardised packaging for tobacco products. (powers UK wide) • smoking in a private vehicle carrying children. (powers for England and Wales) • setting an age of sale for nicotine products such as e-cigarettes. (powers for England and Wales) 	
March	Tobacco tax increased by 2% above inflation and annual duty increases of 2% above inflation will continue until the end of the next Parliament to help improve public health.	UK wide
April	Public Health White Paper issued for consultation. Proposals included the establishment of a tobacco retailers' register; banning smoking in non-enclosed public places – specifically hospital grounds, school grounds and children's playgrounds; delivery of internet sales to be handed over to only those over 18; and restricting use of e-cigarettes in enclosed public places.	Wales
April	Sir Cyril Chantler published his independent review into whether the introduction of standardised packaging is likely to have an effect on public health, particularly for children. The review concluded that if standardised packaging were introduced, it would have a positive impact on public health.	N/A
May	New European Tobacco Products Directive entered into force. Member states have two years to transpose the Directive into national law. New rules include: <ul style="list-style-type: none"> • Picture warnings to cover 65% of the front and back of cigarettes and roll-your-own tobacco packs. • Packs of less than 20 cigarettes are prohibited • Flavoured cigarettes, such as menthol, fruit and vanilla are prohibited • A regulatory framework for electronic cigarettes. 	UK wide
June	Published second consultation on standardised packaging of tobacco products.	UK wide
August	Notified draft regulations for standardised packaging of tobacco to the European Union.	UK wide
September	Consultation launched on smoking in cars carrying those under-18	Wales
October	Stoptober runs in England for the third year; and	England and

	in Wales for the second time.	Wales
December	Consultation launched on Age of Sale for Nicotine Inhaling Products	England and Wales
2015		
March	Regulations made on age of sale restrictions for nicotine inhaling products (such as e-cigarettes)	England and Wales
April	All remaining shops to remove tobacco displays.	England and Wales
June	Introduction of Public Health (Wales) Bill	Wales
October	Prohibition on smoking in cars carrying children to come into force	Wales
October	Proxy purchasing prohibition of tobacco and e cigarettes to come into force	England and Wales
2016		
	New European Tobacco Products Directive to come into force.	UK wide
	Standardised packaging of tobacco products due to come in to force	UK wide