REGULATORY APPRAISAL

NATIONAL HEALTH SERVICE, WALES

The Health and Social Care (Community Health and Standards) Act 2003 (Healthcare Inspections) (Wales) Regulations 2005

Background
1. The Health and Social Care (Community Health and Standards) Act 2003 received Royal Assent on 20 November 2003. The Act provides the Assembly with important new functions and powers to further its objectives of improving the overall standards of health and social care in Wales. In particular, section 70 of the Act provides the Assembly with the ability to undertake reviews of, and investigations into, the provision of healthcare by and for Welsh NHS bodies, together with ancillary powers of rights of entry under sections 72 and 73, power to require documents and information under section 74 and power to require explanations under section 75 of the Act.

2. The Assembly has delegated the functions to a new Assembly inspectorate - Healthcare Inspectorate Wales (HIW). HIW was set up on 1 April 2004 and will be commencing its (published) programme of reviews during 2004/05.

Purpose and intended effect of the Regulations
3. Under Section 75 of the Act, the Assembly may, by Regulations, require prescribed persons to provide the Assembly, or persons authorised by it, with explanations of any documents, records, or items in connection with inspections, reviews and investigations into the provision of health care in Wales.

4. The Assembly’s HIW need Regulations that will allow them to require persons to give appropriate explanations. At present they can only request explanations and, therefore, rely on the co-operation of such persons. Once Regulations are made, the provisions of section 75(3) of the Act will apply, making it an offence if someone fails to comply with any such requirement to provide an explanation. Any person who without reasonable cause fails to comply with any requirement to provide explanations is guilty of an offence and liable on summary conviction to a fine (not exceeding level 4 on the standard scale – currently £2,500 ).

Corresponding Regulations in England for the Commission for Healthcare Audit and Inspection (CHAI) and the Commission for Social Care Inspection (CSCI) under the 2003 Act came into force on 1 April 2004. HIW agreed its inspection programme of work in September 2004, and its full programme of work does not commence until 1 April 2005. Therefore, it is the intention to bring the Instrument into force on 31 March 2005.

5. Accordingly, the Health and Social Care (Community Health and Standards) Act 2003 (Healthcare Inspections) (Wales) Regulations 2005
will provide the Assembly, or any person authorised by it, with the power to require an explanation of:

- any documents, records, or items inspected, copied or provided under sections 72-74 of the Act;
- explanations of any information provided under sections 72-74; and
- any matters which are the subject of the exercise of Section 70 (Reviews and Investigations relating to Wales).

6. The effect of the Regulations will be to require compliance by anyone providing healthcare for Welsh NHS bodies (including persons employed within English NHS bodies who provide care commissioned by Welsh bodies on a cross-border basis), as well as the directors of NHS trusts and members of Local Health Boards. It will also extend to persons providing primary care, including GPs, dentists, ophthalmologists and pharmacists.

7. The following prescribed bodies or persons will be required to provide explanations:

- a Welsh NHS body (in practice an NHS Trust or Local Health Board);
- a chairman, member, director or employee of a Welsh NHS body;
- a member of a committee or sub-committee of a Welsh NHS body;
- a service provider;
- a chairman, director or employee of a service provider;
- any person who is assisting a service provider in the provision of health care for a Welsh NHS body;
- a local authority or a member or officer of a local authority;
- an elected mayor of a local authority within the meaning of section 39(1) of the Local Government Act 2000; and
- a person (other than any person listed above) who is assisting, has assisted, or is to assist a Welsh NHS body in the exercise of its functions.

Risk Assessment
8. At present HIW can only request explanations of any documents, records, or items in connection with inspections, reviews and investigations into the provision of health care in Wales from bodies or persons and, therefore, relies on their co-operation with such requests. Without the Regulations HIW would be powerless to force someone to provide explanations. By virtue of section 75(3) of the Act, if any body or person listed under the Regulations fails to comply with a request it will be an offence, liable on summary conviction to a fine (not exceeding level 4 on the standard scale—currently £2,500). Corresponding Regulations in England in respect of CHAI and CSCI came into force on 1 April 2004.

Options
9. It is not an option to rely on the goodwill and co-operation of bodies and persons in providing HIW with explanations of any documents, records, or items in connection with inspections, reviews and investigations into the provision of health care in Wales. Failure to make these Regulations will
mean that HIW is unable to undertake fully and effectively its functions under the Act.

Benefits
10. The Regulations will benefit service users since it will mean HIW will be able to undertake its functions in an unfettered way. In addition, Welsh NHS bodies and staff will also benefit given the additional clarity in terms of those individuals who may be required to provide explanations.

Costs
11. There are no financial implications for the Assembly arising from these Regulations. HIW will not incur any additional costs as a result of these Regulations and no additional monies have been allocated to HIW as a result of these Regulations. The financial costs of HIW are being met from the existing Commission for Healthcare and Improvement and Clinical Effectiveness budgets held within the Public Health Laboratory Service /National Biological Standards Board and Central Initiatives Budget Expenditure Line.

Consultation
With Stakeholders
12. It was not considered necessary to consult upon the Regulations for the following reasons:-
   • the Assembly has no discretion in the manner in which the Regulations would be applied - effectively their purpose is to implement the provisions of section 75 of the 2003 Act, by making it a requirement that certain classes of people must provide explanations to the Assembly’s Healthcare Inspectorate;
   • the Assembly has little discretion in determining the category of persons it should prescribe as being required to provide explanations, these being persons providing healthcare within or for Welsh NHS bodies or persons responsible for the provision of such care;
   • the principles behind healthcare inspection within Wales, as provided for in the 2003 Act, were subject to extensive debate in Plenary on 10 February 2004; and
   • HIW has also discussed its specific role with a range of its key stakeholders in workshops and meetings during 2004.

13. Additionally, consultation was not considered necessary on the basis that the making of the Regulations does not involve policy development (since this has already been developed through the Wales clauses in the Health and Social Care (Community Health and Standards) Act 2003) and also does not involve identifying needs and priorities to be addressed by Government or public bodies.

With Subject Committee
14. There has been no prior scrutiny of the proposed Instrument by the Health and Social Services Committee. The Instrument was, however, notified to the Committee via the list of forthcoming legislation on 6 October 2004
(HSS(2)-11-04 (p.5a), item no: HSS44(04)), but was not identified for detailed scrutiny.

Review
15. The Regulations and their effect will be monitored as part of the ongoing work of HIW.

Summary
16. The Regulations require prescribed persons to provide the Assembly with explanations of any documents, records, or items in connection with inspections, reviews and investigations into the provision of health care in Wales. There are no costs associated with the implementation of the Regulations. The Regulations will benefit service users since they will mean HIW will be able to undertake its functions in an unfettered way. In addition, Welsh NHS bodies and staff will also benefit given the additional clarity in terms of those individuals who may be required to provide explanations. Corresponding Regulations are already in force in England for CHAI and CSCI.