Explanatory Memorandum to The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008

This Explanatory Memorandum has been prepared by Department of Health and Social Services and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

(i) **Description** - These Regulations contain measures relating to arrangements underpinning the safe management and use of controlled drugs within the sphere of operation of specified health service bodies in Wales.

(ii) **Matters of special interest to the Subordinate Legislation Committee** – None

(iii) **Legislative Background** – The powers to make these Regulations are contained in sections 17, 18, 20(3) and (7) and 79(3) of the Health Act 2006. These functions were conferred on the National Assembly for Wales and transferred to the Welsh Ministers under paragraph 30 of Schedule 11 to the Government of Wales Act 2006. The Regulations will follow the negative procedure.

(iv) **Purpose and intended effect of the legislation** - The Regulations introduce measures for the safe management of controlled drugs as recommended by the Fourth Report of the Shipman Inquiry. The Regulations prescribe a number of health care bodies as designated bodies and these are required to appoint accountable officers. Accountable officers are given a number of functions relating to the safe management and use of controlled drugs within that body's sphere of operation. These include the establishment of arrangements relating to the safe use of controlled drugs, safe disposal arrangements and auditing arrangements. As well as being given functions in relation to their own designated bodies, accountable officers are given functions in relation to health care professionals and others whose work involves the management and use of controlled drugs, for which their designated body is responsible. These responsibilities include maintaining records of and investigating concerns and taking appropriate action where there are well-founded concerns. Accountable officers for Local Health Boards (LHBs) also have particular responsibilities for setting up local intelligence networks, relating to the management and use of controlled drugs, for their area. Part 3 contains arrangements in relation to periodic inspections of premises used for the management and use of controlled drugs, where these issues would not be dealt with as part of other health and social care inspections, and other measures in relation to powers of entry. Part 4 deals with co-operation between a number of listed health care bodies and other organisations and in particular contains detailed arrangements with regards to the disclosure of information between the bodies in connection with the identification of cases where action may need to be taken against individual. There are record keeping

requirement and duties with regard to occurrence reports, which are quarterly statements that accountable officers must make about details of concerns that their designated body has.

(v) **Implementation -** The legislation requires designated bodies to enable broadly similar arrangements to England and Scotland for monitoring controlled drugs and the same arrangements for giving authority for the destruction of controlled drugs. The arrangements in Wales for monitoring of controlled drugs in primary care will be developed locally by LHBs in conjunction with other bodies with an interest in controlled drugs, police chemist inspection officers, local substance misuse teams and HIW

(vi) **Consultation –** This is the third phase of regulations implementing the recommendations of the Fourth Report of the Shipman Enquiry. The UK Governments response Safer Management of Controlled Drugs was published in December 2004, consultation on a UK basis was undertaken in 2005. The first phase was of regulation which took place in 2005 with amendment to non devolved matters by the Home Office. The second wave of regulation in December 2006 brought in new record keeping requirements for bodies and a requirement to keep a controlled drugs register.

(VII) **Regulatory Impact Assessment –**

Options (for achieving the policy objective – as set out in paragraph (iv) above) -

1. Introduce a requirement for responsible bodies to appoint an Accountable Officer for the safe management of controlled drugs.

Accountable officers would be given a number of functions relating to the safe management of the use of controlled drugs. These include the establishment of arrangements relating to the safe use of controlled drugs, safe disposal arrangements and auditing arrangements. Accountable officers for Local Health Boards would be responsible for setting up local intelligence networks relating to the management and use of controlled drugs in their areas. Local intelligence networks would bring together organisations with an interest in controlled drugs in the area and help with sharing of information and coordination of activity between organisations.

2. Do nothing. This would leave no single person accountable for the safe management of controlled drugs within organisations. The lack of communication, sharing of information and coordination of activity between bodies with an interest in controlled drugs was highlighted in the 4th Report of the Shipman Inquiry. Welsh Ministers would be open to criticism for not implementing Shipman inquiry recommendations and not putting in place appropriate safeguards to protect patients Bodies in Wales.

a) **Benefits** –

- Option 1 will put in place valuable safeguards for the protection of the public as recommended by the Shipman Inquiry. Better communication, networking, sharing of information and coordination of activity between existing bodies will result in benefits to society in general.

- Option 2 will leave some weaknesses identified by the Shipman Inquiry unaddressed. Important safeguards for patients will not be implemented. Bodies in Wales will not be operating to the same level of safety with regard to controlled drugs as other areas of the UK.

b) **Costs** – There are no significant costs envisaged for either option. Option A creates a role of Accountable officer, which should be undertaken by someone of sufficient seniority to ensure the designated body has appropriate processes in place for the management of controlled drugs. The regulations will formalise many procedures that already exist and make a single person accountable for them. In LHBs the Accountable Officer role will be undertaken by the Chief Executive.

c) **Competition Assessment** – There are no effects on competition from either option.

d) **Consultation** – Option A is the third phase of regulations implementing the recommendations of the Fourth Report of the Shipman Enquiry. The UK Governments response Safer Management of Controlled Drugs was published in December 2004, consultation on a UK basis was undertaken in 2005. The first phase of regulation took place in 2005 with amendment to non devolved matters concerning controlled drugs by the Home Office. The second wave of regulation took place in December 2006 with the introduction of the Misuse of Drugs Wales Regulations 2006.

e) **Post implementation review –** Policy on the safe management of controlled drugs will continue to be reviewed to ensure appropriate safeguards are in place for the protection of society in general.

f) **Summary** – There are no significant costs envisaged from these Regulations. The benefits are to both the bodies themselves in terms of assurance that robust processes exist for the safe management of controlled drugs and to society in general.