EXPLANATORY MEMORANDUM TO

THE CONTROLLED DRUGS (SUPERVISION OF MANAGEMENT AND USE) REGULATIONS 2006

2006 No. 3148

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1. The Regulations set out the requirements for certain NHS and independent healthcare bodies to appoint an Accountable Officer and describe the duties and responsibilities of Accountable Officers to improve the management and use of controlled drugs. The regulations also require specified bodies to co-operate with each other, including with regard to the sharing of information, about concerns about the use and management of controlled drugs, and set out arrangements relating to powers of entry and inspection. The enhanced governance arrangements for controlled drugs form a key part of the Government's response to fourth report from the Shipman Inquiry, which focussed on controlled drugs.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1. None

4. Legislative Background

4.1. These Regulations make the first use of powers in Chapter 1 of Part 3 of the Health Act 2006. Chapter 1 provides for the making of regulations to require designated bodies to appoint Accountable Officers, and for responsible bodies to share information about concerns about the use and management of controlled drugs. It also gives police officers and other authorised persons powers of entry and inspection in relation to records and stocks of controlled drugs. In relation to England, the Healthcare Commission and the Commission for Social Care Inspection, and in relation to England and Scotland the Royal Pharmaceutical Society of Great Britain, have existing inspection powers under other legislation, and will incorporate assessment of meeting the requirements of these Regulations into their other inspection and assessment arrangements.

4.2. The Misuse of Drugs Act 1971 and the Misuse of Drugs regulations 2001 subject certain drugs, 'controlled drugs', to special legislative control because of their potential to be abused and cause harm. Individuals retain responsibility for following this legislation but Accountable Officers have an overarching responsibility to ensure that their

organisation or those working on its behalf have arrangements in place to comply with misuse of drugs legislation.

5. Extent

5.1. This instrument applies to England and Scotland.

6. European Convention on Human Rights

6.1. As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1. The Shipman Inquiry exposed a number of loopholes in the management of controlled drugs, and these regulations form part of the action programme set out in *Safer management of controlled drugs, the Government's response to the Fourth Report of the Shipman Inquiry*. The action programme and the relevant sections of the Health Act are designed to strengthen the arrangements for the safe management of controlled drugs in healthcare settings. Controlled drugs are subject to special legal controls because of their potential for abuse, causing harm.

7.2. Regulation is necessary to respond to the findings of the Shipman Inquiry and to ensure that the management of controlled drugs is tightened up to reduce the risk of harm to patients, and the risk of illegal diversion.

7.3. The Regulations specify that all NHS healthcare organisations and independent hospitals that provide services that may involve the management or use of controlled drugs will be required to appoint or nominate an Accountable Officer to ensure that the organisation has proper arrangements in place for the safe management and use of such drugs. In NHS primary care, Accountable Officers of Primary Care Trusts and Health Boards will ensure that their contractors, such as GP practices, have appropriate arrangements in place.

7.4. Accountable Officers are required to be of sufficient seniority and suitably removed from the day-to-day management of controlled drugs. Under the regulations, they are given certain duties and responsibilities to ensure safe management and use of controlled drugs. These include monitoring and auditing their organisation's management and use of controlled drugs, in some cases carrying out periodic inspections, investigating concerns about the use of controlled drugs, and taking appropriate action.

7.5. The Regulations also set out the bodies which are required to share information about controlled drugs and to co-operate generally with regard to cases where intervention may be necessary. The information-sharing requirements are intended to ensure concerns about the management and use of controlled drugs by health and social care

professionals can be appropriately shared, and action co-ordinated, in order to protect the public from harm.

7.6. In order to ensure that Accountable Officers can fulfil their responsibilities to ensure the safe management of controlled drugs, for example where they have concerns about storage, they have powers of entry and inspection in relation to the premises used in connection with the management or use of controlled drugs. Routine inspections and assessments of controlled drugs will however only be needed for bodies that are not already subject to parallel inspections. Community pharmacies will be assessed by the Royal Pharmaceutical Society, NHS Trusts will be assessed by the Healthcare Commission and care homes will be assessed by the Commission for Social Care Inspection.

7.7. The principles of the new governance arrangements set out in the regulations were subject to a three-month public consultation. 84 responses were received; the majority felt that the right balance had been achieved between strengthening controls and ensuring patients had access to the drugs they clinically required. The majority of responses also felt that the proposals made best use of existing mechanisms. The results of the consultation are on the Department of Health website: (http://www.dh.gov.uk/Consultations/ResponsesToConsultations/ResponsesToConsultationsDocumentSummary/fs/en?CONTENT_ID=4125988&chk=WmmUZv)

7.8. The regulations have also been shared in draft with the Controlled Drugs Advisory Group, the government's external stakeholder group which involves representatives from a range of organisations, including NHS bodies, the Healthcare Commission, Commission for Social Care Inspection, professional regulatory bodies, and the police.

8. Impact

8.1. A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

9.1. Helen Causley and Liz Dimond at the Department of Health (Tel: 020 79723113/ 020 79725397 or e-mail: helen.causley@dh.gsi.gov.uk/ elizabeth.dimond@dh.gsi.gov.uk) can answer any queries regarding the instrument.

FINAL REGULATORY IMPACT ASSESSMENT – CONTROLLED DRUGS (SUPERVISION OF MANAGEMENT AND USE) REGULATIONS

Purpose and intended effect

Objective

1 To safeguard patients, improve the quality of the management and use of controlled drugs (CDs) and minimise the risk of diversion of CDs to illegitimate uses, in both England and Scotland.

Background

2 Harold Shipman diverted large quantities of CDs for his own criminal purposes. CDs are medicines subject to special legislative controls because of their potential to be misused, causing harm. The Shipman Inquiry's Fourth Report[1] gives a detailed analysis of the shortcomings in the systems then current in the NHS that enabled him to get away with these practices without detection for such a long period. The Inquiry concluded that significant changes were needed in order to provide patients with proper safeguards, to deter future criminal activity, and to maximise the likelihood that any future activity of this kind would be speedily detected and stopped.

3 Significant resources are already devoted to monitoring and inspecting some aspects of the use of CDs in the NHS, but the Shipman Inquiry pointed to:

— some serious gaps (use of CDs in GP practices, the private sector),

— uneven standards of training for inspectors,

— a lack of overall coordination, with no systematic arrangements for integrating the inspections currently carried out by the Royal Pharmaceutical Society of Great Britain (RPSGB) and the police Chemist Inspection Officers (CIOs).

4 The Inquiry recommended setting up a new integrated inspectorate with members drawn from both health professional and investigative backgrounds.

Rationale for Government intervention

5 Fortunately, criminal behaviour on the scale shown by Harold Shipman is extremely rare – though there have been a number of other allegations of deliberate harm by healthcare professionals to their patients. Diversion of CDs to feed personal abuse or for financial gain is however more common. Experience of professionals working in this field suggests that most Primary Care Trusts in England may at any one time be dealing with up to 5 poorly performing doctors of whom one third may have a problem of substance abuse.

6 We agreed with the Inquiry that the current arrangements for monitoring and inspecting use of CDs are inefficient and do not provide an adequate level of

safeguard for patients. Changes in the NHS since Shipman was practising such as the development of clinical governance mean that there is now less risk of such serious abuse escaping detection for so long. We think though that the risk is still significant and justifies tightening up current arrangements. Failing to act would mean that shortcomings would still exist risking the diversion of controlled drugs and potential harm to patients. The risk to patients could potentially affect any member of the population using health or social care. In addition, better arrangements for quality assessment and quality improvement should lead to better use of CDs generally resulting in better care for all patients needing CDs.

Consultation

6 This legislation was developed as part of the government's action programme on controlled drugs through four working groups covering all relevant stakeholders. In addition, the government took account of helpful work from the Advisory Council for the Misuse of Drugs' Shipman Committee and from the National Prescribing Centre, both of which had carried out widespread consultation in developing their proposals.

7 Within government, the Department of Health has worked closely with the Home Office. We have also kept in close touch with colleagues in the health directorates of the devolved administrations, and shared our developing proposals with the Department for Education and Skills, the Department for the Environment, Food and Rural Affairs, the Healthcare Commission, the Commission for Social Care Inspection, Monitor, and the central departments.

8 We have set up a group of relevant stakeholders to steer implementation of the strengthened monitoring and inspection arrangements. This group includes representatives from the NHS and, professional bodies. We also held a public consultation (closed 30th September 2005) on the detail of how these arrangements will work.

Options

9 ***No government intervention***
We have considered the 'do nothing' option, but concluded that in the light of the Shipman Inquiry's findings this would be unacceptable. We would be failing to safeguard patients, and would be doing nothing to improve the quality of the management of CDs in the NHS, social care and private healthcare sector.

10 The existing system of controls over the use of CDs in health and social care has grown up over many years, and has not adapted to changes in the NHS and in the wider context. This created the loopholes that Shipman so skilfully exploited. There are particular gaps in our information on private prescribing, on the use of CDs within GP practices, and in the "audit trail" for CDs administered in patient homes.

11 We also considered the option of proceeding by NHS guidance rather than by creating new statutory responsibilities. We do not consider that this would sufficiently emphasise the importance the government places on tightening up the management of CDs in all health and social care organisations. Also, NHS guidance would not have to be taken into account by private sector organisations. We therefore endorse the view of the Shipman Inquiry that "do nothing" is not a viable option, and that action is needed to reduce the risk of harm to patients and the risk of illegal diversion of CDs.

12 Apart from the "do nothing option", we considered two main options:

Option 1 - A new external inspectorate as proposed by the Inquiry.
This would comprise small multi-disciplinary teams, operating regionally but co-ordinated nationally. Each team would include pharmacists, doctors, inspectors and investigators. The inspectorate would be responsible for inspecting arrangements for the safe management of controlled drugs in pharmacies, dispensaries and surgeries. Compliance would be through legislation.

Risks
Such a system risks duplication and over-regulation. Most importantly, it risks not making the best use of local information on controlled drugs use and management. These risks could be mitigated to some extent by linking the new inspectorate to local healthcare structures and creating Memoranda of Understanding between the various organisations which currently inspect healthcare bodies. Nonetheless, the risks would still be present.

Unintended consequences
An unintended consequence may be that assessing performance on controlled drugs' use and management is seen solely as the inspectorate's role, making improvements less likely.

Option 2 - A system based on current processes in the NHS, with internal quality assessment delivered through clinical governance processes and external quality assessment from the Healthcare Commission, supplemented by new arrangements for collaboration and information sharing between NHS and "partner" organisations (police, health regulatory bodies, social care inspectorates etc). The key innovations would be:

— a new statutory duty on all healthcare organisations to nominate a specific individual (who will need to be sufficiently senior and suitably experienced) to take responsibility for the safe and effective use of CDs in the organisation

— a new statutory duty of collaboration on all healthcare and partner organisations to share information about potential controlled drugs offences.

Compliance would be through legislation; and through the existing inspectorates: Healthcare Commission, Commission for Social Care Inspection and Royal Pharmaceutical Society.

Risks
The system risks being seen as more complicated than creating a single inspectorate. This risk has been mitigated by producing guidance, working with stakeholders and holding a series of regional workshops to explain the new arrangements.

Unintended consequences
We have worked closely with stakeholders and do not foresee any unintended consequences.

Costs and benefits

Sectors and groups affected

14 Both options would benefit all patient groups and health and social care professionals by lessening the risk of diversion of controlled drugs.

Costs and benefits

15 *Option 1 – costs*
Option 1 would establish a separate inspectorate which would build up expertise in controlled drugs matters. It might incur costs of between £18 and 20m pa to cover costs such as staffing, development of methodologies, data collection, and travel and accommodation. The Government considers that this approach may duplicate effort and present an additional burden to health and social care organisations as health and social care organisations are already assessed by other organisations such as the Healthcare Commission and Commission for Social Care Inspection.

Option 1 – benefits
This option would benefit all patient groups and health and social care professionals by lessening the risk of diversion of controlled drugs. It is not considered to have any race equality impact.

16 *Option 2 – costs*
Option 2 involves co-ordinating existing inspection activity and will minimise the risk of duplication. It works “with the grain” of current NHS processes for delivering clinical quality improvements more generally, and is more likely to result in overall improvements in the effective and safe use of CDs in patient care. The net costs for Option 2 are estimated at set up costs of £1m and running costs of £4m pa. These costs include costs associated with monitoring and inspection, restrictions on prescribing and enhancements to the audit trail.

Option 2 – benefits

The new arrangements will work alongside local systems and allow for some local variation. This could be seen as a risk as well as a benefit, but variation will be mitigated by guidance, templates and training. This option would benefit all patient groups and health and social care professionals by lessening the risk of diversion of controlled drugs. It is not considered to have any race equality impact.

Equity and fairness

17 We propose to apply the new duties to all healthcare organisations (Primary Care Trusts, NHS Trusts, NHS Foundation Trusts, Health Boards, Special Health Boards, independent hospitals subject to statutory regulation). We therefore believe that the new arrangements are equitable as between private and public healthcare organisations providing comparable services.

Impact on small firms

18 The requirement to appoint an "Accountable Officer" will only apply to public sector organisations and independent hospitals subject to statutory regulation. Some smaller independent hospitals may fall within the "small firms" definition but they are likely to be few. For any such organisation already complying with the provisions of the Misuse of Drugs Act 1971 there should be no additional impact other than the responsibility to nominate an "Accountable Officer". The duty of collaboration is likely to fall mainly on public sector organisations; any private sector organisation aware of potential CD offences by members of its staff would already be expected under the law and professional codes to share its concerns with the proper authorities and to collaborate with any subsequent investigation.

Competition

19 We have applied the competition filter test and are satisfied that the new regulation:
— would have no differential effect between firms,
— would not affect market structure,
— would not discriminate against new entrants
— would not impact on the range of services or location of private healthcare providers.

20 So although the private healthcare sector is concentrated and marked by rapid technological change, we conclude that detailed assessment is not required.

Enforcement, sanctions and monitoring

21 Enforcement would be through existing mechanisms (the Healthcare Commission for most NHS organisations and for private healthcare organisations, PCT contracts for NHS Foundation Trusts) and sanctions could in extreme cases result in losing authority to continue operating. The powers of entry and inspection set

out in the Health Act 2006 are also enforceable by the police. The bodies responsible for appointing Accountable Officers will be required to have arrangements in place to remove them from office if they are unfit to perform the role.

Implementation and delivery plan

22 We have taken a project planning approach to delivering these new monitoring and inspection arrangements as part of the Government's action programme on controlled drugs. Implementation and delivery plans are reviewed regularly by a project board and the over-arching steering group.

Post-implementation review

23 We intend to implement the new arrangements for monitoring and inspection from January 2007. We propose to monitor implementation and the impact on NHS frontline staff, private and voluntary organisations through the Healthcare Commission who will report on the operation of the new arrangements from the financial year 2007-2008. We are also monitoring the impact of these changes and other parts of the Government's action programme through an overarching implementation steering group with all relevant stakeholders represented. Any changes in the use of controlled drugs are also being monitored through prescribing information.

Summary and recommendation

22. Our conclusion is that to do nothing, in the light of the findings of the Shipman Inquiry, would be unacceptable; we would be failing to safeguard patients and we would be doing nothing to improve the general standards of the management of CDs in the NHS and in the private healthcare sector. Whilst supporting the underlying objective of the Shipman Inquiry's recommendation to create a separate controlled drugs inspectorate, we feel that the arrangements in the Health Act 2006 and associated regulations will work better with the grain of developments in healthcare to improve quality.

Declaration and publication

'I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs'.

Signed by the responsible minister

Andy Burnham…….
Date **21st November 2006**…….

Contact Point for queries

Helen Causley /Liz Dimond
Medicines, Pharmacy and Industry Group
Department of Health
406A Skipton House
80 London Road
London
SE1 6LH5

helen.causley@dh.gsi.gov.uk; elizabeth.dimond@dh.gsi.gov.uk