EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS AND MISUSE OF DRUGS (SAFE CUSTODY) (AMENDMENT) REGULATIONS 2007

2007 No. 2154

1. This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by command of Her Majesty.

2. Description

2.1 This instrument amends the Misuse of Drugs Regulations 2001 (the 2001 Regulations) in order (1) to implement further elements of the action programme published in *Safer Management of Controlled Drugs* (December 2004), the Government's Response to the Fourth Report of The Shipman Inquiry, and (2) to introduce certain other changes to the 2001 Regulations which have been the subject of formal consultation with the Department of Health, RPSGB and other interested stakeholders. It also amends the Misuse of Drugs (Safe Custody) Regulations 1973 (the 1973 Regulations) to update the term 'nursing home' to 'care home'.

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

3.1 None

4. Legislative Background

4.1 This instrument is made under sections 7, 10 and 31 of the Misuse of Drugs Act 1971 ("the Act"). The Act received Royal Assent on 27 May 1971. Section 31(3) of the Act provides that the Secretary of State may not make regulations under the Act except after consultation with the Advisory Council on the Misuse of Drugs (ACMD). ACMD has been consulted and approved the amendments to the 2001 Regulations and the 1973 Regulations. The changes have been subject to a public consultation that ran for 8 weeks from 11 May 2007 to 6 July 2007. The period of consultation was curtailed as many of the proposed changes had already been the subject of consultation in July 2005.

4.2 *Safer Management of Controlled Drugs* set out a series of proposed changes to the 2001 Regulations. Many of these changes have already been introduced (The Misuse of Drugs and Misuse of Drugs (Supply to Addicts)(Amendment) Regulations 2005, the Misuse of Drugs (Amendment No 2) Regulations 2006 and the Misuse of Drugs (Amendment No 3) Regulations 2006)). The amendments made in this instrument in respect of the requirements for requisitions and giving Accountable Officers the authority to appoint persons to witness the destruction of controlled drugs continues the implementation process.

4.3 Not all the changes in this instrument come into force at the same time. The changes relating to the Controlled Drugs Register (CDR) will not come into force until 1 February 2008. Implementation has been delayed to give those who maintain CDRs (including those manufacturers who are responsible for the software of computerised registers) adequate time to adapt and/or prepare for the changes. The re-

scheduling of Midazolam and the new requirements in respect of requisitions come into force on 1 January 2008 in order to allow healthcare professionals to prepare for the necessary changes. The requirement that the originals of Schedule 1-3 private prescriptions (rather than copies) must be sent to the relevant NHS agency comes into force on 1st September 2007, to coincide with changes to NHS legislation which currently require such originals to be returned by the pharmacy.

4.4 Whilst the Home Office has the legislative responsibilities for the Misuse of Drugs Act 1971 and its associated legislation, the policy area is shared with the Department of Health and this instrument has been drawn up in consultation with them.

5. Extent

5.1 This legislation applies to England, Wales and Scotland.-

6. European Convention on Human Rights

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

7. Policy Background

7.1
Policy
The miscellaneous changes being made to the 2001 Regulations described in more detail below have the overall objective of strengthening the systems by which controlled drugs are managed and audited. In formulating the policy that underpins these amendments, full consideration has been given to the fundamental need to ensure that patients have access to the controlled drugs they require in the course of their treatment.

Consultation
Over 150 interested stakeholders within the health, social care and pharmacy sectors were sent a copy of the consultation, which was also made available on the Home Office website. The consultation period ran from 11 May to 6 July and responses were received from 78 interested stakeholder organisations and individuals. The overwhelming majority (96%) were in favour of the proposals. A brief background note on the consultation can be found in the final Regulatory Impact Assessment which is attached.

Guidance
The Department of Health, in consultation with the Home Office will shortly be issuing guidance to accompany the legislative changes to the Controlled Drugs Register and Schedule 1-3 controlled drug requisitions.

Consolidation
There have now been a series of amendments since the Regulations were last consolidated in 2001. The Home Office is fully aware that a consolidation of the Regulations would help to provide greater clarity and convenience, although a timetable for this work has yet to be set.

Giving authority to the Accountable Officer to authorise persons to witness the destruction of controlled drugs

7.2 Currently under Regulation 27 of the 2001 Regulations, those persons required to maintain a Controlled Drugs Register cannot destroy surplus or out of date controlled drugs in Schedules 1-4 without the destruction being witnessed by an authorised person. This destruction normally applies to Schedule 2 controlled drugs only and at present only the Secretary of State can authorise a person or class of persons to act as witnesses.

7.3 The Health Act 2006 introduced the Accountable Officer as the person responsible for monitoring and managing the safe and effective use of controlled drugs within their organisations. The 2001 Regulations will now give the Accountable Officer the same authority as the Secretary of State to authorise a person or a group of persons to witness the destruction of surplus or out of date controlled drugs. He or she will be expected to ensure that there are sufficient authorised witnesses in place in order to prevent a build-up of these drugs waiting to be destroyed and thereby minimise the risk of diversion and misuse.

7.4 The Accountable Officer is not be authorised to personally witness destruction of controlled drugs as he or she must be completely independent from the day to day management of controlled drugs. He/she will be expected to appoint a witness with sufficient authority within the organisation.

Introducing new requirements for requisitions for human use used for the supply of Schedule 1-3 controlled drugs in the community

7.5 Requisitions are required where controlled drugs in Schedules 1-3 of the 2001 Regulations are supplied otherwise than on prescription – for example by dispensing doctors and pharmacists. The 2001 Regulations will now require the original requisitions for all Schedules 1-3 controlled drugs supplied for human use must be sent to the NHS Business Service Authority (or its equivalent in the Devolved Administrations) for monitoring and analysis. Wholesale dealers and persons responsible for the dispensing and supply of medicines at a hospital or care home are exempt from this requirement.

7.6 The supplier will be required to provide his or her name and address on requisitions for Schedule 1-3 drugs supplied in the community for human use for both NHS and private requisitions. The supplier’s name and address can be added by means of a stamp.

7.7 This requirement continues the process of tightening the audit trail for controlled drugs, so that local and regional health officials can gain a better understanding of the pattern of drug usage and supply within the community, by closing one of the few remaining gaps in the monitoring process around controlled drugs. This change mirrors the arrangements already in place for NHS and private prescriptions.

Allowing Operating Department Practitioners (ODPs) to possess and supply controlled drugs in a hospital, theatre or other department

7.8 Operating Department Practitioners (ODPs) are regulated under the Health Professions Order 2001. Many hospital operating departments are now staffed by ODPs, although their role with respect to controlled drugs is limited because of the restrictions in the 2001 Regulations. The Government is aware that this can hinder the smooth and effective running of operating departments and prevent the optimum management of resources for the better treatment of patients.

7.9 In order to support the improvement of peri-operative care of patients, the amendments in this instrument allows ODPs to order, possess and supply any controlled drug in a hospital ward, theatre or other department for the purposes of administration to a patient in accordance with the directions of a doctor, dentist, nurse independent prescriber (in respect of the limited range of controlled drugs they are authorised to prescribe) and a supplementary prescriber acting under a clinical management plan. The authority to be given to ODPs sits alongside that of the authority given in the 2001 Regulations to the senior registered nurse in the same settings.

7.10 The Association of Anaesthetists, the Royal Pharmaceutical Society of Great Britain and the Association of Operating Department Practitioners support this move. It is considered that the risks to patient safety as a result of allowing ODPs to order, possess and supply controlled drugs will be minimal. ODPs have a broad range of healthcare skills and are trained to a high level that is reflected in the care and support they provide to patients in the peri-operative treatment period. ODPs must act within the Health Professions Council's Standards of Conduct, Performance and Ethics and Standard Operating Procedures should be in place.

Replacing the term "sister" with "Senior Registered Nurse" and "nursing home" with "care home"

7.11 The term "sister" is now largely obsolete in the modern health service. The instrument updates the 2001 Regulations to reflect current terminology, namely 'senior registered nurse'. The term "nursing home" is also being replaced with the current terminology, "care home" in both the 2001 Regulations and the 1973 (Safe Custody) Regulations.

Extending the authority of senior registered nurses to supply controlled drugs in certain settings for the purpose of administration in accordance with the directions of an nurse independent prescriber or supplementary prescriber under a clinical management plan .

7.12 This instrument amends the Regulations so that nurse independent prescribers (NIPs) (within their authority) and supplementary prescribers (acting under a clinical

management plan) can direct the senior registered nurse (and ODP) to supply controlled drugs within the hospital ward, theatre or other department for the purposes of administration. Previously the sister (now senior registered nurse) was only able to supply etc on the authority of a doctor or dentist. This amendment reflects the introduction of NIPs for the prescribing of certain controlled drugs for certain purposes.

Removing the requirement to maintain a Controlled Drug Register (CDR) in its prescribed form as currently set out in Schedule 6 of the 2001 Regulations and replace it with a requirement to record designated fields of information in the CDR.

7.13 The 2001 Regulations impose strict requirements in respect of recordkeeping for Schedule 1 and 2 controlled drugs. These requirements are imposed in order to ensure that a clear accounting trail, capable of inspection and audited, of those drugs considered to have the greatest potential for misuse and diversion is maintained All those healthcare professionals and others who are authorised to supply controlled drugs i.e. doctors, dentists, vets, pharmacists, licensed pharmaceutical manufacturers and wholesalers must maintain a CDR and enter details of all Schedule 1 and 2 controlled drugs obtained and supplied. Currently, regardless of whether a CDR is kept in a paper or electronic form, the register must follow the format set out in Schedule 6 of the 2001 Regulations.

7.14 The Government believes that the risks associated with Schedule 1 and 2 controlled drugs justify the need to retain these recordkeeping requirements. However, it accepts that the need to comply with a prescribed format has become too restrictive in the modern healthcare setting and consequently problematic, particularly with use of electronic registers.

7.15 This instrument requires Separate pages in the CDR to be used for each strength and form of drug and removes the prescribed form of the CDR set out in Schedule 6. In its place, it imposes a requirement to record fields of information under specified column headings/titles in a CDR, to ensure consistency in recording and provide a sufficient level of recognition across the sector, for both those maintaining and inspecting a CDR. The fields of information now required to be recorded are largely unaltered, but will include requirements in respect of the identity of the person collecting Schedule 2 controlled drugs on prescription. (Consequential amendments to the Misuse of Drugs (Amendment No. 2) Regulations 2006 and to the Misuse of Drugs (Amendment No. 3) Regulations 2006 are being made to omit prospective changes to the prescribed form of the CDR in relation to these latter requirements.) At Regulation 4(9) of the new S.I., the prescribed headings to be used in the CDR use abbreviated terms. For example the term “patients rep” is used. Although unusual for regulations to use such abbreviations, they are used in this context to ensure that the headings are as succinct as possible so that the CDR does not become too unwieldy for practitioners. The term “patient’s rep” is well understood by stakeholders.

7.16 This new approach to the recording of information in CDRs will improve monitoring and inspection, and allow sufficient flexibility to accommodate further technological innovation and change.

Re-scheduling Midazolam from Schedule 4 to Schedule 3 of the 2001 Regulations

7.17 Midazolam is a short acting sedative in the benzodiazepine family of drugs that is used for pre-medication in minor surgical procedures such as endoscopies or vasectomies. It is currently available for use either orally or by injection. It is currently controlled as a Schedule 4 Part 1 drug under the 2001 Regulations 2001, a fairly light regime of controls. However, after Healthcare Commission concerns that the drug was being used inappropriately, the ACMD recommended that Midazolam should be rescheduled as a Schedule 3 controlled drug, and thereby be subject to a higher level of control, monitoring and audit, with the intention to reduce the risk of diversion and misuse.

7.18 As a Schedule 3 controlled drug, Midazolam is subject to Regulations 14, 15, 16, 18, 22, 23, 24, 26 and 27 of the 2001 Regulations. In particular, a written requisition must be provided when it is supplied or obtained otherwise than on prescription; the form of Midazolam prescriptions must comply with the specific requirements of Regulation 15 and all private prescriptions for Midazolam must be written on a standardised form and include the private prescribers identification number.

7.19 Midazolam can still be supplied and administered under a Patient Group Direction. It will also continue to be exempt from the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973 because the level of risk for diversion is not, on anecdotal evidence, sufficiently high to warrant it. It would also restrict the ability of healthcare professionals to have immediate access to the drug when required. However, this exemption will continue to be monitored.

Requiring original prescriptions (other than health or veterinary prescriptions) relating to Schedule 1 - 3 controlled drugs to be sent to the relevant National Health Service agency (copies may no longer be sent)

7.20 The Misuse of Drugs (Amendment No 2) Regulations 2006 introduced a requirement for all private prescriptions for Schedule 1-3 controlled drugs to be sent to the NHS Business Services Authority (BSA)(or its equivalent in the Devolved Administrations) for analysis, thereby mirroring the requirements for NHS prescriptions. The intention was to ensure that the originals of Schedule 1-3 private prescriptions should be sent to the relevant NHS agency but medicines legislation required such originals to be retained by the pharmacy. With corresponding amendments to the medicines legislation (the Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 and the Medicines (Sale or Supply) Miscellaneous Provisions Amendment Regulations 2007), made at the same time as this instrument, the policy intention for the original prescription to be sent to the NHS BSA can now be achieved. This will eliminate the administrative burden of having to duplicate records. There is no requirement to retain a copy of the dispatched prescription.

Amending the Misuse of Drugs (Safe Custody) Regulations 1973 by replacing the term "nursing homes" with that of "care homes"

7.21 The Misuse of Drugs (Safe Custody) Regulations 1973 sets out the various levels of controls required in those premises that store Schedule 1, 2 and some Schedule 3 controlled drugs. The 1973 Regulations set out the minimum requirements with tighter controls imposed where appropriate for example the particular structural

requirements needed for pharmacies. The amendment is an administrative one, with the purpose of clarifying that care homes are subject to the specific provisions of the 1973 Regulations

7.22 The 1973 Regulations refer to “nursing homes” etc. which references are now obsolete. The appropriate terminology is now “care home” as defined within the Care Standards Act 2000 or, in relation to Scotland, with reference to the Regulation of Care Scotland Act 2001.

7.23 The change in terminology with the introduction of the Care Standards Act 2000 did not exclude care homes from the provisions of the 1973 Regulations as the Interpretation Act 1978 operated to update the reference in any event. Care homes are also covered by the National Minimum Standards for Care Homes for Older People that came into force on 1 April 2002. In Scotland, the National Care Standards for Care Homes for Older People (published in 2001) requires care providers to ensure they have comprehensive systems in place for ordering medication and for its safe storage and administration and for the safe disposal of unwanted medicine. This specifically sets out the direction that controlled drugs administered by staff must be kept in security cabinets that comply with the 1973 Regulations. In addition, the Health Act 2006 also covers care homes and ensures that they are routinely inspected and assessed for controlled drugs.

8. Impact

8.1 A final Regulatory Impact Assessment is attached.

8.2 The regulatory impact on the public sector is expected to be low.

8.3 There are no resource implications for the Home Office.

9. Contact

9.1 Angela Scrutton at the Home Office Tel: 020 7035 0458; e-mail: Angela.Scrutton@homeoffice.gsi.gov.uk or Chris Edwards at the Home Office on 020 7 035 0464 or Chris.Edwards@homeoffice.gsi.gov.uk who can answer any queries regarding the instrument

FINAL REGULATORY IMPACT ASSESSMENT (RIA)

1. Issue

The Government Response to the Fourth Report of The Shipman Inquiry, the *Safer Management of Controlled Drugs*, outlined a substantial programme of work that has been ongoing since its publication in December 2004. In order to implement these changes, various amendments have already been made to the Misuse of Drugs Regulations 2001 and this is, in part, another stage in the ongoing process of implementation.

A number of the proposals for legislative change described in the consultation paper issued on 11 May 2007 have varying levels of impact on various public sector frontline staff, private and voluntary healthcare sectors, social care organisations and companies who provide services to the healthcare sector generally, although it is considered that most of this impact will be in the form of a bureaucratic rather than a financial burden.

Details are given within the annexes to this RIA of those measures that will impact on either all or some healthcare sectors, commercial interests and/or the private or voluntary sectors. These are as follows :

a) the re-scheduling of Midazolam from Schedule 4 to Schedule 3;
b) the authority to allow Operating Department Practitioners (ODPs) to possess and supply controlled drugs in the operating department;
c) the replacement of the prescribed form of the Controlled Drugs Register (CDR) with recording of fields of information.

Excluded are those changes that have already been covered in the Regulatory Impact Assessment statement 2005 (the 2005 RIA) for the *Safer Management of Controlled Drugs,* attached to the July 2005 public consultation paper “Proposed Changes to Misuse of Drugs Legislation”

2. Purpose and intended effect of measures

Objective

The intended objectives of the Government’s legislative changes are threefold – 1) to safeguard patients, 2) improve the methods of legitimate controlled drugs use in the NHS and in the UK healthcare system generally and 3) minimise the risk of diversion of controlled drugs for illegitimate use. In doing these, the Government wishes to avoid placing any barriers in the way of the appropriate use of controlled drugs in modern healthcare.

Background

The Fourth Report of The Shipman Inquiry provided a detailed analysis of the various shortcomings in NHS processes and systems which enabled Shipman to remain undetected for some considerable period of time.

The conclusion of the Inquiry was that significant changes were needed in order to safeguard patients and reduce the chances of such a situation ever reoccurring. Since Shipman, the NHS has put into place new arrangements which have not only improved the level of care that healthcare professionals provide for their patients, but have improved the monitoring and inspection methods that cover the way controlled drugs are used throughout the healthcare sector.

The legislative proposals put forward in the consultation paper and the changes being introduced in this Statutory Instrument will continue this process. The changes discussed in this RIA - giving ODP's the authority to possess and supply controlled drugs in the operating department, allowing more flexibility in the way the CDR is completed and rescheduling Midazolam - are intended to improve the way in which controlled drugs are managed, while at the same time ensuring that good quality healthcare is an integral part of the development of clinical governance.

The Advisory Council on the Misuse of Drugs (ACMD) has been consulted and approved the legislative changes.

The proposal to amend the term "nursing home" as currently defined in the Misuse of Drugs (Safe Custody) Regulations 1973 to "care home" under the Care Standards Act 2000 or, in relation to Scotland, the Regulation of Care (Scotland) Act 2001, is an administrative change only. Under the Health Act 2006, care homes are routinely inspected and assessed on controlled drugs and the National Minimum Standards for Care Homes for Older People sets out how controlled drugs are stored. The proposed amendment simply clarifies that care homes come under the specific provisions of the 1973 Regulations. It is the Government's view that as such there will be no additional impact as a result of the change.

Risk Assessment

The main concerns arise over the risk of diversion of controlled drugs. The 2005 RIA pointed out that diversion of controlled drugs by healthcare professionals had, in the past, not been uncommon. In part, this is because the existing system of controls – including regulation – had not adapted to changes in the NHS and the wider context, creating gaps that could be exploited to divert controlled drugs for illegitimate purposes. Shipman's activities are the most extreme example of such exploitation.

The ongoing work on the action programme - published in *Safer Management of Controlled Drugs* – to close these gaps continues with these current legislative changes, the intention of which is to improve the way in which patients are cared for, while at the same time minimising the risk of harm to patients and the illegal diversion of controlled drugs.

Allowing ODP's to possess and supply controlled drugs and thereby extending the groups of healthcare professionals with access to them is considered to be of minimal risk due to the fact that ODP'S are highly trained individuals and their role is subject to tight Standard Operating Procedures (SOP's) in the operating department setting. In the case of the CDR, the introduction of new

headings for information in place of the current prescribed format is considered to be of minimal risk and may in fact improve the audit trail as there will be greater consistency in approach.

3. Options

There are only two possible options:

Option 1 – Do nothing

Option 2 – Proceed with the proposed changes to the legislation as described in the consultation paper.

The “do nothing” option cannot be realistically considered in the light of the recommendations of The Shipman Inquiry and the commitments made by Government in its Response. Some of the proposals are a further tranche of improvements set out in the Response; the other proposals complement and support this continuing programme of work.

4. Benefits identified and quantified

The proposed changes will result in improvements in the safety, quality and efficiency of the service to patients provided by healthcare professionals while at the same time improving information and audit processes.

Tightening the controls around Midazolam will improve its audit trail, and by doing so reduce the risk of diversion (Appendix A). Giving Operating Department Practitioners the authority to possess and supply controlled drugs will improve efficiency in operating departments and theatres and generally raise the levels of peri-operative care for patients (Appendix B). Replacing the prescribed format of the Controlled Drugs Register will give those maintaining a Register greater flexibility and innovation, particularly with the uptake and the advances in electronic Registers, whilst maintaining consistency in recording requirements. (Appendix C).

The change in term to “care home” will have a positive impact as the Commission for Social Care Inspection (CSCI) will be able to regulate more effectively how controlled drugs are being stored in care homes.

The other legislative changes have already been covered in the 2005 RIA.

Although in general terms, there will be no environmental benefits, the new requirements for authorisation to witness destruction of controlled drugs will ensure that it is done properly and in accordance with DEFRA and EU regulation on the disposal of medicines, so could give some additional environmental protection.

5. Costs

Overall, it has proved extremely difficult to quantify actual costs to the health care sector in respect of the impact the various changes will have, but it is expected that the overall cost will not be significant. In terms of the bureaucratic element to the changes being introduced, there will be an additional administrative burden, particularly for GP's and pharmacists. This is because these duties cannot be passed on to junior administrative personnel to complete because of the restrictions within the Misuse of Drugs Regulations 2001 on who is able to possess and supply controlled drugs.

For example, there may be some very small costs due to the re-scheduling of Midazolam, but these are likely to be limited to time needed to carry out the extra administrative duties as the stricter controls placed on Midazolam will mean that a few additional minutes will be required to comply with prescribing and recordkeeping requirements of the Regulations. However, the current annual number of prescriptions for Midazolam (given in Appendix A) is small so the impact will be minimal.

There will also be a requirement for community pharmacies, pharmaceutical retail chains and other healthcare professionals to take steps to ensure that their controlled drug registers meet the new requirements laid out in the legislation. There will be some financial costs in making the change to a new form of register as well as additional administrative burdens placed on the healthcare groups who under the legislation have to maintain a register. However, the legislation is allowing these groups a six month transition period prior to the requirement coming into effect on 1 February 2008, so that this both the financial and administrative burdens are spread out over this period. The financial cost in implementing the changes will mainly be in respect of new or changed software for computerised registers. More information is provided in Appendix C.

There are no financial costs involved in giving ODP's the authority to order, possess and supply controlled drugs, but there will be an additional administrative burden for hospital operating departments who will have to rewrite their Standard Operating Procedures in order to accommodate this change.

The financial cost of installing controlled drug cabinets in care homes will be minimal, as most already have these in place. For those care homes who will need to install cabinets, the potential cost will depend on the size of the cabinet required. It is not known how many care homes are likely to be affected by the legislative change.

There will be no perceived environmental cost and no social costs.

6. Issues of Equity and Fairness

The proposed changes will apply equally to all healthcare providers (NHS and private sector). In the case of the Controlled Drugs Register, the changes will apply to all those required to maintain a register, affecting small community pharmacies and the larger pharmacy chains equally. Issues of unfairness are

not expected. None of the measures detailed in this RIA will have an impact on any particular racial group.

7. Results of Consultation

A consultation was sent out to approximately 150 trade organisations, medical bodies and other interested parties. Consultees had 8 weeks rather than the normal 12 weeks in which to respond. This was due to the fact that several of the proposals had already been subject to informal discussions among interested stakeholders and the others had already been detailed in the 2005 consultation. In addition the commencement date of the consultations was determined by the devolved administration elections in early May which meant that although the consultation commenced on 11 May after the purdah, there was an urgent need to meet the summer target date for the proposed legislation to be introduced to allow time to prepare for the introduction of the new form of controlled drug register. (printing, distribution etc.) Ministerial approval was obtained for the shortened consultation.

This final RIA has taken account the comments received, which were overwhelmingly (96%) in favour of the proposals put forward in the consultation.

8. Consultation with small business

The Government has considered the comments received by the regulatory organisations who represent small businesses. particularly the independent pharmacists. These included;

1) The National Pharmaceutical Association
2) The Pharmaceutical Services Negotiating Committee
3) The Company Chemists Association.

Their comments were taken into account prior to making the changes to the legislation. The responses confirmed the Government's view that the changes will not have a disproportionate impact on small business. Advice given by the DTI is that there will be a minimal affect on small business as a result of these changes.

9. Competition Assessment

There are no competition issues. The Office of Fair Trading Competition Assessment Test has been applied and as the changes mainly affect the healthcare sector only, there will be no restrictions on suppliers or on their ability to compete with other suppliers in what is a specialised market. The businesses that supply computer software for registers will not be limited in their ability to continue to do this.

10. Enforcement, Sanctions, Monitoring and Review

The proposed changes will be introduced through the Misuse of Drugs Regulations 2001 and the Misuse of Drugs Regulations (Northern Ireland). The change being made to the Misuse of Drugs (Safe Custody) Regulations 1973 will have no impact on enforcement as monitoring of controlled drugs is

already subject to the National Minimum Standards for Care Homes for Older Persons.

As previously discussed in the 2005 RIA, it is the overall responsibility of the various professional regulatory bodies to monitor issues involving compliance where they apply and to impose sanctions where appropriate. Criminal enforcement would be a matter for the police if it was thought to be sufficiently serious to warrant it.

11. Summary and Recommendation

The legislative changes being introduced will strengthen the arrangements for the management of controlled drugs in order to minimise the risk to patient safety of their inappropriate use and of their diversion for illicit use. They also continue to reflect the need for patient care not to be compromised and for patients to have access to the care and medicines they require. The changes being made to the CDR will provide the flexibility to make the recording of running balances and other information easier and will promote compliance. Giving ODP's the authority to possess and supply controlled drugs will speed up and improve the peri-operative treatment of patients in the operating department and allow nurses and doctors to concentrate their resources elsewhere. The changes put forward to amend the legislation are recommended as,

a) the changes will result not only in improvements in safety, quality and efficiency of the service to patients provided by healthcare professionals; and
b) at the same time will improve the information and audit processes across the health and social care sector.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the balance between cost and benefit is the right one in the circumstances.

Signed …Vernon Coaker

Date …23rd July 2007

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RIA - APPENDIX A : RESCHEDULING OF MIDAZOLAM

Objective : To increase the level of control applied to the supply of Midazolam and thereby reducing the risk of diversion or inappropriate use.

Background : Midazolam is a benzodiazepine, a short-acting sedative. It is currently controlled in Schedule 4 Part I of the 2001 Regulations, a fairly light regime of controls. The Advisory Council on the Misuse of Drugs (ACMD) has recommended that the regime of control of Midazolam should be strengthened by transferring it to Schedule 3 of the Regulations in order to limit the risk of diversion and misuse, after concern was prompted by a case involving a GP who used Midazolam to sedate patients prior to indecently assaulting them.

Risk Assessment : The light level of regulation provided by Schedule 4 of the Regulations does not provide an adequate regime of control needed to reduce the risk of diversion or inappropriate use for this particular drug. As a Schedule 3 drug, it will be subject to tighter audit controls in respect of prescribing and record keeping.

Options : To take the “do nothing“option would mean that the risk of diversion or inappropriate use of Midazolam would remain at the current inappropriate level with the attendant risk of harm to patients. Re-scheduling the drug to a regime with tighter controls will reduce this risk.

Costs and Benefits : It is anticipated that the financial cost resulting from the rescheduling will be minimal to the healthcare sector and of no cost to the manufacturers of Midazolam. The only likely real cost is the additional time, largely for the dispenser, to ensure that the prescriptions are compliant with Regulation 15 and that appropriate records are kept. This additional time will add up to no more that 2-3 minutes every time a prescription for Midazolam is written and and it is considered that the cost will be quickly and easily subsumed within the normal day to day duties of dispensers. No additional fees are payable to doctors for the dispensing of a Schedule 3 CD.

The annual number of prescriptions for Midazolam for the year January - December 2006 was 41, 788. (Epact excludes prescriptions written in Wales and Scotland but does include prescriptions written in England but dispensed in Wales and Scotland). Although data for private prescribing did not commence until Summer 2006, there are no records of Midazolam being prescribed on a private prescription.

It is anticipated that the costs to the NHS in respect of remunerating pharmacists will be small, in the region of about £18,000 per annum. This is due to the fact that for every Schedule 3 controlled drug prescription submitted by pharmacy contractors the NHS pays 43p per prescription to cover their costs.

The Commission for Social Care Inspection (CSCI) and other regulatory bodies will have to amend their guidance to take account of the re-scheduling which will mean that there will be a small organisational impact as a result of the change. However, the CSCI have stated in their response to the

consultation that there will be no financial implications because their guidance on the rescheduling of Midazolam will be managed through a planned document review process.

Equity and Fairness : The proposal will impact on health professionals in both the NHS and private sectors equally.

Impact on Small firms : Midazolam is a non-proprietary medicine. It is therefore anticipated that there will be some impact on those companies manufacturing the drug in respect of additional recordkeeping requirements but the overall impact will be minimal.

Competition : Although various companies manufacture Midazolam, it is not thought that there will be any competition issues as a result of re-scheduling.

Enforcement : It is the overall responsibility of the various professional regulatory bodies to monitor issues in relation to compliance where they apply and impose sanctions where appropriate, although criminal enforcement matters will continue to be referred to the police.

RIA – APPENDIX B: OPERATING DEPARTMENT PRACTITIONERS (ODPs)

Objective : To expand the role and responsibilities of Operating Department Practitioners within operating departments by giving ODPs authority to possess and supply any controlled drugs in the operating department (including the theatre) for the purposes of administration to a patient.

Background : ODPs play an important role within the operating department working alongside surgeons, anaesthetists and nurses to ensure that the theatre runs efficiently and safely. They have a major role to play in the peri-operative care of patients. At present, the role that they play with respect to controlled drugs is limited – eg. ODPs can remove and return controlled drugs from safe custody cabinet but only on the express authority of someone with full authority to possess and supply ie the sister or doctor etc.

ODPs are a regulated professional body. The Health Professions (Operating Department Practitioners and Miscellaneous Amendments) Order 2004 (S.I. 2004/2033) designated ODPs as one of the professions regulated under the Health Professions Order 2001. ODPs are regulated by the Health Professional Council.

Risk Assessment : The risk involved with extending to an additional group of healthcare professionals the authority to possess and supply controlled drugs in these limited circumstances is considered to be minimal. ODPs are highly trained individuals with a broad range of management and communication skills who provide high standards of patient care during the peri-operative period. The usual monitoring procedures/SOPs must be in place to ensure there is no risk to patients. There is no evidence to suggest that the extension in the operating theatre/department will lead to increased risk of diversion or misuse.

Options : To take the “do nothing “option means that the benefits to the department and ultimately to patients will not be enjoyed and may lead to local practices being implemented that fall outside the scope of the regulations. There are continual pressures being placed on the surgeons, anaesthetists and nurses working in operating departments and these will continue to grow. By allowing ODPs to extend their role and responsibilities in respect of controlled drugs will enable resources to be better directed across the department and help ensure that patients’ access to drugs will not be impeded.

Costs and Benefits : Healthcare professionals working in operating departments and theatres will have more time to divert their valuable resources to other tasks involving the peri-operative care of their patients rather than having to take responsibility for tasks involving controlled drugs, which although important, can be more routine. Patients will benefit from a more effective and quicker service and higher levels of peri-operative care. In addition, the College of Operating Department Practitioners have stated that as ODPs can also work in the independent healthcare sector, there will be increased flexibility in working arrangements for small independent hospitals.

Equity and Fairness : The proposal will affect equally those groups of healthcare professionals who come into contact with ODPs.

Impact on Small Firms : There is no impact on small firms.

Competition : The proposal does not have any competitive repercussions.

Enforcement : Each NHS Trust now has a senior officer designated as an Accountable Officer for controlled drugs. One of their responsibilities is to ensure that there are robust procedures for the safe and effective management of controlled drugs within their organisation, including the development of standard operating procedures for each area and monitoring issues will come under their authority.

RIA – APPENDIX C : CONTROLLED DRUG REGISTER

Objective : To allow for greater flexibility and local innovation in the use of Controlled Drug Registers by removing the requirement to use a prescribed form (as set out in the Regulations) whilst retaining the need to record certain mandatory fields of information.

Background : A Controlled Drugs Register is required to be kept in order to provide an audit trail of controlled drugs (obtained and supplied) in Schedules 1 and 2. These are the drugs that are considered to have the greatest potential for diversion and harm when misused. The Register can either be in a paper bound or electronic form but it must currently be maintained in the specified format as set out in Schedule 6 to the 2001 Regulations.

Particularly with the uptake and advances in electronic Registers, it has become increasingly clear that the use of a prescribed format has become outdated and too restrictive in that it does not allow for local innovation and flexibility in the layout the Register can take.

The legislative change will remove the prescribed format of Schedule 6 and replace it with a requirement to record certain fields of information in columns with dedicated title headings.

Risk Assessment : The risks associated with Schedule 1 and 2 controlled drugs justify the retention of a Controlled Drugs Register. By requiring certain fields of information in columns with dedicated title headings to be recorded, any risk incurred by removing the prescribed format has been kept to a minimum.

Options : To take the “do nothing” option will exacerbate the current situation and will be very likely to lead to non-compliance as the changes in NHS practice and the wider context out-pace regulation change. To simply update the prescribed format will provide none of the benefits that a “lighter touch” will bring, while at the same time maintaining the integrity of the Register and the recording requirements.

Costs and Benefits : Existing changes to the Controlled Drugs Register were already due to come into force on 1 January 2008. These were introduced in the Misuse of Drugs (Amendment No 2) Regulations 2006 (S.I. 2006/1450), and requires 3 additional columns to be embedded into the Register for the recording of information relating to the identity of a person collecting Schedule 2 controlled drugs. The costs involved here were covered by the 2005 RIA. However these prospective changes are now being repealed as they involved changes to the prescribed form of the CDR. Instead the same information as was to be captured will now be set out in the prescribed headings to be used in the CDR. As a result of a request from the National Pharmacy Association (NPA) and the RPSGB the commencement date for the changes to the register has been put back to 1 February 2008 to give more time to pharmacists to make the appropriate changes. This has been done to ensure overall costs are kept to a minimum and are incurred only once. By amending the legislation in Summer 2007, but not requiring the

change to the CDR to be implemented until I February 2008, there will have been a sufficient transition period to enable pharmacists and others to make adjustments to current registers and/or introduce new ones.

Costs

1. It is considered that the overall cost of the legislative changes will be comparatively low, although there will be some start up costs where new Registers are purchased. This is likely to be dependent on the size of the Register. A complete Controlled Drugs Register with 5 sections costs approximately £32 and extra sections cost about £8 for 5 small sections and £10 for 3 large sections. As it is impossible to predict the numbers of new Registers that will be purchased, an overall cost cannot be given. However it has been pointed out that the cost of a new register is likely to be nearer to £90 and will contain approximately 40 inserts to cover the range of drugs typically supplied through a community pharmacy. It is still considered that the numbers of pharmacies introducing a completely new register will be low though quantitative figures in support of this cannot be provided.

2. It is expected that little or none of the cost of new Registers will be picked up by the public health sector and so the impact will be on the business sector only. This will be mainly due to the supply of software for computerised registers in the healthcare sector. However, as mentioned previously, start- up costs are not expected to be substantial. Also, once purchased, there will be no difference in ongoing costs which were previously incurred under the recording requirements.

3. There will be a potential further cost for pharmacists and others that have already revised their CDR in anticipation of the changes that were due to come into force on 1 January 2008 and will now be 1 February 2008 in that they will need to make further changes to the Register. There will be potential additional costs in respect of this, but as it is uncertain as to how many pharmacists will be affected, overall costs are unknown.

4. There may also be some training costs in order to make staff aware of the changes to the register. These costs are unlikely to be significant.

5. The resource implications in terms of time needed to record additional information, and to become familiar with the new style of register will impose a bureaucratic burden but the difference is unlikely to have any major impact on working practices.

Benefits

1. The changes to the CDR will provide flexibility to make the recording of running balances and other relevant information easier. The introduction of new headings for fields of information to be recorded will mean that the types of information being recorded will be more explicit and as such will reduce the risk of misunderstandings and at the same time improve consistency. The new format will help “future proof” the Regulations.

2 It is thought that the changes to the CDR and the increased flexibility that these will afford will make the introduction of electronic registers easier and so encourage people in the healthcare sector to introduce them. However, a full scale change is unlikely to take place until the Electronic Prescription Service (EPS) system under the Department of Health's Connecting for Health is implemented fully at the earliest. Also, due to outstanding issues with how electronic systems are to be inspected if they are on the same computer as the pharmacy PMR, it is unlikely there will be an immediate widespread changeover.

Equity and Fairness : There are no equity and fairness issues to consider. The measure will impact on all areas equally.

Impact on small firms : There will be some impact on small firms, as there will be on pharmaceutical chains and healthcare professionals, but it is not thought that this will be disproportionate. In their response to the consultation those organisations representing small firms did not raise any specific concerns about the potential costs. Current software packages will have to be changed to accommodate the proposal, but it is considered that there will not be a disproportionate impact on those businesses that provide these. In particular, those representing community pharmacies and the pharmaceutical chains, who are most likely to be affected by the proposals, have been included in the consultation process and their comments have been taken into account.

Competition : There are no competition issues involved. This is a specialist area and those firms supplying the computer software for the registers will not be disproportionately affected.

Enforcement : It is anticipated that the changes to the Controlled Drugs Register will help promote compliance. The Register must be available for inspection and it will be the responsibility of RPSGB Inspectors and the Healthcare Commission to inspect the Registers and monitor to ensure compliance.