Introduction

1. This circular draws attention to the contents of the above Statutory Instrument (S.I.) which comes into force on 16 August 2007, with the exception of Regulation 4(11)(b) which comes into force on 1 September 2007, Regulations 3(4), 4(6)(e), 4(8), 4(11)(a) and Regulations 4(13) to (14) which come into force on 1 January 2008 and Regulations 4(9) to (10) and Regulation 4(15) which come into force on 1 February 2008.
2. The S.I. amends the Misuse of Drugs Regulations 2001 (the 2001 Regulations) and the Misuse of Drugs (Safe Custody) Regulations 1973 (the 1973 Regulations) to:

a) introduce new requirements for Schedule 1-3 controlled drug requisitions (for human use) used in the community to be sent to the NHS Business Services Authority (or its equivalent in the Devolved Administrations)
b) give authority to the Accountable Officer, introduced in the Health Act 2006 as the person responsible for the safe use and management of controlled drugs in his or her healthcare area, to nominate persons to witness the destruction of controlled drugs;
c) allow Operating Department Practitioners (ODPs) to possess and supply or offer to supply controlled drugs in certain settings (ward, theatre or other department); replace the term ‘Sister or Acting Sister’ with that of ‘Senior Registered Nurse or Acting Senior Registered Nurse’; and extend the authority of the Senior Registered Nurse (and ODP) to supply controlled drugs in these specified settings for the purposes of administration to a patient in accordance with the directions of supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to what drugs are being prescribed, a nurse independent prescriber
d) re-schedule Midazolam from Schedule 4 to Schedule 3, a tighter regime of controls in respect of prescribing, requisitioning and record keeping, but allow it to continue to be used under a Patient Group Direction (PGD) and to exempt it from the storage requirements of the Misuse of Drugs (Safe Custody) Regulations 1973
e) remove the requirement to maintain a Controlled Drug Register in the prescribed format previously set out in Schedule 6 of the 2001 Regulations and replace it with the requirement to record designated fields of information underneath specified headings;
f) replace the term ‘nursing home’ in the 1973 Regulations and the 2001 Regulations with that of ‘care home’.

Legislative background

1. 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. These amendments to the 2001 Regulations relate, in part, to the third tranche of changes that the government undertook to make in Safer Management of Controlled Drugs (2005), its Response to the Fourth Report of The Shipman Inquiry, but also include further changes that provide improved treatment and enhance the safety of patients and also tighten the monitoring and auditing of controlled drugs.

2. This instrument is made under sections 7, 10, 22 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).

3. The amendments have been subject to an 8 week public consultation which ended in July 2007. The time period of the consultation was curtailed as the majority of the changes had already been set out in an earlier consultation (July 2005) or had been the subject to informal consultation with key stakeholders. All of the responses to the consultation were broadly supportive. ACMD were consulted and approved these amendments made by this S.I.

4. This S.I. implements the changes by amending the 2001 Regulations and the 1973 Regulations and making consequential amendments to the Misuse of Drugs (Amendment No 2) Regulations 2006 and the Misuse of Drugs (Amendment No 3) Regulations 2006. Regulations 3(1) to (3) and 3(4) make amendments to the 1973 Regulations and Regulations 4(1)(c) to (h), 4(2)(b), 4(3) to 4(16) make amendments to the 2001 Regulations. Regulations 5 and 6 repeal prospective amendments to the 2001 Regulations (as amended) in respect of the Controlled Drug Register as these are redundant as a result of these new Regulations.

Policy context

7. Safer Management of Controlled Drugs set out a substantial programme of work to improve and strengthen the management arrangements for controlled drugs to minimise the risks to patient safety of their inappropriate use. These amendments to the 2001 Regulations partly continue the implementation of this programme of work but include further amendments that will also help to improve the management of controlled drugs throughout the healthcare sector.

1. As The Shipman Inquiry itself recognised, controlled drugs are used for a wide variety of clinical reasons and strengthened controls must be balanced with ensuring that patients can access the medicines they need and that the legitimate use of controlled drugs by healthcare professionals is not compromised. In formulating this policy full consideration has been given to achieving a balance between controls, the risk to patients and patient care.

Requisitions for Schedule 1-3 controlled drugs (for human use) used in the community

1. The 2001 Regulations are amended so that community pharmacies and dispensing doctors issuing requisitions in the community for human use are required to submit
original requisitions for Schedule 1-3 controlled drugs to the relevant NHS authority. This complements an earlier amendment made to the 2001 Regulations (Misuse of Drugs (Amendment No 2) Regulations 2006) which requires Schedule 1-3 private prescriptions to be submitted to the relevant NHS authority.

2. The amendment also requires the name and address of the supplier to be included indelibly on the requisition. A pharmacy stamp which includes the full name of the pharmacy from which the supply is made is acceptable, on the condition that the name and address is clearly legible as required by the legislation. Guidance on the use of a pharmacy stamp for this purpose will be issued by the RPSGB. This information is required to be added by the supplier at the time the supply is made and applies to all requisitions issued in all healthcare settings in the community where Schedule 1-3 controlled drugs are being supplied.

3. These amendments will further improve the way that controlled drugs are managed by providing a more complete audit trail by which controlled drugs entering the community can be monitored. Local health and social care officers, will, as a result, have a clearer picture of the pattern of controlled drug supply and usage in the community, for the benefit of patient and the wider public’s safety.

4. This amendment will be accompanied by guidance to be issued by the Department of Health shortly.

The accountable officer and authority to nominate persons to witness the destruction of controlled drugs

1. The 2001 Regulations are amended to give the Accountable Officer, introduced under the Health Act 2006, the authority within their organisation to nominate persons to witness the destruction of controlled drugs. Previously, under Regulation 27 of the 2001 Regulations, only the Secretary of State is able to nominate specified persons or classes of persons, normally holding senior posts in the healthcare sector, to witness the destruction of controlled drugs. The new powers given to Accountable Officers to authorise witnesses will sit side by side those of the Secretary of State.

2. Under the terms of the Health Act 2006, Accountable Officers have overall responsibility for the safe use and management of controlled drugs within their healthcare sector. With the authority to nominate authorised witnesses, the Accountable Officer will be able to ensure that witnesses are readily available to avoid out of date or surplus controlled drug stocks building up, which has associated risks of diversion or misuse.

3. Accountable Officers are not authorised to personally witness destruction as they must be independent of the day-to-day management of controlled drugs. This amendment is accompanied by guidance to be issued by the Department of Health.

Operating Department Practitioners (ODPs); the term ‘sister or acting sister for the time being in charge’; the extension of the authority of the Senior Registered Nurse (and ODPs) to possess and supply controlled drugs.

1. This amendment gives ODPs the authority to order, possess and supply controlled drugs in certain settings (ward, theatre or other department). ODPs are a regulated healthcare profession under the Health Professions Order 2001.
2. Previously under the 2001 Regulations ODPs were unable to possess and supply controlled drugs, which has hindered the smooth running of the hospital operating departments in which ODPs play a vital role, and prevented the optimum use of resources for the efficient treatment of patients. The amendment will therefore improve the peri-operative care of patients who will benefit from quicker and more effective treatment.

3. Local SOPs will ensure strict monitoring procedures exist. The risks of increased diversion or misuse associated with the granting of this authority to ODPs are considered to be minimal and are outweighed by the benefits to the patient.

4. This amendment will also remove the term ‘sister’ from the 2001 Regulations, as this has long been considered to be obsolete as a descriptive term. Therefore the definition has been changed to that of ‘senior registered nurse’ in order to better reflect current terminology.

5. The amendment also extends the authority of the ‘senior registered nurse’ (and ODP) to supply controlled drugs for the purposes of administration to a patient in certain settings (a ward, theatre or other department) in accordance with the directions of a supplementary prescriber (under a CMP) or a Nurse Independent Prescriber (NIP) (within their authority to prescribe a limited range of controlled drugs). Extending this authority will improve the treatment of patients within the ward theatre or operating department as they will benefit from quicker and more efficient care.

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

1. The amendment re-schedules Midazolam from Schedule 4 to Schedule 3 of the 2001 Regulations. This is a stricter level of controls and will place additional requirements on the recordkeeping, prescribing and requisitioning of the drug.

2. The prescription requirements of Regulations 15 and 16 (for both NHS and private prescriptions) of the 2001 Regulations, the requisition requirements of Regulation 14 (written requisitions must be provided when the drug is supplied otherwise than on a prescription) and the recordkeeping requirements of Regulation 24 (invoices to be kept for two years) will apply. The monitoring and auditing of the drug is therefore tighter, reducing the risk of misuse and diversion.

3. In order for patients to obtain quick and efficient treatment with the drug, there is a strong clinical need for Midazolam to continue to be supplied and administered under a Patient Group Direction (PGD). PGDs are written directions, signed by a senior doctor and pharmacist which allow the supply and administration of named medicines (including some controlled drugs) by specified health professionals in an identifiable clinical
situation. The statutory requirements surrounding PGDs continue to be tightly drawn and controlled in order to safeguard patient safety and prevent diversion.

4. Likewise, Midazolam will continue to be exempt from the requirements of the 1973 Regulations in respect of storage. Healthcare professionals need to have quick and easy access to Midazolam when it is needed. The considered view is that the requirements associated with the rescheduling of Midazolam (see para 22 above) is an adequate measure alone, based on current evidence, to reduce the risk of diversion. However, the situation in respect of both PGDs and safe custody will continue to be monitored and will be reviewed if appropriate.

**The controlled drug register**

1. This amendment removes Schedule 6, the ‘Form of The Register’, from the 2001 Regulations and replaces it with a requirement to maintain, where appropriate, a Controlled Drugs Register (CDR) with specified headings/titles by which to capture mandatory fields of information. Additionally, in the CDR or separate part of the CDR used for each class of drug, the amendment will require separate pages for each strength and form of controlled drug. The name, strength and form of the drug are to be entered at the top of each page and the mandatory fields of information will be recorded under the specified headings.

2. The fields of information to be used are largely unaltered from the previous requirements. They show various headings in respect of entries made under drugs obtained and under drugs supplied. Entries in respect of drugs obtained and drugs supplied may be made on the same page or separate pages within the CDR. These are as follows:

**Headings in respect of entries made of drugs obtained**

- Date supply received
- Name and address from whom received
- Quantity received
Headings in respect of entries made for drugs supplied

- Date supplied
- Name/Address of person or firm supplied
- Details of authority to possess, prescriber or licence holder’s details
- Quantity supplied

The amendment includes a requirement to add specific information in respect of the identity of the person collecting Schedule 2 controlled drugs on prescription. The following additional headings in respect of entries made for drugs supplied must be included in the CDR:

- Person collecting the Schedule 2 controlled drug (patient/patient’s rep/healthcare professional), and if healthcare professional, name and address
- Was proof of identity requested of patient/patient’s representative (Yes/No)
- Was proof of identity of person collecting provided (Yes/No)

1. The CDR provides a complete audit trail of all Schedule 1 and 2 controlled drugs obtained and supplied, as these are considered to have the most potential for diversion and misuse leading to harm. The government considers that the risks involved with the drugs in these particular Schedules justify the need to keep records in the CDR for auditing and monitoring purposes.

However, it is aware that in modern health and social care setting, with the increased use of computerised forms of the CDR, the prescribed form laid out in Schedule 6 had become too restrictive. Consequently, the government is content to take this new approach to the recording of information which will allow greater flexibility, but maintain a regulatory framework for the CDR for monitoring and inspection purposes.

1. This amendment will be accompanied by guidance to be issued by the Department of Health.

The term nursing home in the 1973 Regulations and the 2001 Regulations

1. The 2001 Regulations are amended in order to change the term ‘nursing home’ as previously referred to in the 1973 and 2001 Regulations to that of ‘care home’. The change is an administrative one, as ‘nursing home’ as previously defined is now obsolete. (The 1973 Regulations refer to ‘any nursing home within the meaning of Part vi of the Public Health Act 1936’).

In England and Wales the correct terminology is now ‘care home’ within the meaning of the Care Standards Act 2000. In Scotland it has a slightly different definition as a “care home service” which has the same meaning as that in the Regulation of Care (Scotland) Act 2001. The change simply reflects that care homes still come under the provisions of the 1973 Regulations in respect of the storage of controlled drugs. A consequential amendment has also been made to the 2001 Regulations to reflect the change.
1. It is to be noted that the change in terminology that came into force with the Care Standards Act 2000 did not mean that nursing/care homes were no longer covered under the 1973 Regulations. They still applied due to the National Minimum Standards for Care Homes for Older People that came into effect in 2002 as this made specific reference to the fact that controlled drugs administered by staff must be stored in a metal security cupboard that complied with the 1973 Regulations.

2. The Care Standards Act 2000 does not apply to Northern Ireland where the relevant legislation is the Health and Personal Services (Quality Improvement and Regulation) (Northern Ireland) Order which defines both Nursing and Residential Homes in Northern Ireland. Minimum Standards have been developed and are awaiting implementation in Northern Ireland.

Commencement dates

1. Not all the provisions of this S.I. will come into force at the same time. The new requirements in respect of both Midazolam and requisitions will come into force on 1 January 2008 to allow sufficient time for the healthcare sector to make appropriate changes.

2. The changes to the CDR are fundamental, requiring the production of new stationary and software packages for the computerised registers. To allow these changes to be made in a timely manner and to ensure compliance with the new requirements when the changes come into effect, the amendments to the CDR are delayed until the 1 February 2008.

Application to England, Wales and Scotland

1. The changes in the Misuse of Drugs Regulations 2001 that are described in this Circular apply to England, Wales and Scotland. Northern Ireland will amend its own Misuse of Drugs Regulations separately. The contact there is:

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