

Dear Colleague

CONTROLLED DRUGS (SUPERVISION OF MANAGEMENT AND USE) REGULATIONS 2013

This guidance is intended to provide information on the changes to the UK Controlled Drugs (Supervision of Management and Use) Regulations 2006 ("the 2006 regulations"). The 2006 regulations have been replaced by the Controlled Drugs (Supervision of Management and Use) Regulations 2013 ("the 2013 Regulations") which came into force in England and Scotland on 1 April 2013. The legislative changes and development of the guidance were taken forward with full involvement and agreement of the Controlled Drug Accountable Officers' Executive Group and representatives from Healthcare Improvement Scotland and the Care Inspectorate.

Background

Controlled Drugs (CDs) form an essential part of modern healthcare but have the potential for misuse or diversion. The management and use of controlled drugs is currently reserved under the Scotland Act 1998 and is a matter for the Home Office who have UK-wide legislation in place to govern the therapeutic use of CDs. The 2006 Regulations came into force on 1 March 2007 in Scotland and followed the UK Government's response to the Shipman Inquiries Fourth Report published in 2004. The 2006 Regulations strengthened and improved governance arrangements for CDs and a key component was the creation of Controlled Drug Accountable Officers (CDAOs). Under the terms of the 2006 regulations all designated bodies in England and Scotland, as prescribed under regulation 3, were required to appoint a CDAO who would be required to develop and implement systems for routinely monitoring the management and use of controlled drugs and ensuring they are alerted to any risks, concerns and/or incidents. The arrangements have been in place in Scotland since 2007.

As a consequence of the passing of the Health and Social Care Act 2012 in England, the 2006 Regulations needed to be revised mainly to reflect the new architecture of the NHS in England from April 2013. The opportunity was taken, however, to simplify and modify the Regulations and to reduce any burdens. Scottish Government officials and the Accountable Officer Network in Scotland were fully involved in discussions which have resulted in the 2013 Regulations which came into force on 1 April 2013.

CEL 17 (2014)

14 August 2014

Addresses

For action

Chief Executives of NHS Boards, special Health Boards, NHS National Services Scotland (Common Services Agency) and Healthcare Improvement Scotland. The Care Inspectorate. Chair of Controlled Drugs Accountable Officers' Network.

For information

Medical Directors and Directors of Pharmacy of NHS Boards, special Health Boards NHS National Services Scotland (Common Services Agency) and Healthcare Improvement Scotland.

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The 2013 Regulations contain some specific Scottish amendments and further detail of these, together with handling arrangements, are provided at Annex A. A copy of the Regulations can be found on the Government Legislation Website at:

<http://www.legislation.gov.uk/uksi/2013/373/contents/made>.

General information and a Q&A can be found on the Department of Health web pages at:

<http://www.dh.gov.uk/health/2013/02/cd-regulations>

Action

NHS Boards are asked to ensure that all relevant staff in their area are aware of this guidance.

Yours sincerely



PROFESSOR BILL SCOTT

Chief Pharmaceutical Officer, Scotland

ANNEX A

CONTROLLED DRUGS (SUPERVISION OF MANAGEMENT AND USE) REGULATIONS 2013

Key Impacts in Scotland

1. The 2013 Regulations contain several amendments which are specific to Scotland as follows:

1.1 Expanding the role of Healthcare Improvement Scotland (HIS)

The role of HIS has been extended so that they:

- become the keeper of a list of all Scottish CDAOs and publish the list;
- make a determination on whether or not smaller independent hospitals require to appoint a CDAO - but only where such hospitals make an application seeking exemption; and
- are able to seek self declarations from designated bodies about their management and use of controlled drugs.

1.2 Expanding the role of the Care Inspectorate (CI)

Scottish care home services have been brought within the remit of the amended regulations. In monitoring a Scottish care home services activities, the CI has been designated as a “responsible body” under the terms of the Regulations and has also been given powers to ask for self declarations about how Scottish care home services manage and use controlled drugs at their Scottish care home service premises. The CI has also been added to the list of bodies that a CDAO could ask to undertake inspections.

1.3 Reducing Burdens

The intention is to reduce burdens on independent sector micro or start up businesses with fewer than 10 workers by exempting them from the requirements to appoint a CDAO.

Healthcare Improvement Scotland

2. In taking forward its extended role, HIS wrote to all NHS Boards on 1 May 2013 detailing how it planned to move forward. Work has now developed and detail of the arrangements HIS has put in place around the safer management of controlled drugs can be found using the following link:

http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/controlled_drugs.aspx

3. The HIS web page includes information on the national register for CDAOs in Scotland which can be accessed using the same link. Work is at an advanced stage around developing a declaration and self assessment process which will include full guidance. Guidance is also currently being drawn up to cover the criteria for and how small businesses can apply for exemption from appointing a CDAO.

4. Details of who to contact at HIS for further information are available on the HIS website.

The Care Inspectorate

5. Scottish care home services had been omitted from the definition of a care home in the previous 2006 Regulations. There was no apparent justification for such an omission and so the opportunity was taken in the revised 2013 Regulations to have Scottish care home services included.

6. The practical consequences of including Scottish care home services within the 2013 Regulations are:

- The manager or other person responsible for running the Scottish care home service, and their workers who are engaged in relevant activities, are now “relevant persons” to the Health Board in whose area they are located. This means that they become people whose activities could be monitored by the Health Board CDAO as part of the Local Intelligence Network (LIN).
- To assist Health Boards with this increased role, the CI in Scotland has been appointed as a “responsible body” (that is, a person who is entitled to participate in LIN’s and other information sharing with responsible bodies).
- The CI has been given powers to ask for self declarations about how Scottish care home services manage and use controlled drugs at their Scottish care home service premises.
- The CI has also been included in the list of bodies that a CDAO could ask to undertake inspections relating to the management of controlled drugs in the services it regulates.

Arrangements for Joint Working to Avoid Duplication of Visits or Requests for Self Assessments

7. It is important that duplication of self-assessment requests and visits are avoided wherever possible. The Chairperson of the Controlled Drugs Accountable Officers’ Network and officials from HIS and CI will continue to monitor implementation of the 2013 Regulations via the Controlled Drugs Accountable Officers’ Executive Group. Should they become aware of, or have concerns around duplication, these concerns will be raised with the group and if it is felt necessary, will agree a process to avoid future duplication.

Inspection of GP Practices















8. It is intended that CDAOs in England will not need to inspect GP practices as that will fall within the remit of the Care Quality Commission (CQC) from April 2013. There are no plans in Scotland for HIS to take over this function and so current arrangements will continue to apply with CDAOs of the designated body which the GP practice falls within having responsibility for inspecting GP practices.

Reporting of Incidents

9. All incidents or concerns involving the safe use and management of controlled drugs must be reported to the organisations CDAO. Community pharmacies should continue to report incidents to the NHS CDAO. The Care Inspectorate and HIS will issue guidance about reporting arrangements for incidents and concerns involving the safe use and management of controlled drugs in the services they register.

Status of Previous Guidance

10. For information, previous guidance specific to controlled drugs issued by the Scottish Government are as follows:

CEL(2012)35	Licensing arrangements for prescribing, supplying and administering diamorphine, cocaine and dipipanone for the treatment of drug misuse and addiction	18/10/2012	 
CEL(2010)25	Safer management of controlled drugs: Accountable Officers: updated contact details	02/07/2010	 
CEL(2008)07	Safer management of controlled drugs: a guide to good practice in secondary care (Scotland)	12/02/2008	 
CEL(2007)21	Safer management of controlled drugs: A. changes to record keeping requirements; B. destruction of controlled drugs: new role for accountable officers; C. accountable officers: contact details (updated)	21/12/2007	 
CEL(2007)16	Safer management of controlled drugs: private requisition forms for schedules 1, 2 and 3 controlled drugs	06/11/2007	 
CEL(2007)14	Safer management of controlled drugs: standard operating procedures	17/10/2007	 
HDL(2007)12	Safer management of controlled drugs: guidance on strengthened governance arrangements	14/02/2007	
HDL(2006)27	Safer management of controlled drugs (CDs): private CD prescriptions and changes to NHS prescriptions	12/05/2006	 

The above guidance should be read in conjunction with this circular.