EXPLANATORY MEMORANDUM TO

THE CONTROLLED DRUGS (SUPERVISION OF MANAGEMENT AND USE) REGULATIONS 2013

2013 No. 373

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

2. Purpose of the instrument

2.1 These Regulations replace the Controlled Drugs (Supervision of Management and Use) Regulations 2006 (S.I. 2006/3148, as amended) ("the 2006 Regulations") as the Regulations which underpin the arrangements, in England and Scotland, for securing the safe management and use of controlled drugs, such as opiates, in hospitals and in the wider community. Certain NHS and independent sector healthcare bodies are required to appoint controlled drugs accountable officers ("CDAOs"), and these Regulations describe CDAOs' responsibilities. They also require specified bodies to co-operate with each other in local intelligence networks, and deal with ancillary matters such as powers of entry.

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

3.1 These Regulations include new powers which allow the Care Quality Commission ("CQC") in England, and Healthcare Improvement Scotland ("HIS") in Scotland to exempt certain smaller independent hospitals from coming within the definition of an independent hospital and therefore from the requirement to appoint a CDAO (regulations 3(1)(b) and 4(1)(b)). In doing this, the Department is relying on the powers in section 79(3) of the Health Act 2006 to make different provision for different cases, read with section 17(3) of that Act. In determining the scope of section 79(3), the Department was mindful of the proposition that the courts will seek to avoid a construction of legislation that causes unjustifiable inconvenience to persons who are subject to an enactment, since this is unlikely to have been intended by Parliament (*Bennion on Statutory Interpretation*, 5th Edition, p.979). In this particular case, the Department's view is that Parliament should not be imputed as intending, as a consequence of conferring a power to prescribe particular bodies as designated bodies, that smaller businesses would be put to disproportionate difficulties simply because of the practical difficulty of specifying in the regulations the class of smaller hospitals that should be exempt from the burdens placed on designated bodies. The Department has concluded that it would be practically impossible to decide, other than on an administrative basis, which independent hospitals should be exempt from these burdens, and in particular the requirement to appoint a CDAO. A number of factors are necessarily relevant to that decision. For example, a small clinical unit offering a lot of palliative care (e.g. a hospice) might well need to appoint a CDAO, whereas a clinical unit of similar economic size but whose activities did not involve significant use of controlled drugs (e.g. a facility mostly engaged in offering screening facilities) might not. The Department has adopted the approach of setting out the parameters for a decision to exempt, but giving the CQC and HIS the administrative role of interpreting those parameters in particular cases. The Department, after careful consideration of this matter, has concluded that this approach falls within the available powers.

4. Legislative Context

4.1 In response to the Fourth Shipman Inquiry report of 2004, the previous Government accepted the need to strengthen the governance arrangements for the use and management of CDs in the community, but to do so in a way which did not hinder patients from accessing the healthcare treatments they need. The Inquiry exposed a number of loopholes in the statutory arrangements for the management and use of controlled drugs that Dr Shipman had been able to exploit.

4.2 One consequence was the enactment of sections 17 – 25 of the Health Act 2006. These sections provide for the making of regulations to require health bodies described as "designated bodies" to appoint CDAOs; and for health bodies and other organisations (termed "responsible bodies") to co-operate in sharing information and taking action to deal with concerns about controlled drugs matters. They also deal in outline with some ancillary issues such as inspections. The provisions in the Health Act 2006 are enabling only. Implementation of the scheme that they provide for, and the detail of the scheme, are left to regulations.

4.3 The 2006 Regulations came into effect in England on 1st January 2007 and in Scotland on 1st March 2007. They provided, in England, for Primary Care Trusts to perform a key role in the strengthened CD governance arrangements. Not only were they "designated bodies", with a CDAO responsible for ensuring that appropriate arrangements for the safe management and use of controlled drugs were made by the providers of health care from whom they commissioned services, such as GP practices and community pharmacies, but they were also the "responsible body" that led the local intelligence networks (LINs) made up of representatives of responsible bodies (which included commissioners and providers of health care, and enforcement and regulatory agencies including local authorities, regulatory bodies and the police). The purpose of LINs is to facilitate co-operation between different bodies in sharing information and intelligence where there are concerns about local CD practices and to enable appropriate action to be taken to address those concerns. Health Boards perform a similar role in Scotland, and are additionally responsible for the arrangements for the safe management and use of controlled drugs in the NHS hospitals for which they are responsible.

4.4 The Health and Social Care Act 2012 made fundamental changes to NHS structures in England. These come fully into effect from 1st April 2013. As a consequence, the 2006 Regulations need to be replaced to update the requirements and reflect these new structures. This also has provided an opportunity for a general review of the operation of the regulatory regime.

5. Territorial Extent and Application

5.1 This instrument applies to England and Scotland.

6. European Convention on Human Rights

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

7. Policy background

- ***What is being done and why***

7.1 From 1st April 2013, PCTs in England will no longer exist. As a result, the full responsibilities and powers of PCT CDAOs will transfer to the new NHS Commissioning Board from that date. The Board will determine the number of LINs that will take over the roles and functions of existing PCT-led LINs and will appoint CDAOs to lead them.

7.2 The essential three-part framework of the 2006 Regulations continues in these Regulations. Firstly, the Regulations designate particular bodies as "designated bodies", and these bodies are required to appoint CDAOs. Some detail is given about who may be appointed as a CDAO, and there are obligations to keep national lists of CDAOs, which fall to CQC in England and HIS in Scotland. The core functions of CDAOs are set out, which relate either to the institutions for which CDAOs work or for the contractors from which they commission relevant services. At the heart of these functions are monitoring, auditing and investigation obligations in relation to the management and use of controlled drugs.

7.3 Secondly, the Regulations provide for the establishment of the LINs. They share information about individuals, described for these purposes as "relevant persons", who are engaged in the area covered by the LIN in activities that involve, or may involve, the management or use of controlled drugs. As indicated above, LINs are led by the CDAOs of the National Health Service Commissioning Board in England and Health Boards in Scotland. Membership of a LIN is to be drawn, at the invitation of those CDAOs, from the "responsible bodies" mentioned in paragraph 4.3 above.

7.4 Thirdly, the Regulations cover ancillary matters such as the carrying out inspections, and enable the CQC, HIS and the General Pharmaceutical Council to obtain information from particular persons engaged in relevant activities.

7.5 A number of changes have been made to update and simplify the previous arrangements that were set out in the 2006 Regulations. These include:

- reducing the total number of regulations from 31 to 21, whilst maintaining the essential features and functions of CDAOs;
- providing a clearer and more logical structure based on the three key areas of Accountable Officers, Responsible Bodies, and supplementary matters;
- rebalancing the emphasis within the Regulations on ensuring safe clinical practice as well as the security of controlled drugs throughout the supply chain;
- removing a number of specific record-keeping obligations and clarifying the information management obligations;
- simplifying the list of activities and functions for which CDAOs must have standard written operating procedures in place;
- removing from independent hospitals and NHS hospital trusts the need to ensure that any sub-contractors of theirs that perform relevant activities have appropriate CD management and use systems in place;
- removing some obligations on CDAOs in relation to securing relevant education and training;
- introducing new exemptions from the regulatory obligations for certain types of business (please refer to Section 11 below);

- applying the regulatory scheme, for the first time, to the armed forces; and
- introducing a sun-setting provision so that these Regulations lapse in 2020. This would oblige the Government of the day to legislate to preserve these Regulations, in whole or in part, if it wished to retain them.

7.6 Together, the changes ensure that measures designed to help safeguard patients and the public are sufficiently robust, whilst at the same time facilitating a proportionate response to incidents and concerns relating to controlled drug mismanagement or misuse. It is an important feature of these Regulations that, as before, they include no criminal sanctions. These Regulations sit alongside the Misuse of Drugs Act 1971 and the regulations under that Act, which enable a punitive response to controlled drug misuse, where appropriate. That is not always the case, and these Regulations provide a framework of appropriate safeguards where that is not the case.

- ***Consolidation***

7.7 These Regulations revise and consolidate the Controlled Drugs (Supervision of Management and Use) Regulations 2006.

8. Consultation and outcome

8.1 The draft revised Regulations were developed with the support of a multi-disciplinary Working Group, which included representatives from the NHS and private industry, regulators and the Scottish Government. Papers from the Group's work are available on the Department's website at http://www.transparency.dh.gov.uk/category/minutes-2/controlled-drugs.

8.2 The Group were able to take account of comments received on the 2006 Regulations which were part of the Department's and Medicines and Healthcare products Regulatory Agency's regulations scrutinised under the Medicines theme of the Red Tape Challenge. This Challenge was launched in England in 2011 and is designed to highlight different areas of domestic regulations affecting business, civil society organisations or citizens in England to promote open discussion of how the aims of existing regulation can be fulfilled in the least burdensome way possible. The Challenge on these Regulations ran from 8th March 2012 – 12th April 2012. 46 comments were received. The Department is publishing its final response to those comments alongside the 2013 Regulations. At http://www.dh.gov.uk/health/tag/controlled-drugs.

8.3 Formal consultation on the revised draft Regulations took place from 27th September 2012 until 15th November 2012. Views were requested on 23 different aspects of the proposed Regulations. 93 responses were received from a mixture of national, NHS, private and third sector, professional and representative bodies as well as individual CDAOs. The Department is publishing its summary response to these further comments alongside these Regulations at http://www.dh.gov.uk/health/tag/controlled-drugs.

9. Guidance

9.1 The Department has developed further information to support the roll-out of these new provisions, in partnership with members of the Working Group described in paragraph 8.1 above and others. This supplementary information has been revised for the use of the NHS Commissioning Board and others concerned with the implementation of the new requirements. The Department is publishing this supplementary information alongside these Regulations at http://www.dh.gov.uk/health/tag/controlled-drugs.

10. Impact

10.1 These Regulations are being made primarily as a consequence of changes brought about by the Health and Social Care Act 2012. The Department published a draft Impact Assessment as part of the consultation refereed to in paragraph 8.3 above and the Department's revised final Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on http://www.legislation.gov.uk.

11. Regulating small business

11.1 In addition to the simplification measures described in paragraph 7.5 above, the 2013 Regulations also introduce new provisions designed to reduce the burdens on smaller businesses. In particular, independent sector micro and start-up businesses in England and Scotland with fewer than 10 staff or contractors will be exempt from the requirements of the new Regulations to appoint a CDAO. This accords with the Government's moratorium on new regulations impacting on such businesses introduced in 2011. As mentioned in paragraph 3.1, the English and Scottish regulators (CQC and HIS) will also be able to exempt, on application, small businesses which provide hospital facilities but with 10 or more staff from the need to appoint a CDAO where they are satisfied this would present disproportionate difficulties for that business.

12. Monitoring & review

12.1 The Department has, since 2007, commissioned the Care Quality Commission (CQC) – previously the Healthcare Commission - to monitor progress on the implementation of the regulatory requirements and overall compliance in England. The CQC publish annual reports. Since the first report in 2007, it has tracked continual improvements in CD governance arrangements. Overall, it has found that safer CD management and use has become embedded in organisational healthcare practice. The Department is asking the CQC to continue this work and to take account of the impact of the new simplified regulatory requirements on CD governance arrangements overall.

13. Contact

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