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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations contain measures relating to arrangements underpinning the safe management and use of controlled drugs in England and Scotland. They replace the Controlled Drugs (Supervision of Management and Use) Regulations 2006, which are revoked by these Regulations (regulation 21).

A number of commissioners and providers of health care are prescribed as designated bodies, which are the bodies required to appoint controlled drugs accountable officers (CDAOs) (regulation 7). The list of bodies so prescribed includes independent hospitals, but there are arrangements providing for some small independent hospitals to be exempt from the designated body obligations under these Regulations (regulations 3 and 4).

Provision is also made for who may be appointed as CDAOs (regulation 8), how they may be removed from office (regulation 9) and the national lists that are to be kept of them (regulation 10). The core functions of CDAOs are set out in regulations 11 to 13, and essentially these relate to securing systems for safe management and use of controlled drugs, either at the institutions for which the CDAOs work or at the contractors from which they commission relevant services, depending on whether their designated body is essentially a provider or commissioner of relevant services (or both). The CDAO functions include monitoring, auditing and investigation obligations, in particular where matters are identified through the required incident reporting systems and systems for recording concerns.

Regulation 14 provides for the establishments of local intelligence networks for the sharing of information about individuals, described for these purposes as “relevant persons” (a term explained in regulation 5) who are engaged in activities that involve, or may involve, the management or use of controlled drugs. These local networks are led by the CDAOs of the National Health Service Commissioning Board in England and Health Boards in Scotland, and they draw their membership, at the invitation of the local lead CDAO, from the bodies prescribed as “responsible bodies” (regulation 6). The list of bodies so prescribed includes not only commissioners and providers of health care but also enforcement and regulatory agencies such as the police. Provision is made for co-operation between responsible bodies, and in relation to the handling of, and acting on, shared information – including in relation to the taking of steps to protect the safety of patients and the general public (regulations 15 and 16).

There are provisions relating to the carrying out of inspections (regulations 17 and 18), and enabling the Care Quality Commission, Healthcare Improvement Scotland and the General Pharmaceutical Council to obtain information from particular persons engaged in relevant activities (regulation 19). There is also an information management provision to prevent the inappropriate handling of information received by designated bodies and responsible bodies (regulation 20).

An impact assessment relating to this instrument as it applies to England has been prepared and copies can be obtained from the Department of Health, Skipton House, 80 London Road, London SE1 8LH. It is also available alongside this instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).