STATUTORY INSTRUMENTS

2006 No. 3148

DANGEROUS DRUGS, ENGLAND, SCOTLAND

The Controlled Drugs (Supervision of Management and Use) Regulations 2006

Made - - - -	*21st November 2006*
Laid before Parliament	*30th November 2006*
Coming into force	
as they apply to England	*1st January 2007*
as they apply to Scotland	*1st March 2007*

CONTENTS

The Secretary of State for Health makes these Regulations in exercise of powers conferred by sections 17, 18, 20(3) and (7) and 79(3) of the Health Act 2006(**a**).

The Scottish Ministers have been consulted in accordance with section 24(6) of that Act.

PART 1

Preliminary

Citation, commencement and application

1.—(1) These Regulations may be cited as the Controlled Drugs (Supervision of Management and Use) Regulations 2006, and—

(a) as they apply in relation to England, shall come into force on 1st January 2007; and

(b) as they apply in relation to Scotland, shall come into force on 1st March 2007.

(2) These Regulations apply in relation to England and Scotland only.

(**a**) 2006 c.28.

Interpretation

2.—(1) In these Regulations—

"the 1977 Act" means the National Health Service Act 1977(**a**);

"the 1978 Act" means the National Health Service (Scotland) Act 1978(**b**);

"the 2000 Act" means the Care Standards Act 2000(**c**);

"the 2003 Act" means the Health and Social Care (Community Health and Standards) Act 2003(**d**);

"the 2006 Act" means the Health Act 2006;

"the 2006 Regulations" means the National Health Service (Discipline Committees) (Scotland) Regulations 2006(**e**);

"accountable officer" means a person nominated or appointed under regulation 4;

"Commission for Social Care Inspection" means the Commission for Social Care Inspection established under section 42 of the 2003 Act (the Commission for Social Care Inspection);

"Common Services Agency" means the body constituted under section 10 of the 1978 Act(**f**) (Common Services Agency);

"designated body" shall be construed in accordance with regulation 3;

"English care home" means a body that runs an establishment in England which is a care home for the purposes of the 2000 Act by virtue of section 3 of that Act (care homes);

"English independent hospital" means a body that runs a hospital in England which is not a health service hospital (within the meaning given in section 128(1) of the 1977 Act(**g**) (interpretation and construction)) but which is—

(a) an establishment, the main purpose of which is to provide palliative care or medical or psychiatric treatment for illness or for mental disorder (that is, mental illness, arrested or incomplete development of mind, psychopathic disorder, or any other disorder or disability of mind); or

(b) any other establishment in which treatment or nursing (or both) are provided for persons liable to be detained under the Mental Health Act 1983(**h**);

"Health Board" means a board which is constituted under, and called a Health Board by virtue of, section 2(1)(a) of the 1978 Act(**i**) (Health Boards);

"the health service" means—

(a) as regards England, the health service established in pursuance of the National Health Service Act 1946(**j**); and

(b) as regards Scotland, the health service established in pursuance of the National Health Service (Scotland) Act 1947(**k**);

(**a**) 1977 c.49.
(**b**) 1978 c.29.
(**c**) 2000 c.14.
(**d**) 2003 c.43.
(**e**) S.S.I. 2006/330.
(**f**) Section 10 has been amended by the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13), Schedule 2, paragraph 2(4).
(**g**) Relevant amendments have been made to section 128(1) by: the Health Service Act 1980 (c.53), Schedule 1, paragraph 77(d); the National Health Service and Community Care Act 1990 (c.19), section 26(2)(c); the Health Act 1999 (c.8), Schedule 4, paragraph 38(2)(a); and the Health and Social Care (Community Health and Standards) Act 2003, Schedule 4, paragraph 42.
(**h**) 1983 c.20.
(**i**) Section 2(1) has been amended by: the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 7, paragraph 1; the National Health Service and Community Care Act 1990, section 28(4); and the Smoking, Health and Social Care (Scotland) Act 2005, Schedule 2, paragraph 2(2).
(**j**) 1946 c.81. This Act was repealed by the National Health Service Act 1977.
(**k**) 1947 c.27. This Act was repealed by the National Health Service (Scotland) Act 1978.

"Healthcare Commission" means the Commission for Healthcare Audit and Inspection established by section 41 of the 2003 Act (Commission for Healthcare Audit and Inspection);

"local authority" means—

(a) an English council referred to in section 1 of the Local Authority Social Services Act 1970(**a**) (local authorities);

(b) the Council of the Isles of Scilly; or

(c) a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994(**b**) (constitution of councils) and also includes a joint board or joint committee within the meaning of section 235(1) of that Act);

"local intelligence network" shall be construed in accordance with regulation 18(2);

"misuse of drugs legislation" means the Misuse of Drugs Act 1971(**c**) and any subordinate legislation made under that Act;

"National Waiting Times Centre Board" means the Special Health Board constituted under article 3 of the National Waiting Times Centre Board (Scotland) Order 2002(**d**) (constitution, name and area of the Board);

"NHS Business Services Authority" means the NHS Business Services Authority established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(**e**);

"NHS foundation trust" means an NHS foundation trust authorised under Part 1 of the 2003 Act;

"NHS Quality Improvement Scotland" means the Special Health Board constituted under article 3 of the NHS Quality Improvement Scotland Order 2002(**f**) (constitution, name and area of the Board);

"NHS trust" means an National Health Service trust established by an Order under section 5(1) of the National Health Service and Community Care Act 1990(**g**) (NHS trusts);

"Primary Care Trust" means a Primary Care Trust established under section 16A of the 1977 Act(**h**) (Primary Care Trusts);

"registered dentist" means a person who is registered in the dentists register kept under section 14 of the Dentists Act 1984(**i**) (the dentists register and the registrar);

"registered pharmacist" means a person registered in the register of pharmacists maintained by the Royal Pharmaceutical Society of Great Britain;

"retail pharmacy business" has the meaning given in section 132 of the Medicines Act 1968(**j**) (general interpretation provisions);

"registered pharmacy" means a retail pharmacy business in England or Scotland that is for the time being entered in the register kept under section 75 of the Medicines Act 1968 (registration of premises);

"regulatory body" means a body referred to in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 (the Council for the Regulation of Health Care Professionals);

"relevant premises" shall be construed in accordance with regulation 20;

(**a**) 1970 c.42; amended by the Local Government Act 1972 (c.70), section 195(3), and the Local Government (Wales) Act 1994 (c.19), Schedule 10, paragraph 7.
(**b**) 1994 c.39.
(**c**) 1971 c.38.
(**d**) S.S.I. 2002/305.
(**e**) S.I. 2005/3361.
(**f**) S.S.I 2002/534.
(**g**) Section 5(1) was amended by the Health Act 1999, sections 13(1)(a) and(10) and 65(2) and Schedule 5.
(**h**) Section 16A was inserted by the Health Act 1999, section 2(1), and amended by the National Health Service Reform and Health Care Professions Act 2002 (c.17), section 2(2) and (3).
(**i**) 1984 c. 24.
(**j**) 1968 c.67. There are amendments to section 132 which are not relevant to the definition of "retail pharmacy business".

"responsible body", unless the context otherwise requires, shall be construed in accordance with regulation 22;

"Scottish Ambulance Service Board" means the Special Health Board established under the Scottish Ambulance Service Board Order 1999(**a**);

"Scottish Commission for the Regulation of Care" means the Scottish Commission for the Regulation of Care established under section 1 of the Regulation of Care (Scotland) Act 2001(**b**) (Scottish Commission for the Regulation of Care);

"Scottish independent hospital" means a body that runs a hospital in Scotland that is an independent hospital within the meaning given in section 77(1) and (2) of the Regulation of Care (Scotland) Act 2001(**c**) (interpretation);

"Special Health Board" means a board which is constituted under, and called a Special Health Board by virtue of, section 2(1)(b) of the 1978 Act;

"State Hospitals Board for Scotland" means the Special Health Board constituted under article 3 of the State Hospitals Board for Scotland Order 1995(**d**) (constitution, name and area of the Board);

"Strategic Health Authority" means a Strategic Health Authority established under section 8 of the 1977 Act(**e**) (which relates to Strategic Health Authorities).

(2) Where, by virtue of these Regulations, a person or body is required to ensure a matter, the requirement is to be construed as a requirement to take all reasonable steps to ensure that matter.

(3) Where reference is made in these Regulations to arrangements to provide services, the reference is to be construed as a reference to arrangements to provide services that involve, or may involve, the management or use of controlled drugs.

(4) For the purposes of these Regulations, "enactment" includes, an enactment comprised in, or an instrument made under, an Act of the Scottish Parliament.

PART 2

Accountable officers

Designated bodies

3. The following are prescribed as designated bodies for the purposes of section 17 of the 2006 Act—

(a) a Primary Care Trust;

(b) a Health Board;

(c) an NHS trust;

(d) an NHS foundation trust;

(e) an English or Scottish independent hospital; and

(f) the following Special Health Boards—

(i) the Scottish Ambulance Service Board,

(ii) the National Waiting Times Centre Board, and

(iii) the State Hospitals Board for Scotland.

(**a**) S.I. 1999/686.
(**b**) 2001 asp 8.
(**c**) Relevant amendments have been made to section 77 by the Mental Health (Care and Treatment) (Scotland) Act 2003 (asp 13), section 331, and Schedule 4, paragraph 10, and Schedule 5, Part 1.
(**d**) S.I. 1995/574.
(**e**) Section 8 was substituted by the National Health Service Reform and Health Care Professions Act 2002, section 1(2).

Appointment of accountable officers and national lists

4.—(1) A designated body must nominate or appoint (or under regulation 5(2), (4) or (6) jointly nominate or appoint with one or more other bodies) a fit, proper and suitably experienced person as its accountable officer.

(2) A designated body in England must notify the Head of Operations of the Healthcare Commission in writing of—

(a) any nomination or appointment by it under paragraph (1) as soon as practicable; and

(b) the removal of an accountable officer by it (whether or not under regulation 6) as soon as practicable.

(3) The Healthcare Commission must publish, from time to time and in such manner as it sees fit, a list of accountable officers of designated bodies in England.

(4) A designated body in Scotland must notify the Scottish Ministers in writing of—

(a) any nomination or appointment by it under paragraph (1) as soon as practicable; and

(b) the removal of an accountable officer by it (whether or not under regulation 6) as soon as practicable.

(5) The Scottish Ministers must publish, from time to time and in such manner as they see fit, a list of accountable officers of designated bodies in Scotland.

Persons who may be appointed as accountable officers

5.—(1) An English independent hospital may only nominate or appoint a person as its accountable officer if—

(a) the person is—

(i) its registered manager, or

(ii) one of its officers or employees who is answerable to its registered manager,

and if the person is its registered manager, he must be answerable to the chief executive, chairman or managing director of the hospital; and

(b) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(2) Two or more English independent hospitals may jointly nominate or appoint one registered manager to be the accountable officer for both or all of the hospitals if the registered manager—

(a) is registered as manager in relation to both or all of the hospitals; and

(b) does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(3) A Scottish independent hospital may only nominate or appoint a person as its accountable officer if—

(a) the person is—

(i) its manager, or

(ii) one of its officers or employees who is answerable to its manager,

and if the person is its manager, he must be answerable to the chief executive, chairman or managing director of the hospital; and

(b) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(4) Two or more Scottish independent hospitals may jointly nominate or appoint one manager to be the accountable officer for both or all of the hospitals if the manager—

(a) is the manager of both or all of the hospitals; and

(b) does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(5) Subject to paragraph (6), a designated body which is neither an English nor a Scottish independent hospital may only nominate or appoint a person as its accountable officer if—

(a) the person is an officer or employee of the designated body, and—

(i) a member of the board of directors, or the management or executive committee of the designated body,

(ii) a member of the body (howsoever it may be called) that has responsibility for the management of the designated body, or

(iii) is answerable to a person referred to in paragraph (i) or (ii); and

(b) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(6) Two or more designated bodies which are neither English nor Scottish independent hospitals but which are of the same type may jointly nominate or appoint one person to be the accountable officer for both or all of the bodies, if—

(a) the person satisfies paragraph (5)(a) in relation to one of the designated bodies;

(b) each designated body is satisfied that the person can properly discharge his responsibilities in relation to it; and

(c) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(7) In this regulation—

"manager", in relation to a Scottish independent hospital, means the person appointed as the manager of that hospital pursuant to regulation 17(1) of the Regulation of Care (Requirements as to Care Services) (Scotland) Regulations 2002(**a**) (appointment of manager); and

"registered manager", in relation to an English independent hospital, means the person who is registered under Part II of the 2000 Act as the manager of the hospital.

Removal of accountable officers

6.—(1) A designated body must, having duly considered the matter, remove its accountable officer from office if—

(a) he no longer satisfies the conditions set out in regulation 5; or

(b) he is unfit to be an accountable officer.

(2) A designated body (or, in the case of a joint appointment, the designated bodies that made the joint appointment, acting jointly) must adopt a procedure (which may be part of an internal disciplinary procedure) for consideration, where it is on notice that its accountable officer has breached his duties under these Regulations, of whether or not it needs to remove him under paragraph (1)(b).

(3) A person shall be presumed (unless the contrary is proved) to be unfit to be an accountable officer if he wilfully, negligently or through lack of competence breaches his duties as an accountable officer under these Regulations.

(4) This regulation is without prejudice to any other arrangements that a designated body (or, in the case of a joint appointment, the designated bodies that made the joint appointment, acting jointly) may have for removal of its accountable officer from office as part of the arrangements under which he is employed or engaged.

Funds and other resources available to accountable officers

7.—(1) A designated body must provide its accountable officer with the funds and other resources necessary to enable him to carry out his responsibilities as its accountable officer.

(2) Those other resources may include access to and use of information systems, accommodation and staff.

(**a**) S.S.I. 2002/114; there have been no relevant amending instruments.

Accountable officers to have regard to best practice

8. In discharging his responsibilities, an accountable officer must have regard to best practice in relation to the management and use of controlled drugs.

Accountable officers to secure the safe management and use of controlled drugs

9.—(1) An accountable officer must—

(a) both—

(i) establish and operate, or ensure that his designated body establishes and operates, appropriate arrangements for securing the safe management and use of controlled drugs by the designated body, and

(ii) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his designated body establishes and operates appropriate arrangements for securing the safe management and use of controlled drugs by that body or person; and

(b) both—

(i) review, or ensure that his designated body reviews, arrangements established by him or his designated body in accordance with sub-paragraph (a)(i), and

(ii) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his designated body reviews arrangements established by it or him in accordance with sub-paragraph (a)(ii).

(2) In particular, an accountable officer must, as part of these arrangements—

(a) establish or ensure that his designated body (and any body or person acting on behalf of, or providing services under arrangements made with, his designated body) establishes appropriate arrangements to comply with misuse of drugs legislation; and

(b) ensure that his designated body (and any body or person acting on behalf of, or providing services under arrangements made with his designated body) has adequate and up-to-date standard operating procedures in place in relation to the management and use of controlled drugs.

(3) The standard operating procedures must, in particular, cover the following matters—

(a) who has access to the controlled drugs;

(b) where the controlled drugs are stored;

(c) security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;

(d) disposal and destruction of controlled drugs;

(e) who is to be alerted if complications arise; and

(f) record keeping, including—

(i) maintaining relevant controlled drugs registers under misuse of drugs legislation, and

(ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2001(**a**) (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

Accountable officers to ensure adequate destruction and disposal arrangements for controlled drugs

10. An accountable officer must—

(**a**) 2001/3998; the relevant amending instrument is S.I.2003/1432.

(a) establish and operate, or ensure that his designated body establishes and operates, appropriate arrangements for securing the safe destruction and disposal of controlled drugs by his designated body; and

(b) ensure that any body or person acting on behalf of, or providing services under arrangements made with, his designated body establishes and operates appropriate arrangements for securing the safe destruction and disposal of controlled drugs by that body or person.

Accountable officers to ensure monitoring and auditing of the management and use of controlled drugs by designated bodies etc.

11.—(1) An accountable officer must—

(a) establish and operate, or ensure that his designated body establishes and operates, appropriate arrangements for monitoring and auditing his designated body's management and use of controlled drugs; and

(b) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his designated body establishes and operates appropriate arrangements for monitoring and auditing the person or body's management and use of controlled drugs (that is, their management and use of controlled drugs under their arrangements with the designated body, not under any other arrangements).

(2) Those arrangements must, in particular, provide for the following—

(a) monitoring and analysing health service and private prescribing of controlled drugs through—

(i) in England, the use of ePACT (Electronic Prescribing Analysis and Costs) data (where data is available to the designated body) and analysis tools available from the Prescription Pricing Division of the NHS Business Services Authority, or

(ii) in Scotland, the use of PRISMS (Prescribing Information System for Scotland) data (where data is available to the designated body) and analysis tools available from the Healthcare Information Group of the Information Services Division of the Common Services Agency;

(b) ensuring that the designated body (and any body or person acting on behalf of, or providing services under arrangements made with, the designated body) has systems in place to alert the accountable officer of any complaints or concerns involving the management or use of controlled drugs;

(c) ensuring that the designated body (and any body or person acting on behalf of, or providing services under arrangements made with, the designated body) has an incident reporting system in place for untoward incidents involving the management or use of controlled drugs; and

(d) ensuring that the designated body (and any body or person acting on behalf of, or providing services under arrangements made with, the designated body) has appropriate arrangements in place for analysing and responding to untoward incidents involving the management or use of controlled drugs.

Powers to require declarations and self-assessments, as part of accountable officers' monitoring and auditing arrangements or otherwise

12.—(1) An accountable officer, who is an accountable officer nominated or appointed by a Primary Care Trust or a Health Board, may request a periodic declaration and a self-assessment from a general medical practitioner on (in England) its medical performers list or (in Scotland) its primary medical services performers list, which must state—

(a) whether the practitioner uses controlled drugs at any of the premises from which he provides primary medical services as part of the health service; and

(b) how the practitioner manages and uses controlled drugs at those premises.

(2) The Healthcare Commission may request an appropriate periodic declaration and an appropriate self-assessment from an NHS trust, an NHS foundation trust or a person registered with them that provides health care.

(3) The Commission for Social Care Inspection may request an appropriate periodic declaration and an appropriate self-assessment from an English care home.

(4) The Royal Pharmaceutical Society of Great Britain may request an appropriate periodic declaration and an appropriate self-assessment from a registered pharmacy.

(5) In this regulation, "general medical practitioner" means a medical practitioner whose name is included in the register maintained by the General Medical Council under article 10 of the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003(**a**) (the General Practitioner Register).

Accountable officers to ensure relevant individuals receive appropriate training etc.

13.—(1) An accountable officer must—

(a) establish and operate, or ensure that his designated body establishes and operates; and

(b) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his designated body establishes and operates,

the arrangements mentioned in paragraph (2).

(2) Those arrangements are appropriate arrangements to ensure that persons who are—

(a) as regards the designated body, relevant individuals(**b**); and

(b) involved in prescribing, supplying, administering or disposing of controlled drugs,

receive, from time to time, appropriate training to carry out their responsibilities.

(3) The accountable officer must liaise with his designated body to ensure that arrangements are in place for the relevant individuals referred to in paragraph (2)—

(a) to receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs; and

(b) to be informed when any local standard operating procedures for controlled drugs are subsequently reviewed or amended.

Accountable officers to monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance

14.—(1) An accountable officer must—

(a) establish and operate, or ensure that his designated body establishes and operates; and

(b) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his designated body establishes and operates,

the arrangements mentioned in paragraph (2).

(2) Those arrangements are appropriate arrangements—

(a) for monitoring and auditing the management and use of controlled drugs by a person who is, as regards the designated body, a relevant individual; and

(b) for monitoring and assessing the performance of persons who are, as regards the designated body, relevant individuals, in connection with the management and use of controlled drugs.

(3) The arrangements under paragraph (1) must, where appropriate, provide for the following—

(**a**) S.I. 2003/1250.
(**b**) The expression "relevant individual" is defined in section 17(8)(b) of the Health Act 2006.

(a) recording, in accordance with regulation 15, any concerns raised in relation to the management or use of controlled drugs by a relevant individual;

(b) assessing and investigating, in accordance with regulation 16, any concerns raised regarding the management or use of controlled drugs by a relevant individual; and

(c) determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers should be shared with a responsible body under regulation 25.

Accountable officers to maintain a record of concerns regarding relevant individuals

15.—(1) An accountable officer must—

(a) establish and operate, or ensure that his designated body establishes and operates, appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual; and

(b) ensure that any body or person acting on behalf of, or providing services under arrangements made with, his designated body establishes and operates appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual.

(2) The accountable officer must ensure, as part of the arrangements under paragraph (1), that adequate records are compiled, which must include (but not be limited to), as appropriate—

(a) the date on which the concern was made known to the accountable officer;

(b) any dates on which the matters that led to the concern took place;

(c) details regarding the nature of the concern;

(d) details of the relevant individual in relation to whom the concern was expressed;

(e) details of the person who, or body which, made known the concern;

(f) details of any action taken by the designated body (or a body or person acting on behalf of, or providing services under arrangements made with, the designated body) in relation to the concern;

(g) the assessment of whether information in relation to the concern should be disclosed to another responsible body under regulation 25 or 26; and

(h) if information regarding the concern is disclosed to another responsible body under regulation 25 or 26, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.

(3) Any record of a concern may be kept in paper or electronic format.

(4) The arrangements under paragraph (1) must include arrangements that limit access to the records to—

(a) the accountable officer and his staff; and

(b) others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.

Accountable officers to assess and investigate concerns

16.—(1) An accountable officer must establish and operate, or ensure that his designated body establishes and operates, appropriate arrangements for—

(a) assessing concerns expressed about incidents that involved, or may have involved, the improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual; and

(b) investigating such concerns.

(2) If, after an assessment of a concern expressed, the accountable officer decides that an investigation is needed, the accountable officer may—

(a) carry out that investigation himself;

(b) make a written request for another officer or employee of his designated body to carry out the investigation; or

(c) if appropriate, and subject to paragraphs (5) and (6)—

(i) make a written request for an officer or employee (including, in the case of a designated body, an accountable officer) from any of the responsible bodies listed in paragraph (3) to carry out the investigation, or

(ii) make a written request for a number of officers or employees from any of the responsible bodies listed in paragraph (3) to form a joint investigation team to carry out the investigation.

(3) The following are responsible bodies for the purposes of section 18 of the 2006 Act and this regulation—

(a) a designated body;

(b) the Healthcare Commission;

(c) the Counter Fraud and Security Management Service Division of the NHS Business Services Authority;

(d) the Commission for Social Care Inspection;

(e) a police force;

(f) NHSScotland Counter Fraud Services (which is part of the Common Services Agency); and

(g) a regulatory body.

(4) An accountable officer may use his powers under paragraph (2)(c) to request an investigation (or a joint investigation with other responsible bodies) by—

(a) the Counter Fraud and Security Management Service Division of the NHS Business Services Authority; or

(b) NHSScotland Counter Fraud Services (which is part of the Common Services Agency),

into any possible fraud in relation to the health service.

(5) In Scotland, if an accountable officer decides that an investigation into any possible fraud in relation to the health service is needed, he must exercise his powers under paragraph (2)(c) to request an investigation by NHSScotland Counter Fraud Services (which is part of the Common Services Agency) before exercising those powers in any other way.

(6) The accountable officer must keep, or ensure that his designated body keeps, a record of—

(a) any request made to an accountable officer from another designated body, or to another responsible body, under paragraph (2)(c) to investigate a concern that involved, or may have involved, the improper management or use of controlled drugs;

(b) any assessment or investigation of a concern that involved, or may have involved, improper management or use of controlled drugs by a relevant individual that the accountable officer or his designated body carried out; and

(c) any notification given to another responsible body or accountable officer under regulation 25(4).

Accountable officers to take appropriate action if there are well-founded concerns

17.—(1) An accountable officer must establish and operate, or ensure that his designated body establishes and operates, appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards the designated body, a relevant individual, appear to be well-founded.

(2) If there are well-founded concerns in relation to the management or use of controlled drugs by relevant individuals, or wider concerns of possible fraud in relation to the health service, as part of the arrangements established under paragraph (1), but subject to paragraphs (4) and (5), the action that the accountable officer may take may include (although it need not be limited to) any of the following—

(a) requesting additional advice, support, mentoring or training from an appropriate person, including—

(i) a prescribing advisor,

(ii) a clinical governance lead, or

(iii) in the case of an employee, a line manager within the designated body;

(b) implementation of a serious untoward incident procedure;

(c) referral of the concerns to a regulatory body;

(d) referral of the concerns to a police force;

(e) in a case of possible fraud in relation to the health service, referral of the concerns to—

(i) the Counter Fraud and Security Management Service Division of the NHS Business Services Authority, or

(ii) NHSScotland Counter Fraud Services (which is part of the Common Services Agency);

(f) sharing information with, and requesting information from, other responsible bodies, in accordance with regulation 25 or 26; or

(g) if the accountable officer is an accountable officer nominated or appointed by a Primary Care Trust or Health Board, convening an incident panel, made up of officers from any of the bodies that are responsible bodies for the purposes of Part 4, to investigate the concern and make recommendations as mentioned in paragraph (3).

(3) An incident panel convened under paragraph (2)(g) may recommend that the accountable officer or designated body take action that includes (although it need not be limited to) any of the following—

(a) ongoing monitoring of the relevant individual;

(b) referral of the concerns to another accountable officer;

(c) referral of the concerns to a regulatory body;

(d) referral of the concerns to a police force; or

(e) implementation of a serious untoward incident procedure.

(4) In Scotland, if the accountable officer of a Health Board is aware of well-founded concerns in relation to the management or use of controlled drugs by a person who—

(a) is a relevant individual as respects the accountable officer's Health Board, and the Health Board is an "appropriate Health Board", as defined in regulation 2 of the 2006 Regulations (interpretation), as respects that individual;

(b) is a "practitioner" for the purposes of the 2006 Regulations (that is, a doctor, a dentist, an ophthalmic medical practitioner, an optician, a pharmacist or a pharmacist contractor(**a**)); and

(c) may, in a way that is related to those concerns, have failed to comply with "terms of service", as defined in regulation 2 of the 2006 Regulations, that he has with that or another Health Board,

then subject to paragraph (5), the accountable officer for the Health Board must, as part of the arrangements established under paragraph (1), ensure that his Health Board takes a decision in relation to the possible breach of terms of service under regulation 4(1) of the 2006 Regulations (provisions relating to the start of disciplinary proceedings).

(**a**) *See* the definition of "practitioner" in regulation 2 of the 2006 Regulations.

(5) In Scotland, if, arising out of arrangements under this regulation, an accountable officer becomes aware of well-founded concerns relating to a possible fraud in relation to the health service, the accounting officer must—

(a) refer the concerns to NHSScotland Counter Fraud Services (which is part of the Common Services Agency); and

(b) take advice from NHSScotland Counter Fraud Services before taking any disciplinary action against any person which could compromise any action taken by NHSScotland Counter Fraud Services as a consequence of that referral.

Accountable officers to establish arrangements for sharing information

18.—(1) An accountable officer must establish and operate, or ensure that his designated body establishes and operates, appropriate arrangements for ensuring the proper sharing of information, in accordance with regulation 25 or 26, by his designated body with other responsible bodies regarding the management and use of controlled drugs.

(2) If the accountable officer is an accountable officer nominated or appointed by a Primary Care Trust or Health Board, those arrangements must include establishing a network (a "local intelligence network") for sharing information regarding the management and use of controlled drugs.

(3) The network shall include (although it need not be limited to) the following types of bodies, as appropriate—

(a) in England—

(i) a Primary Care Trust,

(ii) an NHS trust,

(iii) an NHS foundation trust,

(iv) a Strategic Health Authority,

(v) the Healthcare Commission,

(vi) the Commission for Social Care Inspection, and

(vii) the Counter Fraud and Security Management Service Division of the NHS Business Services Authority;

(b) in Scotland—

(i) a Health Board,

(ii) the Scottish Commission for the Regulation of Care,

(iii) NHS Quality Improvement Scotland, and

(iv) NHSScotland Counter Fraud Services (which is part of the Common Services Agency);

(c) a regulatory body;

(d) a police force; and

(e) a local authority.

PART 3

Entering premises, periodic inspections etc.

Accountable officers to carry out periodic inspections

19.—(1) An accountable officer, who is an accountable officer nominated or appointed by a Primary Care Trust or Health Board, must establish and operate appropriate arrangements or ensure that his designated body establishes and operates appropriate arrangements for making, in

connection with the performance of functions under these Regulations, periodic inspections (in accordance with section 20 of the 2006 Act) of premises which are—

(a) used in connection with management or use of controlled drugs; and

(b) not subject to inspection by—

(i) the Healthcare Commission,

(ii) the Commission for Social Care Inspection, or

(iii) the Royal Pharmaceutical Society of Great Britain.

(2) Where a designated body has authorised in writing under section 20(5)(c) of the 2006 Act a person to carry out inspections of relevant premises (or of specific relevant premises), the arrangements under paragraph (1) may (where appropriate) provide for that person to carry out periodic inspections under the arrangements.

(3) The accountable officer, or the person referred to in paragraph (2), is not required to give notice of the inspection to the owner or occupier of the premises.

(4) The accountable officer, or the person referred to in paragraph (2), must keep a record of all the inspections carried out by him as part of the arrangements made under paragraph (1).

(5) That record of inspections may be kept in paper or electronic format.

Relevant premises

20.—(1) For the purposes of section 20 of the 2006 Act, the following are prescribed as relevant premises which may be inspected by an accountable officer who is an accountable officer nominated or appointed by a Primary Care Trust, Health Board or Special Health Board or (where appropriate) by a member of the staff of the Primary Care Trust, Health Board or Special Health Board—

(a) the premises of the Primary Care Trust, Health Board or Special Health Board for which he is the accountable officer or (where appropriate) of which he is a member of staff;

(b) the premises of a body or person acting on behalf of, or providing services under arrangements made with, that Primary Care Trust, Health Board or Special Health Board, unless those arrangements are with an NHS trust, an NHS foundation trust or an English or Scottish independent hospital; and

(c) any other premises which are covered by arrangements established by virtue of regulation 19(1) but which are not mentioned in sub-paragraphs (a) or (b).

(2) For the purposes of section 20 of the 2006 Act, the following are prescribed as relevant premises which may be inspected by an accountable officer who is an accountable officer nominated or appointed by an NHS trust or an NHS foundation trust or (where appropriate) by a member of the staff of the trust—

(a) the premises of the trust for which he is the accountable officer or (where appropriate) of which he is a member of staff; and

(b) the premises of a body or person acting on behalf of, or providing services under arrangements made with, that trust, unless those arrangements are with a Primary Care Trust, a Health Board, Special Health Board or an English or Scottish independent hospital.

(3) For the purposes of section 20 of the 2006 Act, the following are prescribed as relevant premises which may be inspected by an accountable officer who is an accountable officer nominated or appointed by an English or Scottish independent hospital or (where appropriate) by a member of the staff of the independent hospital—

(a) the premises of the independent hospital for which he is the accountable officer; and

(b) the premises of a body or person acting on behalf of, or providing services under arrangements made with, that independent hospital, unless those arrangements are with a Primary Care Trust, a Health Board, a Special Health Board, an NHS trust or a foundation trust.

(4) All the premises mentioned in paragraphs (1) to (3) are also prescribed as relevant premises in relation to constables and persons authorised by the relevant authority under section 20(5)(a) (and accordingly they may exercise the powers under section 20 of the 2006 Act as regards those premises).

(5) An authorisation given under section 20(5)(a) or (c) of the 2006 Act must be in writing.

(6) An accountable officer ("the first accountable officer") may request in writing that an accountable officer of another designated body of the same type (or in the case of a health service body in Scotland, of another health service body in Scotland) inspect—

(a) the premises of the designated body of the first accountable officer; or

(b) the premises of a body or person acting on behalf of, or providing services under arrangements made with the designated body of the first accountable officer,

subject to an appropriate authorisation being granted.

Inspections of private dwellings not requiring the presence of a constable

21. Section 20(3) of the 2006 Act does not apply as regards—

(a) a member of staff of, or person authorised by, the Commission for Social Care Inspection entering an English care home;

(b) an officer of the Royal Pharmaceutical Society of Great Britain entering a registered pharmacy;

(c) a member of staff of, or a person authorised by, a designated body, entering premises which are or form part of a private dwelling of a health care professional—

(i) who is providing health care (which includes the services of a pharmacist) at the private dwelling, and

(ii) the private dwelling is on a statutory register of health care premises or is designated as practice premises under arrangements with a Primary Care Trust or Health Board to provide primary medical or dental services.

PART 4

Co-operation between health bodies and other organisations

Responsible bodies for the purposes of this Part

22.—(1) The following are responsible bodies for the purposes of section 18 of the 2006 Act and this Part—

(a) a Primary Care Trust;

(b) a Health Board;

(c) an NHS trust;

(d) an NHS foundation trust;

(e) a Strategic Health Authority;

(f) an English or Scottish independent hospital;

(g) the Healthcare Commission;

(h) the Commission for Social Care Inspection;

(i) the NHS Business Services Authority, in relation to the performance of its functions by—

(i) the Counter Fraud and Security Management Service Division, and

(ii) the Prescription Pricing Division;

(j) the Common Services Agency, in relation to the performance of its functions by—

(i) NHSScotland Counter Fraud Services,

(ii) the Information Services Division, and

(iii) the Practitioner Services Division;

(k) the following Special Health Boards—

(i) the Scottish Ambulance Service Board,

(ii) the National Waiting Times Centre Board, and

(iii) the State Hospitals Board for Scotland;

(l) a police force;

(m) a local authority; and

(n) a regulatory body.

Relevant persons

23. In accordance with section 19(1)(a) of the 2006 Act, the following are prescribed as relevant persons (and accordingly are "relevant persons" for the purposes of this Part in addition to those persons who are mentioned in section 19(1)(b) of the 2006 Act)—

(a) a registered medical practitioner or registered dentist who is providing medical services to private patients only;

(b) a person engaged in any activity carried on by a registered medical practitioner or registered dentist referred to in paragraph (a) that involves, or may involve, the supply or administration of controlled drugs;

(c) a registered pharmacist who is providing services on behalf of, or under arrangements made with, a registered pharmacy, in circumstances where that registered pharmacy is not providing services as part of the health service (whether under arrangements made with a designated body or on behalf of a person or body that has such arrangements);

(d) a person, other than a registered pharmacist, engaged in any activity carried on or by a registered pharmacist referred to in paragraph (c) that involves, or may involve the supply or administration of controlled drugs;

(e) a registered midwife or nurse who is providing midwifery or nursing services to private patients only that involve, or may involve, the supply or administration of controlled drugs;

(f) in England, a person who is carrying on or engaged in any activity that involves, or may involve, the supply or administration of controlled drugs, and who is—

(i) a person who is registered under Part II of the 2000 Act as the manager of, or the person who is carrying on, a care home (referred to in this paragraph as "a registered person"), or

(ii) a person engaged in any activity carried on by a registered person.

General duty on responsible bodies to co-operate with each other as regards relevant persons

24. Responsible bodies must co-operate with each other in connection with—

(a) the identification of cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person;

(b) the consideration of issues relating to the taking of action in respect of such matters; and

(c) the taking of action in respect of such matters.

Duty to co-operate by disclosing information as regards relevant persons

25.—(1) A responsible body may disclose to any other responsible body any information in its possession or control which it reasonably considers it should share with that body for the purposes of—

(a) identifying cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person;

(b) the consideration of issues relating to the taking of action in respect of such matters;

(c) the taking of action in respect of such matters.

(2) If the responsible body wishes to disclose information under this regulation which—

(a) contains confidential information which relates to and can identify a patient; and

(b) that confidential information is not required for the purposes of identifying cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person, or for considering or taking action in such a case,

the responsible body must, so far as it is practical to do so, remove from the information the confidential information which relates to and can identify the patient.

(3) If the responsible body—

(a) is unable, under paragraph (2), to remove from any information to be disclosed any confidential information which relates to and can identify a patient; or

(b) considers it necessary to disclose information which contains the confidential information that relates to and can identify the patient,

the responsible body must, where practicable, obtain the consent of the patient to whom the information relates.

(4) If the responsible body (or its accountable officer) has—

(a) commenced an assessment of or an investigation into a matter of concern in relation to the management or use of controlled drugs by a relevant individual under regulation 16 (that individual being a relevant person for the purposes of this Part); or

(b) completed an assessment of or an investigation into a matter of concern under regulation 16,

it must notify the persons and bodies listed in paragraph (5) of the commencement or completion of the assessment or investigation, as the case may be, and provide appropriate details regarding the nature of the assessment or investigation.

(5) Those persons and bodies are—

(a) if the responsible body has an accountable officer and he is unaware of the action taken, that accountable officer;

(b) the accountable officer nominated or appointed as accountable officer for any Primary Care Trust or Health Board in whose area the relevant individual lives or provides health care or services related to health care; and

(c) any other responsible body that it considers it appropriate to notify.

(6) A responsible body is not required to notify any person or body, or to provide any details, under paragraph (4) where to do so would prejudice or would be likely to prejudice—

(a) any investigation being conducted by the responsible body, or any other responsible body, under any enactment; or

(b) any civil or criminal proceedings.

(7) In Scotland, if information that a responsible body wishes to share relates to a possible fraud in relation to the health service, the information may only be shared between members of a local intelligence network under this regulation where to do so is in accordance with the partnership agreement known as the NHSScotland Counter Fraud Services Partnership Agreement with Health Boards and Special Health Boards, established under section 10(6) of the 1978 Act(**a**) (Common Services Agency).

(**a**) Section 10 was amended by: the Health Services Act 1980 (c.53), Schedule 6, paragraph 2; the National Health Service and Community Care Act 1990 (c.19), Schedule 10; and the Health Act 1999 (c.8), Schedule 4, paragraph 4.

(8) Nothing in this regulation requires or permits any disclosure of information which is prohibited by or under any other enactment.

(9) In determining for the purposes of paragraph (8) whether disclosure is not prohibited by reason of being a disclosure of personal data which is exempt from the non-disclosure provisions of the Data Protection Act 1998(**a**) by virtue of section 35(1) of that Act (disclosure required by law or made in connection with legal proceedings etc.), it is to be assumed that the disclosure is required by this regulation.

Responsible bodies requesting additional information be disclosed about relevant persons

26.—(1) If a responsible body has in its possession or control information relating to the management or use of controlled drugs by a relevant person that it considers to be of serious concern (which may be fitness to practise information that is unrelated to any specific instance of the management or use of a controlled drug), it may request in writing additional information in relation to the matter from any other responsible body which it considers may have relevant information.

(2) If a responsible body has received a request under paragraph (1)—

(a) it shall determine within a reasonable period of time whether or not to comply with the request; and

(b) it may disclose any information relating to the management or use of controlled drugs by a relevant person which it reasonably considers to be relevant to the request.

(3) If the responsible body wishes to disclose information under this regulation which contains confidential information which relates to and can identify a patient, the responsible body must, so far as it is practical to do so, remove from the information the confidential information which relates to and can identify the patient.

(4) If the responsible body—

(a) is unable, under paragraph (3), to remove from any information to be disclosed any confidential information which relates to and can identify a patient; or

(b) considers it necessary to disclose information which contains the confidential information that relates to and can identify the patient,

the responsible body must, where practicable, obtain the consent of the patient to whom the information relates.

(5) A responsible body is not required to disclose information under this regulation if the disclosure—

(a) would prejudice, or would be likely to prejudice, any investigation being conducted by the responsible body, or by any other responsible body, under any enactment;

(b) would prejudice, or would be likely to prejudice, any civil or criminal proceedings; or

(c) would involve disproportionate cost.

(6) In Scotland, if information that a responsible body wishes to share relates to a possible fraud in relation to the health service, the information may only be shared between members of a local intelligence network under this regulation where to do so is in accordance with the partnership agreement known as the NHSScotland Counter Fraud Services Partnership Agreement with Health Boards and Special Health Boards, established under section 10(6) of the 1978 Act (Common Services Agency).

(7) Nothing in this regulation requires or permits any disclosure of information which is prohibited by or under any other enactment.

(8) In determining for the purposes of paragraph (7) whether disclosure is not prohibited by reason of being a disclosure of personal data which is exempt from the non-disclosure provisions of the Data Protection Act 1998 by virtue of section 35(1) of that Act (disclosure required by law

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(**a**) 1998 c.29.

or made in connection with legal proceedings etc.), it is to be assumed that the disclosure is required by this regulation.

Restrictions relating to disclosures

27.—(1) If a responsible body that is disclosing or to which is being disclosed any information under regulation 25 or 26 has an accountable officer, the disclosure must be made by or to the accountable officer or his staff (and not by or to any other person who may act on behalf of the responsible body).

(2) If a responsible body has received information under regulation 25 or 26, it must not process that information more than is necessary for the purposes of—

(a) identifying cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person;

(b) considering issues relating to the taking of action in respect of such matters; or

(c) taking action in respect of such matters.

(3) In particular, the responsible body must—

(a) not allow any person access to that information unless he is a person who, by virtue of his contract of employment or otherwise, is aware of the purposes for which the information may be processed; and

(b) ensure that appropriate organisational measures are taken to prevent unauthorised disclosure or processing of the information.

Record keeping requirements relating to regulations 25 and 26

28.—(1) A responsible body must keep a record of—

(a) a decision to disclose information under regulation 25;

(b) details of the nature of the information disclosed;

(c) details of the responsible body to which information was disclosed; and

(d) any other details which the responsible body considers to be relevant to the disclosure.

(2) A responsible body must keep a record of—

(a) any request received from another responsible body to disclose information under regulation 26;

(b) details of the nature of any information disclosed;

(c) details of the responsible body to which the information was disclosed; and

(d) any other details which the responsible body considers to be relevant to the disclosure.

(3) The records may be kept in paper or electronic format.

Occurrence reports

29.—(1) An accountable officer (other than an accountable officer nominated or appointed as accountable officer for a Primary Care Trust or Health Board) must give, on a quarterly basis, an occurrence report to the accountable officer nominated or appointed as accountable officer for the Primary Care Trust or Health Board that is leading any local intelligence network of which he or his designated body is a member.

(2) The occurrence report may contain the following information—

(a) details of any concerns that his designated body has regarding its management or use of controlled drugs; or

(b) confirmation by his designated body that it has no concerns to report regarding its management or use of controlled drugs.

(3) Nothing in this regulation requires or permits any disclosure of information which is prohibited by or under any other enactment.

(4) In determining for the purposes of paragraph (3) whether disclosure is not prohibited by reason of being a disclosure of personal data which is exempt from the non-disclosure provisions of the Data Protection Act 1998 by virtue of section 35(1) of that Act (disclosure required by law or made in connection with legal proceedings etc.), it is to be assumed that the disclosure is required by this regulation.

Accountable officers' duties to protect the safety of patients and the general public

30.—(1) If the information shared by a responsible body under regulation 25 or 26 shows a concern about inappropriate or unsafe use of controlled drugs by a relevant person, the accountable officer of any designated body responsible for—

(a) entering into any arrangements with the relevant person; or

(b) entering into any arrangements with any other person or body, under which the relevant person provides or may provide services,

that has possession or control of that information may make recommendations to any responsible body (including, where appropriate, his own designated body) as to any action which the accountable officer considers that the responsible body should take to protect the safety of patients or the general public.

(2) If the concern relates to a relevant person who is not providing services to, or under arrangements that another person or body has with, a designated body, the accountable officer leading the local intelligence network for any area in which the relevant person lives or provides services must—

(a) seek to take reasonable steps to protect the safety of patients or the general public; and

(b) where appropriate, refer the matter to a relevant responsible body (for example, a regulatory body or a police force).

Disclosure of information in good faith

31. Civil proceedings do not lie against a person in respect of loss, damage or injury of any kind suffered by another person as a result of the disclosure of information in good faith under regulation 25, 26, 29 or 30.

Signed by authority of the Secretary of State for Health

Andy Burnham
Minister of State,
Department of Health

21st November 2006

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations contain measures relating to arrangements underpinning the safe management and use of controlled drugs in England and Scotland.

Part 1 outlines preliminary matters.

Part 2 relates to accountable officers. A number of health care bodies are prescribed as designated bodies (regulation 3), and these are required to appoint accountable officers (regulation 4). There are limitations on who may act as accountable officers (regulation 5) and a duty on designated bodies to establish arrangements for their removal from office in specified circumstances (regulation 6). Designated bodies are required to ensure that their accountable officers are sufficiently resourced (regulation 7).

Accountable officers are given a number of functions relating to the safe management and use of controlled drugs. Essentially, these require the establishment by the accountable officer of a number of sets of arrangements which relate to the safe management and use of controlled drugs. As well as the basic arrangements (regulation 9), these include safe disposal arrangements (regulation 10) and auditing arrangements (regulation 11). As well as being given functions in relation to their own designated bodies, accountable officers are given functions in relation to health care professionals and others whose work involves the management and use of controlled drugs, for which their designated body is responsible. These responsibilities include maintaining records of and investigating concerns (regulations 15 and 16), and taking appropriate action where there are well-founded concerns (regulation 17). Accountable officers for Primary Care Trusts and Health Boards also have particular responsibilities for setting up local intelligence networks, relating to the management and use of controlled drugs, for their area (regulation 18).

Part 3 contains arrangements in relation to periodic inspections of premises used for the management and use of controlled drugs, where these issues would not be dealt with as part of other health and social care inspections, and other measures in relation to powers of entry.

Part 4 deals with co-operation between a number of listed health care bodies and other organisations (regulation 22), and in particular contains detailed arrangements with regard to the disclosure of information between the bodies that are required, by the Regulations, to co-operate with each other in connection with the identification of cases where action may need to be taken against individuals (regulations 24 to 27). There are record keeping requirements (regulation 28), and duties with regard to occurrence reports, which are quarterly statements that accountable officers must make about details of concerns that their designated body has (regulation 29). Accountable officers have duties to take action with regard to concerns that they have (regulation 30), and persons acting in good faith under the arrangements for sharing information under this Part are protected from damages claims (regulation 31).

A regulatory impact assessment relating to the effect that this instrument will have is available from the Department of Health, Skipton House, 80 London Road, London SE1 6LH. Copies of the assessment have been placed in the libraries of both Houses of Parliament.

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