

STATUTORY RULES OF NORTHERN IRELAND

2009 No. 225

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

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) the Regional Board;
- (b) a HSC Trust;
- ^{F1}(c)
- (d) [^{F2}a relevant independent hospital].
- [^{F3}(e) the headquarters in Northern Ireland of regular or reserve forces.]

- F1** Reg. 3(c) omitted (16.7.2015) by virtue of [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), **5(a)**
- F2** Words in reg. 3(d) substituted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), **5(b)**
- F3** Reg. 3(e) inserted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), **5(c)**

Commencement Information

- II** [Reg. 3](#) in operation at 1.10.2009, see [reg. 1](#)

[^{F4}Appointment of and support for accountable officers

4.—(1) Each designated body shall nominate or appoint, or in a group with one or more other designated bodies shall jointly nominate or appoint, a fit, proper and suitably experienced person to be its accountable officer.

(2) Where more than one part of an undertaking is a designated body, an aggregate of parts of that undertaking jointly appointing or nominating an accountable officer is a group of designated bodies for the purposes of this regulation, whether or not the aggregate is, or is part of, a single legal person.

(3) All the designated bodies in a group of designated bodies that are jointly nominating or appointing an accountable officer shall be in Northern Ireland.

(4) A person appointed under paragraph (1) (P) shall satisfy Conditions 1, 2 and 3.

(5) Condition 1 is that P shall be—

- (a) in the case of the headquarters of regular or reserve forces, or headquarters of regular or reserve forces acting jointly, a senior officer (that is, a lieutenant colonel or a person of equivalent or superior rank) of the regular or reserve forces (and sub-paragraphs (b) to (d) do not apply in such cases);
 - (b) a senior manager of P's designated body;
 - (c) where designated bodies are jointly acting—
 - (i) unless head (ii) applies, a senior manager of one of the designated bodies jointly acting,
 - (ii) if the designated bodies jointly acting are part of the same undertaking, a senior manager of that undertaking; or
 - (d) answerable to a senior manager who satisfies sub-paragraph (b) or (c).
- (6) Condition 2 is that P shall be an officer or employee—
- (a) of the designated body that nominates or appoints P; or
 - (b) if P is nominated or appointed by designated bodies jointly acting—
 - (i) of one of the designated bodies jointly acting, or
 - (ii) where those bodies are part of the same undertaking, of that undertaking.
- (7) Condition 3 is that P does not, or does only exceptionally, prescribe, supply, administer or dispose of controlled drugs as part of P's duties as an employee or officer—
- (a) of P's designated body; or
 - (b) if P is nominated or appointed by designated bodies jointly acting and those bodies are part of the same undertaking, of that undertaking.
- (8) Two or more designated bodies may only jointly nominate or appoint a person to be their accountable officer if they are satisfied that P is capable of properly discharging P's functions under these Regulations in relation to each and all of them.
- (9) A designated body of a description given in paragraph (b) or (d) of regulation 3 may only jointly nominate or appoint a person to be their accountable officer with another designated body of the same description.
- (10) Each designated body that has an accountable officer shall provide P with the funds and other resources necessary for enabling P to discharge P's responsibilities as accountable officer (in the case of joint nominations or appointments, this obligation may be discharged through joint arrangements for provision of funds and other resources).
- (11) The other resources may include access to and use of information systems, accommodation and staff.]

F4 [Reg. 4](#) substituted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), 6

Persons who may be appointed as accountable officers

^{F5}5.

F5 [Reg. 5](#) revoked (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), 22

Removal of accountable officers

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

- (a) he no longer satisfies [^{F6}condition 1, 2 or 3] set out in regulation [^{F6}4(5) to (7)]; 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) shall 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, [^{F7}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.

F6 Words in reg. 6(1)(a) substituted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), **7(a)**

F7 Word in reg. 6(2) substituted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), **7(b)**

Commencement Information

I2 [Reg. 6](#) in operation at 1.10.2009, see [reg. 1](#)

[^{F8}List of accountable officers

6A.—(1) Each designated body shall as soon as is practicable notify the Department in writing of—

- (a) any nomination or appointment by it of an accountable officer, or
- (b) the removal from office by it of an accountable officer.

(2) Where the nomination or appointment of an accountable officer, or removal from office of an accountable officer, is by a group of designated bodies, notification under paragraph (1) may be undertaken by the designated body or undertaking of which the accountable officer is or was an employee or officer, on behalf of the group.

(3) The Department shall compile, maintain and publish from time to time, and in such manner as it sees fit, a list of accountable officers of designated bodies in Northern Ireland.]

F8 [Reg. 6A](#) inserted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), **8**

Funds and other resources available to accountable officers

^{F9}7.

F9 Reg. 7 revoked (16.7.2015) by The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015 (S.R. 2015/278), regs. 1(1), 22

Accountable officers to have regard to best practice

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

Commencement Information

I3 Reg. 8 in operation at 1.10.2009, see **reg. 1**

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

- 9.—(1)** An accountable officer shall—
- (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 any 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 any 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 shall, as part of these arrangements—
- (a) establish or ensure that his designated body (and any 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 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 shall, in particular, cover the following matters [^{F10}unless not applicable to his designated body]—
- (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 (Northern Ireland) 2002⁽¹⁾ (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients^[F11;]
- [^{F12}(g) best practice relating to—
- (i) the prescribing, supply and administration of controlled drugs, and
 - (ii) clinical monitoring of patients who have been prescribed controlled drugs.]

- F10** Words in [reg. 9\(3\)](#) inserted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), [regs. 1\(1\), 9\(a\)\(i\)](#)
- F11** [Reg. 9\(3\)\(f\)](#): semi colon substituted for full stop (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), [regs. 1\(1\), 9\(a\)\(ii\)](#)
- F12** [Reg. 9\(3\)\(g\)](#) added (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), [regs. 1\(1\), 9\(b\)](#)

Commencement Information

- I4** [Reg. 9](#) in operation at 1.10.2009, see [reg. 1](#)

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

- 10.**—(1) An accountable officer shall—
- (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 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.

Commencement Information

- I5** [Reg. 10](#) in operation at 1.10.2009, see [reg. 1](#)

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

- 11.**—(1) An accountable officer shall—
- (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 any person acting on behalf of, or providing services under arrangements made with, his designated body, establishes and operates appropriate arrangements for monitoring and auditing their 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 shall, in particular, provide for the following—
- (a) monitoring and analysing health care and private prescribing of controlled drugs through the use of data and analysis tools available from RBSO;
 - (b) ensuring that the designated body (and any 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 person acting on behalf of, or providing services under arrangements made with, the designated body) has an incident reporting system in place for adverse incidents involving the management or use of controlled drugs; and
 - (d) ensuring that the designated body (and any 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 adverse incidents involving the management or use of controlled drugs.

Commencement Information

I6 [Reg. 11](#) in operation at 1.10.2009, see [reg. 1](#)

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

12.—(1) The accountable officer, nominated or appointed by the Regional Board, may request a periodic declaration and a self-assessment from a general medical practitioner on its primary medical services performers list or from a registered dentist providing general dental services or piloted services under a pilot scheme, which shall state—

- (a) whether he uses controlled drugs at any of the premises from which the above services are provided; and
- (b) how he manages and uses controlled drugs at those premises.

(2) The Department may request a periodic declaration and a self-assessment from a registered pharmacy.

(3) RQIA may request a periodic declaration and a self-assessment from a HSC Trust or any person registered with them that provides health care.

(4) In this regulation, “general medical practitioner” means a medical practitioner whose name is included in the register, (the General Practitioner Register) maintained by the General Medical Council under [^{F13}section 34C of the Medical Act 1983].

F13 Words in [reg. 12\(4\)](#) substituted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), [regs. 1\(1\), 10](#)

Commencement Information

I7 [Reg. 12](#) in operation at 1.10.2009, see [reg. 1](#)

Accountable officers to ensure relevant individuals receive appropriate training etc.

13.—(1) An accountable officer shall—

- (a) establish and operate, or ensure that his designated body establishes and operates; and
- (b) ensure that any 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; 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 shall 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.

Commencement Information

18 Reg. 13 in operation at 1.10.2009, see [reg. 1](#)

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

14.—(1) An accountable officer shall—

- (a) establish and operate, or ensure that his designated body establishes and operates; and
- (b) ensure that any 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) shall, where appropriate, provide for the following—

- (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.

Commencement Information

19 [Reg. 14](#) in operation at 1.10.2009, see [reg. 1](#)

Accountable officers to maintain a record of concerns regarding relevant individuals

15.—(1) An accountable officer shall—

- (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 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 shall 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 any 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) shall 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.

Commencement Information

110 [Reg. 15](#) in operation at 1.10.2009, see [reg. 1](#)

Accountable officers to assess and investigate concerns

16.—(1) An accountable officer shall 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 paragraph (5)—
 - (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 Department;
- (c) the Counter Fraud Unit of RBSO;
- (d) the Police Service of Northern Ireland;
- (e) RQIA;
- (f) 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 the Counter Fraud Unit of RBSO into any possible fraud in relation to health care.

(5) The accountable officer shall 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; and
- (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).

Commencement Information

111 Reg. 16 in operation at 1.10.2009, see [reg. 1](#)

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

17.—(1) An accountable officer shall 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 health care, as part of the arrangements established under paragraph (1), 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 or body, 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, or
 - (iv) the Department;
- (b) implementation of a serious adverse incident procedure;
- (c) referral of the concerns to a regulatory body;
- (d) referral of the concerns to the Police Service of Northern Ireland;
- (e) in a case of possible fraud in relation to health care, referral of the concerns to the Counter Fraud Unit of RBSO;
- (f) sharing information with, and requesting information from, other responsible bodies, in accordance with regulation 25 or 26; or
- (g) requesting that an incident panel be convened by the ^{F14}accountable officer nominated or appointed by the Regional Board], 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) ^{F15}... 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 the Police Service of Northern Ireland; or
- (e) implementation of a serious adverse incident procedure.

F14 Words in reg. 17(2)(g) substituted (16.7.2015) by The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015 (S.R. 2015/278), regs. 1(1), **11(a)**

F15 Words in reg. 17(3) omitted (16.7.2015) by virtue of The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015 (S.R. 2015/278), regs. 1(1), **11(b)**

Commencement Information

I12 Reg. 17 in operation at 1.10.2009, see **reg. 1**

Arrangements for sharing information

18.—(1) An accountable officer shall 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.

[^{F16}(2) The accountable officer nominated or appointed by the Regional Board, shall establish and operate a network (a local intelligence network) for the purposes mentioned in paragraph (3).]

[^{F17}(3) Those purposes are facilitating the co-operation of responsible bodies who are members of the local intelligence network 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 relevant persons;
- (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.]

^{F18}(4)

F16 Reg. 18(2) substituted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), **12(a)**

F17 Reg. 18(3) substituted (16.7.2015) by [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), **12(b)**

F18 Reg. 18(4) omitted (16.7.2015) by virtue of [The Controlled Drugs \(Supervision of Management and Use\) \(Amendment\) Regulations \(Northern Ireland\) 2015 \(S.R. 2015/278\)](#), regs. 1(1), **12(c)**

Commencement Information

I13 [Reg. 18](#) in operation at 1.10.2009, see [reg. 1](#)

Changes to legislation:

There are currently no known outstanding effects for the The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, PART 2.