STATUTORY RULES OF NORTHERN IRELAND

2009 No. 225

DANGEROUS DRUGS

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

Made - - - -	*5th June 2009*
Coming into Operation-	*1st October 2009*

The Department of Health, Social Services and Public Safety(**1**), makes the following Regulations in exercise of the powers conferred on it by sections 17, 18, 20(3) and (7) and 79(3) of the Health Act 2006(**2**).

PART 1

Preliminary

Citation and commencement

1. These Regulations may be cited as the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 and shall come into operation on 1st October 2009.

Commencement Information
I1 Reg. 1 in operation at 1.10.2009, see **reg. 1**

Interpretation

2.—(1) The Interpretation Act (Northern Ireland) 1954(**3**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

(2) In these Regulations—

"the 2003 Order" means the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003(**4**);

(**1**) *See* S.I 1999/283(N.I. 1) Article 3(6)
(**2**) 2006 c.28
(**3**) 1954 c.33 (N.I.)
(**4**) S.I. 2003/431 (N.I. 9)

"the 2006 Act" means the Health Act 2006;

"the 2009 Act" means the Health and Social Care (Reform) Act (Northern Ireland) 2009(**5**);

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

"the Department" means the Department of Health, Social Services and Public Safety;

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

[[F1]"domiciliary care agency" has the meaning assigned to it by Article 2(2) of the 2003 Order;**]**

[F2]...

"general dental services" has the meaning given in Article 2(2) of the Health and Personal Social Services (Northern Ireland) Order 1972(**6**);

"health care" means any services designed to secure improvement in the physical and mental health and prevention, diagnosis and treatment of illness in the people of Northern Ireland;

[[F3]"hospital" shall be construed in accordance with Article 2(2) of the 2003 Order;**]**

"HSC Trust" means a Health and Social Care Trust established under Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991(**7**);

"Independent hospital" means a hospital which is not vested in the Department or managed by a HSC trust and excludes dental practices;

"Local Intelligence Network" shall be construed in accordance with regulation 18(2);

"misuse of drugs legislation" means the Misuse of Drugs Act 1971(**8**) and any subordinate legislation made under that Act;

[F4]...

"nursing home" shall be construed in accordance with Article 11 of the 2003 Order;

"pilot scheme" has the meaning given in Article 3 of the Health Services (Primary Care) (Northern Ireland) Order 1997(**9**);

"piloted services" has the meaning given in Article 3 of the Health Services (Primary Care) (Northern Ireland) Order 1997;

[[F5]"Primary medical services performers list" means the list of persons performing primary medical services prepared in accordance with regulations made under Article 57G of the Health and Personal Social Services (Northern Ireland) Order 1972;**]**

"RBSO" means the Regional Business Services Organisation established under section 14 of the 2009 Act;

"Regional Board" means the Regional Health and Social Care Board established under section 7 of the 2009 Act;

"registered dentist" means a person who is registered in the dentists register kept under section 14 of the Dentists Act 1984(**10**);

"registered medical practitioner" means a person who is registered in the register of medical practitioners under Section 2(2) of the Medical Act 1983(**11**);

(**5**) 2009 c.1
(**6**) S.I. 1972/1265 (N.I. 14)
(**7**) S.I 1991/194 (N.I. 1), and renamed by s. 1(3) of 2009 c.1 (N.I.)
(**8**) 1971 c.38
(**9**) S.I. 1997/1177 (N.I. 7)
(**10**) 1984 c.24
(**11**) 1983 c.54. Section 2 was amended by S.I. 1996/1591 and S.I. 2002/3135

"registered pharmacist" means a person registered in the register of pharmacists maintained by the Pharmaceutical Society of Northern Ireland under Article 6 of the Pharmacy (Northern Ireland) Order 1976(**12**);

"registered pharmacy" means a retail pharmacy business in Northern Ireland that is for the time being entered in the register kept under section 75, (registration of premises), of the Medicines Act 1968(**13**);

[[F6]"regular force" means the Royal Air Force, the Royal Navy, the Royal Marines or the regular army (that is, Her Majesty's military forces other than the Army Reserve, the Territorial Army or the forces raised under the law of a British overseas territory);**]**

[[F7]"regulatory body" means—

(i) a body referred to in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 (the Professional Standards Authority for Health and Social Care); and

(ii) the Northern Ireland Social Care Council;**]**

[[F8]"relevant activities" means activities that involve, or may involve, the management or use of controlled drugs;

"relevant independent hospital" shall be construed in accordance with regulation 2A;**]**

"relevant individual" shall be construed in accordance with section 17(8)(b) of the 2006 Act;

[[F9]"relevant person" shall be construed in accordance with regulation 23;**]**

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

[[F10]"reserve force" means the Royal Air force Reserve, the Royal Auxiliary Air Force, the Royal Fleet Reserve, the Royal Naval Reserve, the Royal Marines reserve, the Army Reserve or the Territorial Army;**]**

"residential care home" shall be construed in accordance with Article 10 of the 2003 Order;

"responsible body" shall be construed in accordance with regulation 22;

"retail pharmacy business" has the meaning given in **[**[F11]regulation 8(1) of the Human Medicines Regulations 2012**]**;

"RQIA" means the Health and Social Care Regulation and Quality Improvement Authority(**14**)**[**[F12];**]**

[[F13]"senior manager", in relation to a body or undertaking means one of the individuals who play significant roles in—

(a) the making of decisions about how the whole or a substantial part of its activities are to be managed or organised; or

(b) the actual managing or organising of the whole or a substantial part of those activities;

"statutory provision" has the meaning assigned to it by section 1(f) of the Interpretation Act (Northern Ireland) 1954.**]**

[[F14]"the UK GDPR" has the same meaning as in Parts 5 to 7 of the Data Protection Act 2018 (see section 3(10) and (14) of that Act);**]**

(3) 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.

(**12**) S.I. 1976/1213 (N.I. 22)
(**13**) 1968 c.67
(**14**) Established by Article 3 of S.I. 2003/431 (N.I. 9) and renamed by s 1(2) of 2009 c.1 (N.I.).

(4) 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.

F1 Words in reg. 2(2) 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), **3(a)**

F2 Words in reg. 2(2) omitted (31.12.2020) by virtue of The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (S.I. 2019/419), reg. 1(2), **Sch. 3 para. 80(a)** (with Sch. 3 para. 112); 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in reg. 2(2) 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), **3(b)**

F4 Words in reg. 2(2) 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), **3(c)**

F5 Words in reg. 2(2) 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), **3(d)**

F6 Words in reg. 2(2) 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), **3(e)**

F7 Words in reg. 2(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), **3(f)**

F8 Words in reg. 2(2) 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), **3(g)**

F9 Words in reg. 2(2) 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), **3(h)**

F10 Words in reg. 2(2) 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), **3(i)**

F11 Words in reg. 2(2) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 123** (with Sch. 32)

F12 Reg. 2(2): 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), **3(j)**

F13 Words in reg. 2(2) 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), **3(k)**

F14 Words in reg. 2(2) inserted (31.12.2020) by The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (S.I. 2019/419), reg. 1(2), **Sch. 3 para. 80(b)** (with Sch. 3 para. 112); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I2 Reg. 2 in operation at 1.10.2009, see **reg. 1**

[F15 Meaning of "relevant independent hospital"

2A.—(1) For the purposes of these Regulations, "relevant independent hospital" means an independent hospital which the Department has determined satisfies the conditions set out in paragraph (2).

(2) The conditions are—

(a) the independent hospital is directly or indirectly concerned with the provision of health care; and

(b) management or use of controlled drugs forms part of the activities of the independent hospital; and

(c) requiring that independent hospital to appoint or nominate an accountable officer would not give rise to difficulties that would be disproportionate to the benefits to be derived from such an appointment or nomination, having regard to—

(i) the usual number of relevant individuals who work at the independent hospital;

(ii) the usual level of relevant activities at or provided from the independent hospital; and

(iii) any difficulties there may be in identifying a suitable individual to act as an accountable officer for that independent hospital, taking into account the size of the business being carried on at or from the independent hospital and any possibility of a joint appointment or nomination by that independent hospital together with other independent hospitals.

(3) A determination under paragraph (1) is to be notified to the independent hospital and is for such duration as the Department specifies, but the determination may thereafter be—

(a) renewed for such further period as the Department specifies; or

(b) rescinded, after the Department has given the independent hospital to which the determination relates reasonable notice of the rescission.

(4) A refusal of a determination under paragraph (1), renewal or refusal to renew under paragraph (3)(a) or rescission under paragraph (3)(b) must be notified to the independent hospital.

(5) Where, in respect of an independent hospital, the Department—

(a) makes a determination, or decides to refuse a determination, under paragraph (1);

(b) renews or refuses to renew a determination under paragraph (3)(a); or

(c) rescinds a determination under paragraph (3)(b),

that independent hospital may request a review of that determination, refusal, renewal or rescission as the case may be.

(6) A request under paragraph (5) must be made in writing within a period of 28 days beginning with the date of the determination, refusal, renewal or rescission as the case may be.

(7) Where an independent hospital has requested such a review under paragraph (5), the Department may ask that independent hospital to furnish such additional information as it thinks fit.

(8) The accountable officer of a relevant independent hospital shall inform the Department of any change in its circumstances which is likely to affect the conditions set out in paragraph (2).**]**

F15 Reg. 2A 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), **4**

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;

F16(c) . . . . . .

(d) **[**F17a relevant independent hospital**]**.

[F18(e) the headquarters in Northern Ireland of regular or reserve forces.**]**

F16 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)**

F17 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)**

F18 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

I3 Reg. 3 in operation at 1.10.2009, see **reg. 1**

[F19**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.**]**

F19 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

[F20 5. . . . . . .

F20 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 **[**[F21]condition 1, 2 or 3**]** set out in regulation **[**[F21]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, **[**[F22]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.

F21 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)**

F22 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
I4 Reg. 6 in operation at 1.10.2009, see **reg. 1**

[F23List 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.**]**

F23 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

F24**7.** . . . . . .

F24 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
I5 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 **[**F25unless 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(**15**) (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients**[**F26;**]**

[F27(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.**]**

F25 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)**

F26 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)**

F27 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

I6 Reg. 9 in operation at 1.10.2009, see **reg. 1**

(**15**) S.R. 2002 No. 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

I7 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

I8 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 **[**F28section 34C of the Medical Act 1983**]**.

F28 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

I9 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

I10 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

I11 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
I12 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

I13 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 **[**F29accountable 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) [F30]... 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.

F29 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)**

F30 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

I14 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.

[[F31](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).**]**

[[F32](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.**]**

[F33](4) . . . . . .

F31 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)**

F32 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)**

F33 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

I15 Reg. 18 in operation at 1.10.2009, see **reg. 1**

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 the Regional Board, shall 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) RQIA[F34]... **[**[F35];**]**

(ii) the Department **[**[F36];**]**

[[F37](iii) an accountable officer of a regular or reserve force.**]**

(2) Where the 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), shall 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.

F34 Word in reg. 19(1)(b)(i) 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), **13(a)**

F35 Semi colon in reg. 19(1)(b)(i) 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), **13(a)**

F36 Reg. 19(1)(b)(ii): 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), **13(b)**

F37 Reg. 19(1)(b)(iii) 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), **13(c)**

Commencement Information

I16 Reg. 19 in operation at 1.10.2009, see **reg. 1**

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 the accountable officer nominated or appointed by the Regional Board, or (where appropriate) by a member of staff of the Regional Board—

(a) the premises of the Regional Board;

(b) the premises of any person acting on behalf of, or providing services under arrangements made with the Regional Board, unless those arrangements are with a HSC Trust **[**F38or regular or reserve force**]**;

(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 nominated or appointed by a HSC trust F39..., or (where appropriate) by a member of the staff of the HSC trust F39...—

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

(b) the premises of any person acting on behalf of, or providing services under arrangements made with the HSC trust, unless those arrangements are with the Board **[**F40, regular or reserve force**]** or **[**F41a relevant 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 nominated or appointed by **[**F42a relevant independent**]** hospital or (where appropriate) by a member of the staff of **[**F42the relevant independent**]** hospital—

(a) the premises of the **[**F43relevant**]** independent hospital for which he is the accountable officer; and

(b) the premises of any person acting on behalf of, or providing services under arrangements made with, that **[**F44relevant**]** independent hospital, unless those arrangements are with the Regional Board **[**F45, regular or reserve force**]** or a HSC Trust.

[F46(3A) 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 nominated or appointed by the regular or reserve force or (where appropriate) by a member of the staff of the regular or reserve force —

(a) the premises of that regular or reserve force in Northern Ireland for which he is the accountable officer or (where appropriate) of which he is a member of staff; and

(b) the premises of anyone acting on behalf of, or providing services under arrangements made with that regular or reserve force, unless those arrangements are with the Regional Board, a HSC Trust or a relevant independent hospital.**]**

(4) All the premises mentioned in paragraphs (1) to **[**F47(3A)**]** are also prescribed as relevant premises in relation to constables and persons authorised by the relevant authority under section 20(5)(a) of the 2006 Act (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 inspect—

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

(b) the premises of any 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.

F38 Words in reg. 20(1)(b) 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), **14(a)**

F39 Words in reg. 20(2) 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), **14(b)(i)**

F40 Words in reg. 20(2)(b) 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), **14(b)(ii)(aa)**

F41 Words in reg. 20(2)(b) 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), **14(b)(ii)(bb)**

F42 Words in reg. 20(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), **14(c)(i)**

F43 Word in reg. 20(3)(a) 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), **14(c)(ii)**

F44 Word in reg. 20(3)(b) 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), **14(c)(iii)(aa)**

F45 Words in reg. 20(3)(b) 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), **14(c)(iii)(bb)**

F46 Reg. 20(3A) 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), **14(d)**

F47 Word in reg. 20(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), **14(e)**

Commencement Information

I17 Reg. 20 in operation at 1.10.2009, see **reg. 1**

Inspections of private dwellings not requiring the presence of a constable

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

(a) a member of staff of, or person authorised by, RQIA entering a residential care home or nursing home;

(b) a member of staff of the Department 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 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 the Regional Board to provide primary medical or dental services.

Commencement Information

I18 Reg. 21 in operation at 1.10.2009, see **reg. 1**

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 designated body;

(b) the Department;

(c) RQIA;

(d) RBSO;

(e) the Police Service of Northern Ireland;

(f) a Regulatory Body.

Commencement Information

I19 Reg. 22 in operation at 1.10.2009, see **reg. 1**

Relevant persons

[[F48]**23.**—(1) Each of the individuals listed in paragraph (2) is a "relevant person" for the purposes of these Regulations (whether or not that person is also a "relevant person" for the purposes of these Regulations by virtue of them being an individual to whom section 19(3) of the 2006 Act applies)—

(2) As regards the Regional Board the individuals are—

(a) a health care professional who provides health care services to private patients other than at or from a relevant independent hospital, where doing so involves or may involve that health care professional in the supply or administration of controlled drugs;

(b) an individual, not being a health care professional, who is engaged in any activity carried on with or on behalf of a health care professional as mentioned in paragraph (a) that involves or may involve that individual in the supply or administration of controlled drugs;

(c) an individual (whether or not paragraph (a) or (b) also applies to that individual) who—

(i) is registered under Part III of the 2003 Order as the manager of, or the person who is carrying on, a residential care home, a nursing home or a domiciliary care agency (referred to in this paragraph as "a registered person") which involves that individual in the supply or administration of controlled drugs, or

(ii) not being the registered person, is or may be engaged in the supply or administration of controlled drugs which are carried on with or on behalf of that registered person.**]**

F48 Reg. 23 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), **15**

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

24. Responsible bodies shall 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.

Commencement Information

I20 Reg. 24 in operation at 1.10.2009, see **reg. 1**

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 shall, 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 shall, 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 shall 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 the Regional Board; 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 **[**F49statutory provision**]**; or

[F50(aa) a regular or reserve force's arrangements for service discipline; or**]**

(b) any civil or criminal proceedings.

(7) Nothing in this regulation requires or permits any disclosure of information which is prohibited by or under any other **[**F51statutory provision**][**F52or the **[**F53UK GDPR**]]**.

[F54(8) In determining for the purposes of paragraph (7) whether disclosure is prohibited, it is to be assumed for the purposes of paragraph 5(2) of Schedule 2 to the Data Protection Act 2018 and paragraph 3(2) of Schedule 11 to that Act (exemptions from certain provisions of the data protection legislation: disclosures required by law) that the disclosure is required by this regulation.**]**

F49 Words in reg. 25(6)(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), **20(a)**

F50 Reg. 25(6)(aa) 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), **16**

F51 Words in reg. 25(7) 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), **20(a)**

F52 Words in reg. 25(7) inserted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 347(2)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

F53 Words in reg. 25(7) substituted (31.12.2020) by The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (S.I. 2019/419), reg. 1(2), **Sch. 3 para. 81** (with Sch. 3 para. 112); 2020 c. 1, Sch. 5 para. 1(1)

F54 Reg. 25(8) substituted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 347(3)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

Commencement Information

I21 Reg. 25 in operation at 1.10.2009, see **reg. 1**

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 shall, 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 shall, 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 **[**F55statutory provision**]**;

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

[F56(ba) would prejudice, or would be likely to prejudice, a regular or reserve force's arrangements for service discipline; or**]**

(c) would involve disproportionate cost.

(6) Nothing in this regulation requires or permits any disclosure of information which is prohibited by or under any other **[**F57statutory provision**][**F58or the **[**F59UK GDPR**]]**.

[F60(7) In determining for the purposes of paragraph (6) whether disclosure is prohibited, it is to be assumed for the purposes of paragraph 5(2) of Schedule 2 to the Data Protection Act 2018 and paragraph 3(2) of Schedule 11 to that Act (exemptions from certain provisions of the data protection legislation: disclosures required by law) that the disclosure is required by this regulation.**]**

F55 Words in reg. 26(5)(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), **20(b)**

F56 Reg. 26(5)(ba) 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), **17**

F57 Words in reg. 26(6) 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), **20(b)**

F58 Words in reg. 26(6) inserted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 348(2)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

F59 Words in reg. 26(6) substituted (31.12.2020) by The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (S.I. 2019/419), reg. 1(2), **Sch. 3 para. 82** (with Sch. 3 para. 112); 2020 c. 1, Sch. 5 para. 1(1)

F60 Reg. 26(7) substituted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 348(3)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

Commencement Information

I22 Reg. 26 in operation at 1.10.2009, see **reg. 1**

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 shall 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 shall 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 shall—

(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.

Commencement Information
I23 Reg. 27 in operation at 1.10.2009, see **reg. 1**

Record keeping requirements relating to regulations 25 and 26

28.—(1) A responsible body shall 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 shall 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.

Commencement Information
I24 Reg. 28 in operation at 1.10.2009, see **reg. 1**

Occurrence reports

29.—**[**[F61](1) An accountable officer (P), other than the accountable officer nominated or appointed by the Regional Board, shall give, on a quarterly basis (or more frequently if there have been concerns that warrant it and the accountable officer of the Regional Board has made a request of P), an occurrence report to the accountable officer for the Regional Board.**]**

(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 **[**[F62]statutory provision**][**[F63]or the **[**[F64]UK GDPR**]]**.

[[F65](4) In determining for the purposes of paragraph (3) whether disclosure is prohibited, it is to be assumed for the purposes of paragraph 5(2) of Schedule 2 to the Data Protection Act 2018 and paragraph 3(2) of Schedule 11 to that Act (exemptions from certain provisions of the data protection legislation: disclosures required by law) that the disclosure is required by this regulation.**]**

F61 Reg. 29(1) 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), **18**

F62 Words in reg. 29(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), **20(c)**

F63 Words in reg. 29(3) inserted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 349(2)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

F64 Words in reg. 29(3) substituted (31.12.2020) by The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (S.I. 2019/419), reg. 1(2), **Sch. 3 para. 83** (with Sch. 3 para. 112); 2020 c. 1, Sch. 5 para. 1(1)

F65 Reg. 29(4) substituted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 349(3)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

Commencement Information

I25 Reg. 29 in operation at 1.10.2009, see **reg. 1**

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

[F66 30.—(1) If information shared under regulation 25 or 26 by a responsible body with another body that is a designated body (DB) shows a concern about the inappropriate or unsafe management or use of controlled drugs by a person who is or who could become as regards DB a relevant individual (RI), paragraph (2) applies.

(2) The accountable officer of the DB may—

(a) make recommendations to any responsible body (including any DB) as to any action that the accountable officer considers that the responsible body should take in relation to RI to protect the safety of patients and the general public; and

(b) in connection with doing so, share information about the concern with that responsible body.

(3) If information is shared under regulation 25 or 26 with the accountable officer of the Regional Board about a person (P), who—

(a) is a relevant person as regards the Regional Board; and

(b) is not providing services to a designated body as a relevant individual;

paragraph 4 applies.

(4) The accountable officer of the Regional Board must take all reasonable steps to protect the safety of patients or the general public in connection with P engaging, or the possibility of P engaging, in relevant activities, including where appropriate—

(a) referral of the matter to a responsible body (for example a regulatory body); and

(b) sharing of information about P with any person or a representative of any body (including at a meeting of the local intelligence network of which that person or representative is not a part) who employs or may employ P in relevant activities.**]**

F66 Reg. 30 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), **19**

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 **[F67**under these Regulations if it is done in good faith and there are reasonable grounds for doing it.**]**

F67 Words in reg. 31 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), **21**

Commencement Information

I26 Reg. 31 in operation at 1.10.2009, see **reg. 1**

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 5th June 2009

L.S.

Christine Jendoubi
A senior officer of the Department of Health,
Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

Part 1 provides for preliminary matters.

Part 2 provides for 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 the 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). The Department of Health, Social Services and Public Safety shall direct accountable officers to set up a local intelligence network, relating to the management and use of controlled drugs in Northern Ireland (regulation 18).

Part 3 provides for 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, along with other measures in relation to powers of entry.

Part 4 provides for 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 shall 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).

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.