

STATUTORY RULES OF NORTHERN IRELAND

2009 No. 225

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

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

II [Reg. 22](#) in operation at 1.10.2009, see [reg. 1](#)

Relevant persons

[^{F1}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.]

F1 [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

I2 [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 [^{F2}statutory provision]; or

[^{F3}(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 [^{F4}statutory provision][^{F5}or the [^{F6}UK GDPR]].

[^{F7}(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.]

- F2** 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)**
- F3** 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**
- F4** 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)**
- F5** 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)
- F6** 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)
- F7** 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

- I3** 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 [^{F8}statutory provision];
- (b) would prejudice, or would be likely to prejudice, any civil or criminal proceedings; or
- [^{F9}(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 [^{F10}statutory provision][^{F11}or the [^{F12}UK GDPR]].

[^{F13}(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.]

- F8** 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)**
- F9** [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**
- F10** 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)**
- F11** 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)
- F12** 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\(1\)](#)
- F13** [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

- I4** [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

I5 [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

I6 [Reg. 28](#) in operation at 1.10.2009, see [reg. 1](#)

Occurrence reports

29.—^[F14](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 [^{F15}statutory provision][^{F16}or the [^{F17}UK GDPR]].

[^{F18}(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.]

- F14** 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**
- F15** 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)**
- F16** 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)
- F17** 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)
- F18** 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

- I7** [Reg. 29](#) in operation at 1.10.2009, see [reg. 1](#)

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

[^{F19}**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.]

F19 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 [^{F20} under these Regulations if it is done in good faith and there are reasonable grounds for doing it.]

F20 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

18 [Reg. 31](#) 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 4.