
STATUTORY RULES OF NORTHERN IRELAND

2009 No. 225

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

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

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

Interpretation

2.—(1) The Interpretation Act (Northern Ireland) 1954⁽¹⁾ 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⁽²⁾;

“the 2006 Act” means the Health Act 2006;

“the 2009 Act” means the Health and Social Care (Reform) Act (Northern Ireland) 2009⁽³⁾;

“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⁽⁴⁾;

“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;

(1) 1954 c.33 (N.I.)

(2) S.I. 2003/431 (N.I. 9)

(3) 2009 c.1

(4) S.I. 1972/1265 (N.I. 14)

[^{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(**5**);

“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(**6**) 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(**7**);

“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(**8**);

“registered medical practitioner” means a person who is registered in the register of medical practitioners under Section 2(2) of the Medical Act 1983(**9**);

“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(**10**);

“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(**11**);

[^{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;]

(5) S.I. 1991/194 (N.I. 1), and renamed by s. 1(3) of 2009 c.1 (N.I.)

(6) 1971 c.38

(7) S.I. 1997/1177 (N.I. 7)

(8) 1984 c.24

(9) 1983 c.54. Section 2 was amended by S.I. 1996/1591 and S.I. 2002/3135

(10) S.I. 1976/1213 (N.I. 22)

(11) 1968 c.67

[^{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(12)[^{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.

(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

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 1.