Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

A CONSULTATION ON THE PROPOSED AMENDMENTS TO THE CONTROLLED DRUGS (SUPERVISION OF MANAGEMENT AND USE) REGULATIONS (NORTHERN IRELAND) 2009

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1. Introduction

1.1 The purpose of this document is to invite views on the Department of Health, Social Services, and Public Safety's ("the Department") proposal to make amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009[1].

2. Policy Background

2.1. Controlled Drugs (CDs) are controlled under the Misuse of Drugs Act 1971 ("the Act"). Access to CDs for healthcare is regulated, in a Northern Ireland context, under the Misuse of Drugs Regulations (Northern Ireland) 2002 (MDR). The main purpose of the Act is to prevent the misuse of CDs and it achieves this by imposing a complete ban on the possession, supply, manufacture, import and export of CDs except as allowed by regulations or by licence. While the Act contains all of the prohibitions, the authorities are contained in the MDR and these govern the legitimate clinical use of CDs. The MDR divide CDs into 5 Schedules according to the level of control required and provide reducing levels of control, depending on the perceived risk of social harm.

Shipman Inquiry

2.2. Lady Justice Dame Janet Smith chaired the Shipman Inquiry which reported on the activities of Dr Harold Shipman who was convicted of 15 murders, and sentenced to life imprisonment on 31 January 2000.

2.3. The Inquiry began in 2001 and released its findings in a series of six reports published between July 2002 and January 2005. The Inquiry established that Harold Shipman probably committed many more than 15 murders primarily through the ease by which he was able to access quantities of diamorphine (a CD).

[1] http://www.legislation.gov.uk/nisr/2009/225/contents/made

2.4. The Fourth Shipman Inquiry report of 2004 concerned the overall management and use of CDs and made recommendations to strengthen the arrangements for CDs. The powers to improve CD governance were provided under Sections 17 - 25 of the Health Act 2006 resulting in the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 ("the Regulations") which came into operation on 1 October 2009. The Regulations were designed to improve CD governance without hindering patients from accessing the treatment they needed.

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

2.5. The Regulations, as far as possible, replicated measures for the supervision of management and use of CDs which came into force in England and Scotland in 2007 and in Wales in 2009. They have not been subject to amendment until now.

2.6. The Regulations prescribe certain health bodies as designated bodies (DBs). In Northern Ireland there are 18 currently, made up of the Regional Board (HSC Board), HSC Trusts and independent hospitals each of which must appoint and resource an Accountable Officer (AO).

2.7. The Regulations assign certain responsibilities to the AO who is required to:

- secure the safe management and use of CDs within their own organisation and by any person or body providing services to their organisation;
- ensure adequate destruction and disposal arrangements for CDs;
- ensure monitoring and auditing of the management and use of CDs;
- ensure relevant individuals receive appropriate training;
- monitor and audit the management and use of CDs by relevant individuals, and to monitor and assess their performance;
- maintain a record of concerns regarding relevant individuals;
- to assess and investigate concerns;
- take appropriate action if there are well-founded concerns;

- co-operate by disclosing information as regards relevant persons;
- submit quarterly Occurrence Reports;
- maintain appropriate records of their actions in accordance with legislative requirements.

Further information on these Regulations can be found in "Safer Management of Controlled Drugs - A Guide to Strengthened Governance Arrangements in Northern Ireland" which sets out the governance arrangements for the management and use of CDs in Northern Ireland (under review).
http://www.dhsspsni.gov.uk/safer-man-of-ctld-dgs-a-gd-to-str-gov-agts-ni.pdf

Issues and Developments

2.8. In 2013 England and Scotland reviewed and amended their equivalent regulations, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 ("the 2006 Regulations"), as a consequence of the Health and Social Care Act 2012 which introduced significant structural changes for the NHS in England. A stakeholder group was established to review the 2006 Regulations and following an extensive consultation the Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force on 1 April 2013.

2.9. Changes in governance arrangements which were introduced in England and Scotland by the Controlled Drugs (Supervision of Management and Use) Regulations 2013 include:

- the inclusion of the armed forces in the list of designated bodies;
- change of definition for independent hospitals providing an exemption for micro businesses with less than 10 employees. Subject to an application an exemption may be granted to larger organisations where Care Quality Commission (CQC) / Healthcare Improvement Scotland (HIS) is satisfied that the appointment of an Accountable Officer (AO) would place disproportionate difficulties on the independent hospital;
- more flexibility for designated bodies in appointing an AO;

- simplification of the meaning of a 'relevant person' which now includes all health care professionals;
- removal of a mandatory list of Standard Operating Procedures (SOPs) on matters such as access, storage and disposal. A requirement for up-to-date SOPs relating to the prescribing, supply and administration of CDs and clinical monitoring of patients using CDs has been included.

3. Northern Ireland Issues and Proposals

3.1. The range of health care workers whose employment does or could require them to have some involvement in the management and use of controlled drugs extends beyond the regulatory bodies captured under the current regulations. Currently regulators prescribed as responsible bodies include, for example, the General Medical Council, the Health and Care Professions Council, the Nursing and Midwifery Council and the Pharmaceutical Society of Northern Ireland.

Proposal: *Regulation 3 – interpretation*
To amend the interpretation of a "regulatory body" to include the Northern Ireland Social Care Council as a "responsible body" and member of the Local Intelligence Network (LIN).

3.2. In February 2014 there was an increase in the number of independent hospitals in Northern Ireland when 32 services, previously registered with the Regulation and Quality Improvement Authority (RQIA) as independent clinics, were re-registered as independent hospitals. The unintended consequence of this change in registration is that these organisations, as with all other independent hospitals, are now prescribed as designated bodies under the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. Many of these newly registered independent hospitals would be required to nominate an AO with legislative responsibilities for the management and use of CDs while having little or no CD usage.

Proposal: *Regulation 4 – Meaning of "relevant independent hospital"*
To ensure that only independent hospitals providing health care and which manage and use CDs are required to appoint an AO.

3.3. Some of the newly registered independent hospitals have only limited CD activity. For these smaller independent hospitals inclusion within the Regulations is likely to impose a disproportionate burden on their organisation.

Proposal: *Regulation 4 – Meaning of "relevant independent hospital"*
To enable the Department to make a determination that an independent hospital will not be required to appoint an AO where the Regulations would impose a disproportionate burden on the organisation. The decision as to whether or not the organisation must appoint an AO would be based on criteria including size, CD activity and the balance between the benefits associated with the appointment of an AO and the potential difficulties encountered by the independent hospital. It is proposed that the Department will make these determinations. An appeal mechanism has been provided.

3.4. The armed forces are not currently prescribed as a designated body by the Regulations and, while they use CDs and employ healthcare professionals, presently they are unable to participate in the activities of the LIN or share relevant information. While they have developed their own equivalent internal arrangements relating to the management and use of CDs, to enable the armed forces to share concerns it is proposed to include them in the list of designated bodies in Northern Ireland.

Proposal: *Regulation 5 – designated bodies*
To align with the arrangements in England and Scotland and include the armed forces in the list of designated bodies. The list of designated bodies in Northern Ireland is now proposed to be as follows:

a) the Regional Board
b) an HSC Trust
c) a relevant independent hospital
d) the headquarters in Northern Ireland of regular or reserve forces.

3.5. The 2009 Regulations stipulate that the AO appointed by an independent hospital must be the registered manager or answerable to the registered manager. This has presented difficulties for some smaller independent hospitals particularly where separating the duties of the registered manager from routine involvement with CDs has been challenging.

Proposal: *Regulation 6 – appointment of accountable officers*
To introduce more flexibility in appointing an AO while ensuring that the AO is a person of sufficient seniority within the organisation.

3.6. The list of Standard Operating Procedures (SOPs) has been simplified in England and Scotland. Their list is now less prescriptive and requires SOPs to be maintained on the prescribing, supply and administration of CDs and the clinical monitoring of patients using CDs.

Proposal: *Regulation 6 – accountable officers to secure the safe management and use of controlled drugs*
To maintain the current mandatory list of SOPs and to add a requirement for SOPs on prescribing, supply and administration of CDs and the clinical monitoring of patients using CDs.

3.7. The 2009 Regulations came into operation at a time of major re-organisation for HSC organisations. As a consequence, the responsibility for establishing the Local Intelligence Network was not assigned to the Accountable Officer of the HSC Board, as in England, Scotland and Wales. This responsibility has been transferred from the Department to the Accountable Officer of the HSC Board.

Proposal: *Regulation 12 – arrangements for sharing information*
To enshrine in legislation that the HSC Board AO will now have responsibility for matters such as the operation of the LIN and for receipt of occurrence reports. Additionally, similarly to England and Scotland, we propose to make

provision for AOs to submit occurrence reports more frequently than quarterly should there be concerns that warrant it.

3.8. The Regulations place a duty of co-operation on organisations (responsible bodies) permitting them to share information giving rise to concerns about the management or use of controlled drugs by any "relevant person". The current definition of "relevant person" does not, however, currently capture the full range of health care workers who have involvement with the management and use of controlled drugs.

Proposal: *Regulation 15 – relevant persons*
To simplify and widen the definition of 'relevant person' to capture all health care professionals engaged in controlled drug activities.

3.9. Where there are concerns about a 'relevant person' the actions which can be taken are limited to those relating to the individual's activities in Northern Ireland while working within or on behalf of a designated body, or as a private practitioner.

Proposal: *Regulation 19 – accountable officers' duties to protect the safety of patients and the general public*
To extend the provisions for information sharing to enable a well founded concern to be shared about the inappropriate or unsafe management or use of controlled drugs by a person, who may or may not currently be a 'relevant person', with a designated body where it is considered that the person could become a 'relevant individual' for the designated body.

Furthermore clarification has been provided that one of the actions available to the HSC Board AO, in certain circumstances, is to share information with any person, whether they are a member of the LIN or not, who employs or may employ an individual if there are well-founded concerns about that individual's activities which might jeopardise patient or public safety.

4. Consultation Questions

Q1 Do you agree to the interpretation of a “regulatory body” being amended to include the Northern Ireland Social Care Council?

Q2 Do you agree that only independent hospitals which provide health care and which manage and use CDs should be required to appoint an AO?

Q3 Do you agree that the Department should be able to determine, but only where it is desirable to do so, that an independent hospital should not be required to appoint an AO and the proposed criteria that the Department would adopt?

Q4 Do you agree the list of designated bodies required to appoint AOs including the armed forces?

Q5 Do you agree the conditions for the appointment of an Accountable Officer?

Q6 Do you agree that Standard Operating Procedures (SOPs) on prescribing, supply and administration of CDs and the clinical monitoring of patients using CDs should be added to the current list of SOPs?

Q7 Do you agree that the HSC Board AO should have legislative responsibility for the operation of the LIN and the arrangements for occurrence reports?

Q8 Do you agree that the definition of a ‘relevant person’ should be extended to include all health care professionals?

Q9 Do you agree the information sharing provisions of regulation 19?

5. Consultation Paper and How to Respond

This consultation invites views on a number of amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

We are keen to hear from everyone who will be affected by these proposals. A list of consultees is attached (**Appendix 3**) and a Consultation Response Questionnaire (**Appendix 4**).

This consultation applies to Northern Ireland and will run for 14 weeks until **Friday 1 May 2015**

A response can be submitted by letter, fax or e-mail.

Details are:

Amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 Consultation
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Please ensure that responses are clearly marked '*A Response to the Consultation on Amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.'*

The Department will consider requests to produce this document in other languages or in alternative formats.

STATUTORY RULES OF NORTHERN IRELAND

2015 No.

DANGEROUS DRUGS

The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015

Made - - - -	*xxxx 2015*
Coming into operation -	*xxxx 2015*

The Department of Health, Social Services and Public Safety([a]), makes the following Regulations in exercise of the powers conferred on it by sections 17, 18, 19(1)(a), 20(3), and (7) and 79(3) of the Health Act 2006([b]).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015, and shall come into operation on xxxx 2015.

(2) In these Regulations, "the principal Regulations" means the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009([c]).

(3) The Interpretation Act (Northern Ireland) 1954([d]) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Amendment of the principal Regulations

2. The principal Regulations shall be amended as provided by regulations 3 to 21.

Amendment of regulation 2

3. In regulation 2(2) (interpretation)—

(a) after the definition of "health care" insert the following definition—

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

(b) omit the definition of "NIAS";

(c) after the definition of "piloted services" insert the following definition—

""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([e]);";

(d) after the definition of "registered pharmacy" insert the following definition—

""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);";

([a]) See S.I. 1999/283 (N.I. 1) Article 3(6)
([b]) 2006 c.28
([c]) S. R. 2009 No. 225
([d]) 1954 c.33 (N.I.)
([e]) S.I. 1972/1265 (N.I. 14); Article 57G was inserted by Article 8 of the Primary Medical Services (Northern Ireland) Order 2004

(e) in the definition of a "regulatory body", for "the Council for the Regulation of Health Care Professionals" substitute "the Professional Standards Authority for Health and Social Care([a]) and the Northern Ireland Social Care Council([b])";

(f) after the definition of "regulatory body" insert the following definitions—

""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;";

(g) after the definition of "relevant individual" insert the following definition—

""relevant person" shall be construed in accordance with regulation 23;";

(h) after the definition of "relevant premises" insert the following definition—

""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;";

(i) in the definition of "RQIA" replace the full stop with a semi colon; and

(j) after the definition of "RQIA" add the following definition—

""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.".

Meaning of "relevant independent hospital"

4. After regulation 2 insert—

"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.

([a]) Words substituted by the Health and Social Care Act 2012 c. 7 Pt 7 s.222(2)(a)
([b]) Established by s.1 of the Health and Personal Social Services Act (Northern Ireland) 2001, 2001 c.3 (N.I)

(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).".

Amendment of regulation 3

5. In regulation 3 (designated bodies)—

(a) omit paragraph (c);

(b) in paragraph (d), for "an Independent Hospital" substitute "a relevant independent hospital"; and

(c) after paragraph (d) insert—

"(e) the headquarters in Northern Ireland of regular or reserve forces.".

Amendment of regulation 4

6. For regulation 4 (appointment of accountable officers) substitute—

"**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.".

Amendment of regulation 6

7. In regulation 6 (removal of accountable officers)—

(a) in paragraph (1)(a) for "the conditions" substitute "condition 1, 2 or 3 and for "5" substitute "4(5) to (7)";

(b) in paragraph (2) after "these Regulations," for "or" substitute "of".

List of accountable officers

8. After regulation 6 insert—

"List of accountable officers

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

(a) any nomination or appointment by it of an accountable officer, or

(b) the removal from office by it of an accountable officer.

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

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

Amendment of regulation 9

9. In regulation 9 (accountable officers to secure the safe management and use of controlled drugs)—

(a) in paragraph (3)(f) replace the full stop with a semi colon; and

(b) after paragraph (3)(f) add—

"(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.".

Amendment of regulation 12

10. In regulation 12 (Powers to require declarations and self-assessments, as part of accountable officers monitoring and auditing arrangements or otherwise) in paragraph (4) for "Article 10 of the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003" substitute "section 34C of the Medical Act 1983([a])".

Amendment of regulation 17

11. In regulation 17 (accountable officers to take appropriate action if there are well-founded concerns)—

(a) in paragraph (2)(g) for "chair of the local intelligence network (LIN), established under regulation 18(2)" substitute "accountable officer nominated or appointed by the Regional Board";

(b) in paragraph (3) omit "of regulation 18(3),".

Amendment of regulation 18

12. In regulation 18 (arrangements for sharing information)—

(a) for paragraph (2) substitute—

"(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).";

(b) for paragraph (3) substitute—

"(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."; and

(c) omit paragraph (4).

Amendment of regulation 19

13. In regulation 19 (accountable officers to carry out periodic inspections)—

(a) in paragraph (1)(b)(i) omit ", or" and insert a semi colon;

(b) in paragraph (1)(b)(ii) replace the full stop with a semi colon; and

(c) after paragraph (1)(b)(ii) add—

"(iii) an accountable officer of a regular or reserve force.".

Amendment of Regulation 20

14. In regulation 20 (relevant premises)—

(a) in paragraph (1)(b) after "HSC Trust" insert "or regular or reserve force";

(b) in paragraph (2)—

(i) omit the words "or the NIAS" where they appear, both times;

(ii) in sub paragraph (b)—

(aa) after "Board" insert " , regular or reserve force";

(bb) for "an independent" substitute "a relevant independent";

(c) in paragraph (3)—

(i) for "an independent" substitute "a relevant independent" and for "the independent" substitute "the relevant independent";

([a]) 1983 c. 54. Section 34C was inserted by the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2010 (S.I. 2010/234)

(ii) in sub-paragraph (a) before "independent" insert "relevant";

(iii) in sub-paragraph (b)—

(aa) before "independent" insert "relevant";

(bb) after "Regional Board" insert ", regular or reserve force";

(d) after paragraph (3) insert—

"(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."; and

(e) in paragraph (4) for "(3)" substitute "(3A)".

Amendment of regulation 23

15. For regulation 23 (relevant persons) substitute—

"**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 or nursing home (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.".

Amendment of regulation 25

16. In regulation 25 (duty to co-operate by disclosing information as regards relevant persons) after paragraph (6)(a) insert—

"(aa) a regular or reserve force's arrangements for service discipline; or".

Amendment of regulation 26

17. In regulation 26 (responsible bodies requesting additional information be disclosed about relevant persons) after paragraph (5)(b) insert—

"(ba) would prejudice, or would be likely to prejudice, a regular or reserve force's arrangements for service discipline; or".

Amendment of Regulation 29

18. In regulation 29 (occurrence reports) for paragraph (1) substitute—

"(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.".

Amendment of Regulation 30

19. For regulation 30 (accountable officers' duties to protect the safety of patients and the general public) substitute—

"**30.**—(1) If information shared by a responsible body with another body that is a designated body (DB) shows a concern which appears to be well founded 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.".

Amendment of Regulation 31

20. In Regulation 31 (disclosure of information in good faith) for "in good faith under regulation 25, 26, 29 or 30" substitute "under these Regulations if it is done in good faith and there are reasonable grounds for doing it.".

Revocations

21. Regulations 5 (persons who may be appointed as accountable officers) and 7 (funds and other resources available to accountable officers) are revoked.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on xxxx 2015

L.S.

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015, "the Regulations", amend the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, "the principal Regulations".

These amendments have been made to make provision for additional safeguards for the safe management and use of controlled drugs introduced in England and Scotland when the Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force on 1 April 2013.

The opportunity has also been taken to align certain arrangements with those in England, Scotland and Wales.

The definition of relevant independent hospital has been inserted to take account of those independent hospitals which are not providing healthcare, have no controlled drug activity, and where a determination would create disproportionate difficulties for the independent hospital in question (regulation 4). These independent hospitals will not be caught by the Regulations.

The armed forces are given the status of a designated body and discrete provision for Northern Ireland Ambulance Services, "NIAS", has been omitted. NIAS is a Health and Social care trust, the individual NIAS references are therefore unnecessary and superfluous, they have been omitted (regulation 5).

The conditions for appointing an accountable officer have been amended to provide more flexibility for smaller organisations while ensuring that the accountable officer has sufficient seniority to have credibility within their organisation (regulation 6).

The list of standard operating procedures, "SOPs", which designated bodies shall have has been extended to include a requirement for SOPs covering the prescribing, supply and administration of controlled drugs and the clinical monitoring of patients prescribed controlled drugs (regulation 9).

The accountable officer of the Regional Health and Social Care Board, "the Regional Board", is responsible for establishing the local intelligence network (regulation 12).

The premises of the armed forces have been added to those which are exempted from inspection by the accountable officer of the Regional Board (regulation 13) and authority provided for the accountable officer of the armed forces to inspect relevant premises (regulation 14).

The definition of a relevant person has been extended and now includes all health care professionals and is not limited to healthcare professionals providing medical, dental, pharmaceutical and nursing or midwifery services to private patients (regulation 15).

Exemption from a requirement to disclose information has been provided for the armed forces where this would prejudice, or would be likely to prejudice, service discipline (regulations 16 and 17).

A provision has been made for occurrence reports to be submitted more frequently than quarterly where there are concerns that warrant it and a request has been made by the accountable officer of the Regional Board (regulation 18).

Provision has been made, for the purpose of protecting patients and members of the public, for well founded concerns to be shared about persons who are not relevant persons but who it is considered could become relevant individuals (regulation 19).

Protection from civil proceedings has been extended to include all Regulations (regulation 20).

Appendix 2

Freedom of Information

DHSSPS will publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be disclosed on request. The Department can only refuse to disclose information in exceptional circumstances. **Before** you submit your response, please read the paragraphs below on the confidentiality of consultations, they will give you guidance on the legal position about any information given by you in response to this consultation.

The Freedom of Information Act 2000 gives the public a right of access to any information held by a public authority, namely, DHSSPS in this case. This right of access to information includes information provided in response to a consultation. DHSSPS cannot automatically consider as confidential, information supplied to it in response to a consultation.

However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity should be made public or be treated as confidential. **If you do not wish information about your identity to be made public, please include an explanation in your response.**

This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances. The Secretary of State for Constitutional Affairs' Code of Practice on the Freedom of Information Act provides that:

- The Department should only accept information from third parties in confidence, if it is necessary to obtain that information in connection with the exercise of any of the Department's functions, and it would not otherwise be provided;

- The Department should not agree to hold information received from third parties "in confidence" which is not confidential in nature; and

- Acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

For further information about confidentiality of responses please contact the Information Commissioner's Office (or see the web site at: https://ico.org.uk/)

Appendix 3

List of organisations to which this consultation is being sent.

Committee for Health, Social Services and Public Safety Members
OFMDFM, Machinery of Government Division
OFMDFM, Central Management Unit
Northern Ireland Office - Devolution and Legislation Division
Health and Social Care Board
Health and Social Care Trusts
Public Health Agency
Regional Business Services Organisation
Patient Client Council
Regulation and Quality Improvement Authority
Professional Standards Authority for Health and Social Care
Royal College of General Practitioners (NI)
General Practitioners Committee (NI)
National Clinical Assessment Service (NI)
NI Medical and Dental Training Agency
NI Centre for Pharmacy Learning and Development
NI Human Rights Commission
NI Practice and Education Council for Nursing and Midwifery
NI Social Care Council
Attorney General for Northern Ireland
Pharmaceutical Society of Northern Ireland
General Medical Council
General Chiropractic Council
General Dental Council
General Osteopathic Council
General Optical Council
Nursing and Midwifery Council
British Medical Association
British Dental Association
Royal College of Nursing
Ulster Chemists Association
Community Pharmacy NI
National Pharmacy Association
Pharmaceutical Defence Association
Optometry Northern Ireland
Prison Service for Northern Ireland
Police Service of Northern Ireland
Guild of Healthcare Pharmacists
Unite the Union
Ministry of Defence
Independent Hospitals
Health and Care Professions Council
Members of the Northern Ireland Local Intelligence Network

Appendix 4

Consultation Response Questionnaire on proposed amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

The Department of Health, Social Services and Public Safety welcomes your views on the proposed amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

(Please tick a box)

I am responding: as an individual ☐ on behalf of an organisation ☐

Name: _____

Job Title: _____

Organisation:_____

Address: _____

_____

Postcode _____

Email: _____

I do not wish information about my identity to be made public ☐

(See Appendix 2)

If you do not wish information about your identity to be made public please include an explanation.

Views are invited on the following questions by 5pm Friday 1 May 2015.

Q1 Do you agree to the interpretation of a "regulatory body" being amended to include the Northern Ireland Social Care Council? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Additional Comments

Q2 Do you agree that only independent hospitals which provide health care and which manage and use CDs should be required to appoint an AO? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Additional Comments

Q3 Do you agree that the Department should be able to determine, but only where it is desirable to do so, that an independent hospital should not be required to appoint an AO and the proposed criteria that the Department would adopt? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Additional Comments

Q4 Do you agree the list of designated bodies required to appoint AOs including the armed forces? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Additional Comments

Q5 Do you agree the conditions for the appointment of an Accountable Officer? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Additional Comments

Q6 Do you agree that Standard Operating Procedures (SOPs) on prescribing, supply and administration of CDs and the clinical monitoring of patients using CDs should be added to the current list of SOPs? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Additional Comments

Q7 Do you agree that the HSC Board AO should have legislative responsibility for the operation of the LIN and the arrangements for occurrence reports? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Additional Comments

Q8 Do you agree that the definition of a 'relevant person' should be extended to include all health care professionals? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Additional Comments

Q9 Do you agree the information sharing provisions of regulation 19? (Please tick a box)

Yes ☐ No ☐ Don't know/ no views ☐

Additional Comments

Human Rights and Equality Implications

Section 75 of the Northern Ireland Act 1998 requires Departments in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity:

- between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- between men and women generally;
- between person with a disability and persons without; and
- between persons with dependants and persons without.

In addition, without prejudice to the above obligation, Departments should also, in carrying out their functions relating to Northern Ireland, have due regard to the desirability of promoting good relations between persons of different religious belief, political opinion or racial group. Departments also have a statutory duty to ensure that their decisions and actions are compatible with the European Convention on Human Rights and to act in accordance with these rights.

In accordance with guidance produced by the Equality Commission for Northern Ireland and in keeping with Regulation 75 of the Northern Ireland Act 1998, the proposed amendment has been equality screened and a preliminary decision has been taken that a full EQIA is not required.

The Department is inviting responses to the following questions:

Q10 Are the actions/proposals set out in this consultation document likely to have an adverse impact on any of the nine equality groups identified under Section 75 of the Northern Ireland Act 1998?

Yes ☐ No ☐

If yes, please state the group or groups and provide comment on how these adverse impacts could be reduced or alleviated in the proposals

Q11 Are you aware of any indication or evidence – qualitative or quantitative – that the actions/proposals set out in this consultation document may have an adverse impact on equality of opportunity or on good relations?

Yes ☐ No ☐

If yes, please give details and comment on what you think should be added or removed to alleviate the adverse impact.

Q12 Is there an opportunity for the proposed amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 to better promote equality of opportunity or good relations? Is there an opportunity to better promote equality of opportunity or good relations?

Yes ☐ No ☐

If you answered yes" to this question please give details as to how.

Q13 Are there any aspects of this where potential human rights violations may occur?

Yes ☐ No ☐

Any other comments:

Further Comments

Please use the box below to provide any further comments you would like to make in relation to the proposed amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

Thank you for your comments.

You should send your completed consultation response questionnaire to:

Email: MRGconsultation@dhsspsni.gov.uk

Fax: (028) 9052 2335

Post:

Amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 Consultation
Medicines Regulatory Group
Department of Health, Social Services and Public Safety
Room D4.3
Castle Buildings
BELFAST
BT4 3SQ

Please ensure that responses are clearly marked '*A Response to the Consultation on Amendments to the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.'* Completed consultation response questionnaires must be received by the Department by **5pm** on **Friday 1 May 2015**. Responses received after this date will only be considered with prior agreement from the Department.

If you have any queries regarding the consultation please telephone 028 9052 3326 or 028 9052 2669 or send an email with your query to email: MRGconsultation@dhsspsni.gov.uk