

**EXPLANATORY MEMORANDUM TO**  
**The Controlled Drugs (Supervision of Management and Use) (Amendment)**  
**Regulations (Northern Ireland) 2015**

**SR 2015 No. 278**

**1. Introduction**

- 1.1. This Explanatory Memorandum has been prepared by the Department of Health, Social Services and Public Safety to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.
- 1.2. The Statutory Rule is made under the Health Act 2006 and is subject to the negative resolution procedure.

**2. Purpose**

- 2.1. The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015 ('amendment Regulations') amend the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 ('2009 Regulations') which were introduced as part of the Government's response to the Shipman Inquiry's Fourth Report in 2004.

**3. Background**

- 3.1. The 2009 Regulations were designed to improve controlled drug (CD) governance without hindering patients from accessing the treatment they needed. As a consequence of the Health and Social Care Act 2012, England and Scotland carried out a review of their equivalent Regulations resulting in the Controlled Drugs (Supervision of Management and Use) Regulations 2013 which came into force on 1 April 2013.
- 3.2. To further enhance governance arrangements in Northern Ireland and to, in general, maintain parity with arrangements in England and Scotland it is necessary to amend the 2009 Regulations.
- 3.3. The key provisions introduced by the amendment Regulations are:  
The management of the Local Intelligence Network became the responsibility of the HSC Board Accountable Officer.
- 3.4. The armed forces have been added to the list of designated bodies.
- 3.5. Only those independent hospitals which have CD activity and provide healthcare will be required to appoint an Accountable Officer. Provision has been made for the Department to determine if the requirement to appoint an Accountable Officer places a disproportionate burden on an independent hospital. In Northern Ireland independent hospitals with no CD activity cannot be determined to be a relevant independent hospital and so will not be required to appoint an Accountable Officer. This differs from England and Scotland which does not automatically exempt independent hospitals with no CD activity but does exempt all those with less than 10 staff irrespective of the level of CD activity. In Northern Ireland the Department will consider those independent hospitals

providing healthcare which have any CD activity on a case by case basis. An appeal process has been provided.

- 3.6. More flexibility has been introduced for appointing an Accountable Officer while ensuring that the appointee is a person of sufficient seniority within the organisation.
- 3.7. The Northern Ireland Social Care Council has been included within the definition of a “regulatory body”.
- 3.8. The meaning of a ‘relevant person’ has been extended to capture all health care professionals; furthermore social care workers, engaged in the supply or administration of controlled drugs in a domiciliary care agency setting, are captured by the Regulations, insofar as they would be regarded as a ‘relevant person’.
- 3.9. Additional standard operating procedures (SOPs) covering the prescribing, supply and administration of CDs and the clinical monitoring of patients have been incorporated into the existing list of SOPs.

#### **4. Consultation**

- 4.1. The Department carried out a 14 week consultation with key stakeholders including health and social care organisations, independent hospitals, Ministry of Defence, professional bodies and regulators. The consultation was launched on 26 January 2015 and closed on 1 May 2015. There was a total of 14 responses received.
- 4.2. Respondents were generally supportive of the proposed amendment Regulations. Officials have analysed the responses and have prepared a consultation report which sets out the main issues raised and the Department’s response. A copy of the report can be found at xxx

#### **5. Equality Impact**

- 5.1. The Department has screened the amendment Regulations for the purposes of section 75 of the Northern Ireland Act 1998, and has concluded that an Equality Impact Assessment is not necessary.

#### **6. Regulatory Impact**

- 6.1. A Regulatory Impact Assessment is not considered necessary because the proposals do not result in any costs or savings, or increased fees by a predetermined formula such as the rate of inflation. It is not anticipated that the proposals will create any adverse impact on business, charities, social economy or voluntary bodies.

#### **7. Financial Implications**

- 7.1. These regulations will not have any financial impact for Northern Ireland and funding is not required.

#### **8. Section 24 of the Northern Ireland Act 1998**

- 8.1. The Department is satisfied that the amendment Regulations do not breach s24 of the Northern Ireland Act 1998 as they are not incompatible with any of the Convention rights or community law, and they do not discriminate against a person on the grounds of religious belief or political opinion.

## **9. EU Implications**

- 9.1. Not applicable

## **10. Parity or Replicatory Measure**

- 10.1. The amendment Regulations make provision for arrangements which are substantially aligned to those established in England and Scotland.
- 10.2. One area where arrangements are not aligned is that Northern Ireland independent hospitals with no CD activity cannot be determined to be a relevant independent hospital and so will not be required to appoint an Accountable Officer. This differs from England and Scotland where independent hospitals with no CD activity are not automatically exempt while all those with less than 10 staff irrespective of the level of CD activity are exempt. In Northern Ireland the Department will consider those independent hospitals providing healthcare which have any CD activity on a case by case basis. An appeal process has been provided.
- 10.3. Furthermore the Northern Ireland Social Care Council has been included within the definition of a “regulatory body”.
- 10.4. Northern Ireland has maintained its existing list of standard operating procedures (SOPs) and added SOPs covering the prescribing, supply and administration of CDs and the clinical monitoring of patients. England and Scotland did not retain the mandatory list of SOPs.

## **11. Additional Information**

- 11.1. Not applicable