EXPLANATORY MEMORANDUM TO

THE CONTROLLED DRUGS (SUPERVISION OF MANAGEMENT AND USE) (AMENDMENT) REGULATIONS 2020

2020 No. 189

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument makes a series of amendments to the Controlled Drugs (Supervision of Management and Use) Regulations 2013 (the 2013 Regulations), namely:

- Removing the statutory expiry date of 31st March 2020 to maintain the 2013 Regulations in force beyond this date
- Introducing a statutory review clause which requires that the 2013 Regulations are reviewed every five years to ensure that proper and due consideration is given to the factors set out in the Small Business, Enterprise and Employment Act 2015 at appropriate intervals.
- Six technical legal amendments to the 2013 Regulations to reflect changes to some definitions, and the names and/or responsibilities of the 'Responsible bodies' as defined in the Regulations, which have occurred since the 2013 Regulations were introduced. Further details are given in paragraph 7.6.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As the instrument is subject to the negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Scotland.

4.2 The territorial application of this instrument is England and Scotland.

4.3 The 2013 Regulations are replicated in the other parts of the UK by the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008, and the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015. These are not affected.

5. European Convention on Human Rights

5.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation no statement is required.

6. Legislative Context

6.1 The Fourth Shipman Inquiry Report of 2004 exposed a number of loopholes in the statutory arrangements for the management and use of controlled drugs that Dr Harold Shipman exploited to cause harm to his patients. In response to the Inquiry the Controlled Drugs (Supervision of Management and Use) Regulations 2006 (the 2006 Regulations) were introduced to strengthen the governance arrangements for the use and management of controlled drugs in the community, but to do so in a way which did not hinder patients from accessing the healthcare treatments they need.

6.2 The Health and Social Care Act 2012 made fundamental changes to NHS structures in England. These changes came into effect on 1st April 2013. As a consequence, the 2006 Regulations were replaced to reflect these new structures and to update the requirements accordingly. The 2013 Regulations came into force on 1st April 2013.

6.3 In line with the Government's Better Regulation Framework, the 2013 Regulations include a statutory expiry date of 31 March 2020. The 2013 Regulations will cease to have effect following this date, unless the Government takes legislative action. This instrument amends the 2013 Regulations to remove the statutory expiry date, to enable the Regulations to continue to have effect.

6.4 The 2013 Regulations sit alongside the Misuse of Drugs Act 1971 and the Regulations under that Act, which enable a punitive response to controlled drug misuse, where appropriate.

7. Policy background

What is being done and why?

7.1 The 2013 Regulations underpin the arrangements, in England and Scotland, for securing the safe management and use of controlled drugs, such as opiates, in hospitals and in the wider community. The 2013 Regulations ensure that measures designed to help safeguard patients and the public are sufficiently robust, whilst at the same time facilitating a proportionate response to incidents and concerns relating to controlled drug mismanagement or misuse.

7.2 The 2013 Regulations require certain NHS and independent sector healthcare bodies to appoint controlled drugs accountable officers ("CDAOs"), and these Regulations describe CDAOs' responsibilities. They also require specified bodies to co-operate with each other in local intelligence networks, and deal with ancillary matters such as powers of entry.

7.3 The Department made an administrative commitment to undertake and publish a post implementation review (PIR) of the 2013 Regulations by the current expiry date of the 2013 Regulations, which is the 31st of March 2020, in line with the Small Business, Enterprise and Employment Act 2015. The Department worked closely with the Scottish Government to undertake a PIR of the Regulations to consider their appropriateness and effectiveness, and to assess whether the regulatory measures remain fit for purpose. Consultation with stakeholders indicated strong support for the

2013 Regulations remaining in force. A breakdown of the results of this consultation is provided in section 10.

7.4 Given the strong support for maintaining the Regulations and the need to provide certainty for the health system and employers, this instrument amends the 2013 Regulations to remove the statutory expiry date to enable the 2013 Regulations to remain in force.

7.5 Instead a policy decision has been made to have a review clause in the 2013 Regulations rather than an expiry clause. This will ensure that proper and due consideration is given to the factors set out in the Small Business, Enterprise and Employment Act 2015 at appropriate intervals, whilst at the same time ensuring that the public health benefits from the provisions are not ended without a proper and appropriate review. The clause sets out the requirement that the 2013 Regulations must be reviewed within five years of coming into force. Subsequent reviews must then be undertaken and the reports published at intervals not exceeding 5 years. The reviews should set out the objectives of the Regulations, assess the extent to which the objectives have been achieved, assess whether the objectives remain appropriate and assess the extent to which they could be achieved in a less onerous way.

7.6 This instrument also makes technical legal amendments to the definitions and responsibilities of some of the organisations named in regulations 2, 6 and 13 to reflect developments and changes which have occurred since the 2013 Regulations were introduced. The amendments made are described in detail in Annex A.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union or trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 This instrument does not consolidate the 2013 Regulations.

10. Consultation outcome

10.1 This instrument has been drafted in response to the results of a post-implementation review of the 2013 Regulations, as mentioned in paragraph 7.3. Extensive consultation with stakeholders was undertaken to inform the post-implementation review. Consultation was conducted through a series of meetings and workshops with English and Scottish stakeholders. A questionnaire was also conducted. The questionnaire was hosted online and was live from 23rd April 2018 until 21st May 2018.

10.2 The aim of the questionnaire was to gather information on how the 2013 Regulations are working in practice and offered an opportunity for respondents to express their view on the necessity of maintaining the regulations and flag areas of improvement for any future potential regulations.

10.3 Of the 128 responses, 120 (94%) were received from respondents working in England and 8 (6%) from respondents working in Scotland. In total, 58 (45%) responses came from a CDAO or a member of their team; 32 (25%) came from another health or social care professional; and 28 (22%) came on behalf of organisations represented on

local intelligence networks (LINs); and 10 (8%) came from a respondent who selected "other".

10.4 There was a clear consensus that the 2013 Regulations are effective, appropriate and proportionate in ensuring the safe management and use of controlled drugs. The majority of questionnaire respondents (112, 88%) agreed that the general objectives remain appropriate or very appropriate, and 106 respondents (83%) suggested the 2013 Regulations should be maintained post 31 March 2020. It should be noted that where respondents suggested that the 2013 Regulations should not be maintained, there appears to have been some confusion in the reading of the question – i.e. accompanying comments typically supported replacing the 2013 Regulations with the same or similar measures.

10.5 Though the vast majority of respondents agreed that the Regulations should be maintained, the questionnaire indicated some areas where stakeholders felt additional improvements to the Regulations could be made. The areas referenced include:

- The range of organisations captured within the scope of the 2013 Regulations, ensuring that new structures and models of care are adequately covered by Regulations and wider system governance;
- Following completion of the restructuring of NHS England - NHS Improvement (NHSE-I), assess whether the roles and responsibilities of NHSE-I lead CDAOs remain appropriate and that the post and regional teams are adequately resourced to carry out their statutory duties and that there is sufficient national oversight;
- Assess the effectiveness and organisation of LINs;
- Review and streamline as necessary the reporting of controlled drug incidents to avoid duplication, maximise opportunities for learning and minimise the administrative burden on CDAOs (~NHS and private providers).
- Review the powers of entry of CDAOs and assess whether these remain appropriate.

10.6 These areas will be considered further, and any proposed changes will be subject to consultation. The impact of any changes will be assessed under the first statutory review of the Regulations, which will be undertaken by March 2025.

10.7 A full summary of the consultation responses is provided in the PIR of the 2013 Regulations, which will be published on legislation.gov.uk.

10.8 Scottish Ministers have been consulted on the approach adopted in the 2020 Regulations in accordance with section 24(6) of the Health Act 2006 and have indicated that they are content.

11. Guidance

11.1 As this instrument does not introduce any new requirements, no further accompanying guidance has been prepared.

12. Impact

12.1 The impact on business, charities or voluntary bodies is assessed in the PIR of the 2013 Regulations. The PIR assesses the burden on business of all the statutory provisions of the 2013 Regulations, including those carried over from the 2006 Regulations. As of November 2019, there were 766 CDAOs in non-NHS

organisations in England and Scotland, covering independent hospitals, social care providers and other private sector organisations that are designated bodies under the 2013 Regulations. The total cost of CDAO staffing in these organisations is estimated to be £31.8 million per year. However, in the absence of the 2013 Regulations, private healthcare providers still have legal obligations to achieve fundamental standards of care and maintain patient safety. Therefore, the projected savings from allowing the 2013 Regulations to expire would be expected to be low:

- Up to £0.6 million from ceasing participation in local information-sharing networks;
- Up to £0.5 million from ceasing participation in national incident reporting.

12.2 The impact on the public sector is estimated to be £10.4 million per year, which reflects CDAO staffing costs to the NHS. However, in the absence of the 2013 Regulations, like private healthcare providers, the NHS still has legal obligations to achieve fundamental standards of care and maintain patient safety. This would be reflected in the projected savings from allowing the 2013 Regulations to expire.

12.3 An Impact Assessment has not been prepared for this instrument because the instrument relates to maintenance of existing regulatory standards and does not introduce any new burden or cost to business. However, as described above, the PIR does make an assessment of the costs to business. Input from stakeholders received through the consultation questionnaire described in section 10 was considered in the assessment of burden. The PIR of the 2013 Regulations will be published on legislation.gov.uk.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 To minimise the impact of the requirements on small businesses, the 2013 Regulations include an exemption for independent sector micro and start-up businesses in England and Scotland, with fewer than 10 staff or contractors, from the requirement to appoint a CDAO. The English and Scottish regulators (the Care Quality Commission and Healthcare Improvement Scotland) are able to exempt, on application, small businesses which provide hospital facilities, but with 10 or more staff, from the need to appoint a CDAO, where they are satisfied that this would present disproportionate difficulties for that business. This measure is maintained and unaffected by this instrument.

14. Monitoring & review

14.1 The approach to monitoring of this legislation will ensure that proper and due consideration is given to the factors set out in the Small Business, Enterprise and Employment Act 2015 at appropriate intervals. The amended 2013 Regulations include a statutory review clause, requiring a review within five years of coming into force. Subsequent reviews will then be undertaken and published at intervals not exceeding 5 years.

15. Contact

15.1 Stephen Knight at the Department of Health and Social Care, Telephone: 020 7972 4155 or email: stephen.knight@dhsc.gov.uk, can be contacted with any queries regarding the instrument.

15.2 Jeannette Howe, Deputy Director for Pharmacy, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Jo Churchill, Parliamentary Under Secretary of State for Prevention, Public Health and Primary Care at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex A – Amendments introduced by the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020

The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020 remove the statutory expiry date from the Controlled Drugs (Supervision of Management and Use) Regulations 2013 and introduce a statutory review clause. The statutory review clause requires that a review of the Regulations is carried out every five years. A report setting out the conclusions of the review must be published. The first report will be published before the end of March 2025.

This table outlines the technical legal drafting amendments introduced by the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020. These amendments reflect the updates and changes which have been implemented since the Regulations came in to force in 2013.

Previous text	New text	Justification
The Information Services Division of the Common Services Agency'	Public Health Scotland	The Public Health Scotland Order 2019 established Public Health Scotland and transferred information functions to that body from the Common Services Agency
NHS Protect	Remove references	The NHS Counter Fraud Authority (Establishment, Constitution, and Staff and Other Transfer Provisions) Order 2017 replaced NHS Protect with the NHS Counter Fraud Authority. This new body is not reflected in the 2020 Regulations as in practice NHS Protect had no operative functions relating to controlled drugs.
The Prescription Pricing Division of the NHS Business Services Authority (NHS BSA)	NHS BSA	Amendment reflects internal reorganisation of the NHS BSA.
Definitions of reserve force: "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;	"reserve force" means the Royal Fleet Reserve, the Royal Naval Reserve, the Royal Marines Reserve, the Regular Reserve, the Army Reserve, the Air Force Reserve and the Royal Auxiliary Air Force	Updated definition aligns with that given in the Reserve Forces Act 1996
ePact	ePact2	Updated to reflect the new name of the NHS data system