Title: The Controlled Drugs (Supervision of Management and Use) Regulations 2013	Post Implementation Review
PIR No: 9554P	**Date:** 19/03/2020
Original IA/RPC No: 6077/RPC-DH-4442(1)	**Type of regulation:** Domestic
Lead department or agency: Department of Health and Social Care	**Type of review:** Non-statutory
Other departments or agencies: Scottish Government - Medicines Division	**Date measure came into force:** 01/04/2013
Contact for enquiries: Stephen Knight (Stephen.Knight@dhsc.gov.uk)	**Recommendation: Amend** / **RPC Opinion: Green**

1. What were the policy objectives of the measure?

The legislative policy objectives of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 were to:

(a) maintain and, where possible, improve the system of good governance concerning the safe management and use of controlled drugs in the healthcare system;
(b) protect patient and public health;
(c) promote co-operation and information sharing between different local bodies and organisations;
(d) enable effective mechanisms to monitor and audit the use of controlled drugs as medicines; and
(e) enable adequate powers to investigate, and to take prompt and effective action where appropriate, when concerns are raised.

The intended effect is to ensure the safe management and use of controlled drugs and reduce the risk of patient harm and criminal diversion, maintaining access for legitimate use in healthcare whilst minimising regulatory burden.

The 2013 Regulations repealed and replaced the Controlled Drugs (Supervision of Management and Use) Regulations 2006, updating them in response to changes in the NHS structure in England and Scotland. This review considers the impacts of the 2013 Regulations, including the measures carried over from the 2006 Regulations.

2. What evidence has informed the PIR?

In assessing whether the objectives of the policy have been met, evidence has been drawn from several sources, including:

- A Department of Health and Social Care and Scottish Government survey of key stakeholders.
- Annual reports of the Care Quality Commission (CQC) on controlled drugs and the Controlled Drug Accountable Officers Executive Group in Scotland.
- Data on prescribing of controlled drugs in primary care settings from NHS Business Service Authority (NHS BSA) and NHS Scotland's Information Services Division
- National data on controlled drug incidents from the NHS England online controlled drug reporting tool and the National Reporting and Learning System (NRLS).
- Annual local reports of controlled drugs incidents from local lead Controlled Drug Accountable Officers (CDAOs) in England.
- Qualitative feedback on examples of controlled drug incident occurrences from NHS England local lead CDAOs.

3. To what extent have the policy objectives been achieved?

The evidence considered by this review, both quantitative and qualitative, indicates that the 2013 Regulations are achieving the original objectives.

Controlled drugs are an essential part of modern healthcare but are associated with a potential for misuse or diversion. Lessons learnt from the Shipman and Gosport Inquiries – investigating system failures concerning the serious mismanagement of controlled drugs - remain relevant and highlight that "do nothing" is not a viable option. Regional and national governance systems enshrined in the 2013 Regulations are still needed to reduce the risk of harm to patients and the risk of illegal diversion of controlled drugs. While businesses would reasonably be expected to continue some of the statutory functions in the absence of the 2013 Regulations, the statutory requirements complement professional regulation and clinical best practice and other initiatives concerning medicines safety to minimise the risk associated with controlled drugs and provide a safer service to the public.

This review therefore recommends that the 2013 Regulations are maintained to ensure important statutory safeguards remain in place. To accomplish this, it is proposed that the statutory expiry clause be removed and a new statutory review clause inserted to ensure that the Government of the day conducts a review of the impact and effectiveness of the Regulations, including an assessment of the extent to which the objectives of the Regulations have been achieved, every five years in-line with the Small Business, Enterprise and Employment Act.

Sign-off for Post Implementation Review: Chief economist/Head of Analysis and Minister

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed: ***Chris Mullins (Chief Economist Department of Health and Social Care)***
Date: 19/12/2019

Signed: ***Jo Churchill MP (Parliamentary Under Secretary of State for Prevention, Public Health and Primary Care)***
Date: 30/03/2020

Further information sheet

Please provide additional evidence in subsequent sheets, as required.

4. What were the original assumptions?

The original assumptions about the costs and benefits of the Regulations, and their impact on business, were set out in the original 2006 Regulatory Impact Assessment. These included:

- Costs of a new statutory duty for designated healthcare organisations to appoint a Controlled Drugs Accountable Officer (CDAO);
- Costs of a new statutory duty of collaboration on all healthcare and partner organisations to share information about potential controlled drug offences;
- Benefits of improved oversight of the use of controlled drugs in healthcare organisations to reduce risks of inappropriate clinical use, misuse and diversion.

The 2006 Impact Assessment estimated that the total net costs of the new duties would be around £1m in set-up costs and £4m per year in running costs. Expected benefits were not quantified, but it was noted that the "do nothing" option was unacceptable considering the Shipman Inquiry conclusions. The impact on business was limited to the duty to appoint a CDAO, applying only to independent hospitals subject to statutory regulation.

The 2013 Impact Assessment evaluated the impact of the changes to the Regulations involving the creation of new CDAO posts within the NHS. Net additional costs were estimated to be around £4m per year to the NHS, with expected health benefits from reducing patient safety incidents valued at £8.5m per year. NHS treatment costs were expected to be reduced by nearly £0.5m per year. It noted that unquantified benefits (i.e. avoiding another Shipman-like case) were likely to be of significantly greater magnitude than quantified benefits. The 2013 Regulations solely focused on changes to the NHS structures and the 2013 Impact Assessment reflected this.

This review looks at the costs and benefits of the 2013 Regulations, including the measures carried over from the 2006 Regulations. The key intended benefit of preventing wilful or institutional harm applies equally to the NHS and private business.

5. Were there any unintended consequences?

No unintended consequences of the Regulations have been identified. However, issues have been identified that may have limited the impact of the Regulations:

- Certain organisations, especially those involved in new models of care introduced since the 2013 Regulations came into effect, may not be appropriately covered, therefore will not have a statutory duty to comply with their provisions. Consequently, there is a risk that governance in these organisations is less developed. However, some new models of care, such as primary care networks will include a range of organisations, some of which with already have CDAOs (e.g. hospitals) and some that are exempt (e.g. community pharmacies), therefore the degree of impact will vary.
- Stakeholder engagement has highlighted some anxieties around the sharing of confidential, sensitive or patient-identifiable information risks hindering appropriate intelligence sharing between responsible bodies. The General Data Protection Regulation 2016/679 (GDPR) is cited as a barrier. To address this issue the 2013 Regulations were updated by the Data Protection Act 2018 to provide exemption from the GDPR for CDAOs and other defined bodies with regard to the disclosure of personal data in the course of meeting statutory obligations i.e. there are no legal barriers. It is therefore important that the statutory data sharing provisions and GDPR exemption remain in place and that ongoing support and assurance is given to ensure the appropriate sharing of information to protect patients and the public.

Both of these issues are considered further in this report and are subject to further action, as set out in the recommendations

6. Has the evidence identified any opportunities for reducing the burden on business?

No further opportunities to reduce burden on business have been identified.

Existing provisions to limit the regulatory burden should remain in place, such as the exemption of independent hospitals that have less than 10 members of staff from appointing a CDAO.

This review of the 2013 Regulations considers that letting them expire would result in increased risk to patients, risk to public safety, and harm public confidence in healthcare services.

7. For EU measures, how does the UK's implementation compare with that in other EU member states in terms of costs to business?

N/A

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Introduction

Review Summary

1. In order to meet the requirements of the Small Business, Enterprise and Employment Act 2015 and guidance on Better Regulation, the Controlled Drugs (Supervision of Management and Use) Regulations 2013 – "the 2013 Regulations" – include a statutory expiry date of 31 March 2020. The Department made an administrative commitment to undertake and publish a post implementation review (PIR) of the 2013 Regulations to consider their appropriateness and effectiveness, and to assess whether the regulatory measures remain fit for purpose by 31 March 2020. This report presents the findings of the PIR, including the impact of measures carried over from the Controlled Drugs (Supervision of Management and Use) Regulations 2006 ("the 2006 Regulations").

2. This review recommends that the 2013 Regulations are extended to remain on the statute book to ensure that important safeguards concerning governance arrangements for the management and use of controlled drugs (CDs) are maintained. To accomplish this, it is proposed that the statutory expiry clause be removed, and a new statutory review clause inserted to ensure that the Government of the day conduct a review every five years in-line with the Small Business, Enterprise and Employment Act 2015.

3. Removal of the 2013 Regulations is not considered appropriate on the grounds that their provisions provide a framework that significantly decreases risks to patient and public safety and their removal may harm public trust and confidence in the healthcare system. If the 2013 Regulations were allowed to expire, it is expected that most private businesses/independent providers currently covered by the Regulations would continue to perform the statutory functions on a voluntary basis, at least in the short-term. This is because of the nature and seriousness of the incidents they were designed to prevent, and businesses need to demonstrate they have systems and procedures in place to assure patient safety. It is assumed that the burden on business would not be fully recovered even if the Regulations were to expire. Therefore, we consider that retaining the regulations imposes a minimal additional burden on business.

4. The lessons learned from the Shipman and Gosport Inquiries demonstrate that we cannot rely on internal and voluntary governance alone. Regional and national external scrutiny and information sharing between organisations is important to identify and address any misuse or diversion of CDs. The evidence presented under this review indicates that the statutory requirements of the 2013 Regulations complement and sit alongside professional regulation and clinical best practice and other initiatives concerning medicines safety, to minimise the risk associated with CDs. No system can ever completely prevent the mismanagement or intentional misuse of CDs. However, the measures in the 2013 Regulations mean that the inappropriate use of opioids and other harmful CDs can be detected more quickly and stopped, so that protracted poor practice, or criminal activity, is less likely to continue unchecked.

5. Whether the 2013 Regulations are replaced, extended (i.e. maintained on the statute book) or allowed to expire is a decision for Ministers. This PIR ensures Ministers have sufficient information to make an informed decision.

6. In addition, the report also highlights areas in the 2013 Regulations that warrant further consideration, as a result of stakeholder feedback. These recommendations and any further Government proposals, such as those falling out of the Gosport Inquiry and

recent reviews prescribing and misuse of opioid medicines, will be subject to separate consultation and scrutiny in the usual way.

Aim and Scope of the Review

7. Under the Government's Better Regulation Framework, the Secretary of State for Health and Social Care committed to undertake a review of the 2013 Regulations which:

   - sets out the objectives intended to be achieved by these Regulations;
   - assesses the extent to which those objectives have been achieved;
   - assesses whether those objectives remain appropriate; and
   - if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.

   This PIR does not bring about or introduce any changes to the 2013 Regulations, and any specific recommendations made in this report are subject to further policy development and Ministerial agreement.

Assessment of Impact on Business

8. For the purposes of this review, the Department has considered the burden of all the statutory provisions of the 2013 Regulations, including those carried over from the 2006 Regulations. This review assumes that the main costs to business are associated with:

   - the statutory Controlled Drugs Accountable Officer (CDAO) role; and
   - the statutory duty to share information about CD incidents, including participation in Local Intelligence Networks (LINs) and formal reporting of CD incidents.

   Independent hospitals in England and Scotland with less than 10 members of staff, or bodies granted an exemption by the Care Quality Commission (CQC) or Healthcare Improvement Scotland (HIS), are exempt from the 2013 Regulations.

9. To assess impacts on business, the Department carried out a stakeholder survey (see paragraphs 54-57 for further detail) and sought views from key private sector organisations. In total, 127 people responded to the survey in an individual capacity or on behalf of their organisations. Although most responses came from NHS organisations, there were also responses from a wide range of private providers and charities, including 17 responses from independent hospitals, 14 from hospices and 1 from a care home. Among these respondents, there was unanimous support for maintaining the 2013 Regulations.

10. For example, among 30 respondents from independent hospitals and hospices, there was unanimous agreement that it remained appropriate for each designated body to appoint a fit, proper and suitably experienced person to be its CDAO. All agreed that the 2013 Regulations had met their objective to maintain the system of good governance.

11. In the absence of the 2013 Regulations, private healthcare providers, like the NHS, still have legal obligations to achieve fundamental standards of care and maintain patient safety. In order to meet these duties, it is reasonable to expect that most businesses would implement voluntary measures to replace the arrangements under the 2013 Regulations to ensure the safe management and use of CDs. However, without regulations in place, it is assumed that a small number of organisations may divert funds and resources away from CD governance. For example, in the year the 2006 Regulations

came in to force (2007/8) the CQC inspected 114 independent healthcare organisations to assess their compliance with national minimum standards for handling CDs. Of these, 68% met the standard and 25% “almost met” it. Eight organisations that were assessed as having “not met” the standards: these organisations were issued with requirement notices to make improvements (source: CQC ‘Safer Management of CDs Annual Report 2008’). Without the statutory underpinning of the 2013 Regulations we could not be assured of the overall effectiveness of any national governance system.

Statutory CDAO role

12. The CDAO role is often an additional duty placed on the organisation’s senior pharmacist or senior nursing officer. The 2013 Regulations permit the CDAO to delegate some of the more day-to-day tasks to other staff members but do not allow them to delegate responsibility.

13. If the 2013 Regulations were not renewed, much of the work currently undertaken by CDAOs and their support staff would be spread across other roles. However, some organisations may reduce the amount of resource devoted to these activities and risks informational sharing and oversight. Table 1 summarises the main activities undertaken by CDAOs, including an assessment of whether these activities would continue in full, in part, or not at all if the Regulations were not renewed.

14. 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 Regulations (see Table 2 for further detail). The total cost of CDAO staffing in these organisations is estimated to be around £32m, based on annual average cost of about £41.5k per CDAO role, including support staff. It is unclear how much resource devoted to core activities might be reduced if there was no longer a statutory CDAO role, or whether responsibilities would be delegated to more junior staff. Given the strong support for the role expressed in the stakeholder survey that informed this review, it is unlikely that core activities internal to organisations would cease. Reducing resource devoted to these core activities would also increase risks to patients.

Statutory duty to share information

15. The Regulations enable sharing of information and intelligence about local CD concerns amongst LIN members without risk of breaching data protection legislation.

16. If there were no longer a statutory duty of collaboration on all healthcare and partner organisations to share information, some organisations may cease participation in LINs and cease participation in national CD reporting. Without the exemption from the GDPR that prevents disclosure of personal information it would also be more difficult for organisations to share information, potentially putting patients and the public at risk. Any savings achieved from ceasing these activities are likely to be low and would also result in a loss of knowledge and shared learning from incidents.

17. Savings to independent hospitals and other non-NHS organisations from ceasing participation in LINs are estimated to be less than £0.6m (£32m x 2%). This estimate is based on the following considerations:

    - The responsibility for establishing and organising LINs lies with a small number of NHS local lead CDAOs, not with CDAOs in the private sector.

- Costs associated with participating in LINs are likely to represent less than 2% of the total cost of CDAO staff time. This assumption is informed by the fact that the amount of full time equivalent (FTE) local lead CDAO time devoted to organising LINs was just 2% based on a survey carried conducted by the National Prescribing Centre of all CDAOs.

18. There was widespread support for LINs from all CDAOs and other stakeholders who responded to the stakeholder survey (see Annex C) including unanimous support from all CDAOs responding from independent hospitals. Case study evidence demonstrates the learning and improvements in clinical care and safety that can be achieved through LINs (see paragraphs 92-98).

19. It is also possible that participation in national reporting of CD incidents would decrease if there were not a statutory duty to share information. In 2018/19, there were 9,793 CD incidents reported via the NHS England online CD reporting tool that covers CD incident reporting by non-NHS as well as NHS organisations. The reduction in administrative costs from ceasing this reporting is likely to be very low (e.g. less than £100,000), based on the following assumptions:

    - about 7,350 (~75%) of incidents were reported by non-NHS organisations. This reflects the share of non-NHS organisations that are designated bodies under the Regulations; and
    - it costs about £9 in staff time to report an incident (15 minutes staff time x £35 per hour total staff costs). This applies CDAO staff time costs.

20. Even under the scenario where reporting rates continued to improve, if the Regulations were renewed, the annual savings from ceasing reporting would be low, e.g. the administrative costs of reporting would remain below £0.5m even with a five-fold increase in number of incidents reported.

21. In summary, out of a total of around £32 million spent by private healthcare organisations on CDAO staffing, it is expected that voluntary compliance with internal governance requirements would remain high and savings from allowing the Regulations to expire would be much lower, including:

    - Up to £0.6 million from ceasing participation in LINs;
    - Up to £0.5 million from ceasing participation in national incident reporting

22. In addition, a small minority of private healthcare organisations may reduce investment in internal governance and core functions of CDAOs. As an illustration, if one in five organisations reduced their investment by half, this would result in savings of just over £3m, but with a potential increase in risk to patients. In total, this suggests potential savings to business of less than £5m. This would need to be weighed up against the increase in risk to patients.

Table 1 Assessment of impact of retaining/removing Regulations on activities that are currently the responsibility of Controlled Drugs Accountable Officers (CDAOs)

Activities that currently form CDAO main responsibilities	**Renew Regulations** (Mandatory requirement	**Allow Regulations to expire** (Leave to voluntary compliance)

	under 2013 Regulations)	
Establish Standard Operating Procedures and best practice for securing the safe management and use of CDs within their organisation, including regular review.	✔	✔/✘
Ensure staff receive training in their organisation on securing the safe management and use of CDs.	✔	✔/✘
Monitoring and auditing within their organisation, including periodic inspections of their organisations' management and use of CDs and reporting of incidents.	✔	✔/✘
Investigating concerns about the use of CDs and taking appropriate action, including learning from incidents.	✔	✔/✘
Establish and operate LINs to share information and co-operate to share information and learning about incidents.	✔	✘

✔ indicates that the activity would continue in full, ✘ indicates that it would discontinue, and ✔/✘ indicates that it may continue but only in part, with potentially less resource devoted to it and fewer benefits realised from learning and best practice developed from the LINs

Section 1 - Controlled Drugs

Overview

23. CDs are an essential part of modern healthcare but are associated with a potential for misuse or diversion (i.e. diverting drugs from their original purpose, either for pecuniary motives, feeding drug misuse and addiction, or in order to cause wilful harm).

24. CDs include medicines such as opioids (e.g. morphine, methadone and fentanyl) and benzodiazepines (e.g. diazepam and temazepam), which are used in a wide variety of clinical treatments, for example for the relief of acute and chronic pain, end-of-life care or the treatment of substance misuse. Other medicines, such as anxiolytics, steroids and growth hormones are also designated CD status, albeit these are subject to less rigorous regulation.

25. The 2006 Regulations set out the requirements for certain NHS and independent healthcare bodies to appoint a CDAO and describe the duties and responsibilities of that role to improve the management and use of CDs. The 2006 Regulations also require specified bodies to co-operate with each other. These enhanced governance arrangements for CDs formed a key part of the Government's response to fourth report from the Shipman Inquiry, which focussed on CDs (further details at paragraphs 28-31).

26. The 2013 Regulations updated the 2006 Regulations to reflect changes made via the Health and Social Care Act 2012. Changes included the removal of Care Trusts (PCTs)

from the NHS structure transferring the responsibilities and powers of PCT CDAOs to NHS England-NHS Improvement (NHSE-I). The roles of both Healthcare Improvement Scotland and the Care Inspectorate in Scotland were expanded. The current 2013 Regulations also introduced deregulatory measures, including an exemption for smaller independent hospitals (fewer than 10 staff members) in England or Scotland from the requirement to appoint or nominate a CDAO.

27. The 2013 Regulations are part of a wider regulatory framework that aim to improve the safe use and management of CDs and minimise the risk of misuse and diversion. The following measures sit alongside and complement the 2013 Regulations:
    - The Misuse of Drugs Act 1971 – which aims to prevent the misuse and diversion of CDs and regulate the lawful possession, supply and manufacture of CDs
    - The Misuse of Drugs Regulations 2001 – which govern the legitimate clinical use of CDs
    - The Misuse of Drugs (Safe Custody) Regulations 1973 – which set out controls on the safe custody and storage of CDs
    - The Coroners (Investigation) Regulations 2013
    - The CQC regulatory framework (England)
    - HIS governance (Scotland)
    - NHS best practice
    - Professional Regulation and best practice

The Shipman Inquiry

28. The Shipman Inquiry reported on the activities of general practitioner (GP) and serial killer Dr Harold Shipman. The police became aware of the activities of Dr Shipman during 1998.

29. Dr Shipman was convicted of 15 murders, for using lethal injections of morphine. The Inquiry established that he probably committed up to 250 murders in total, although the true number is potentially higher.

30. The Fourth Report of the Shipman Inquiry[1] in 2004 concerned the management and use of CDs and made 32 recommendations to the Government. In its response[2] to the Inquiry's recommendations, the Government accepted the need to strengthen the arrangements for the management of CDs, but to do so in a way which did not hinder legitimate use of CDs and patients from accessing the treatments they needed.

31. The Government took the necessary powers in sections 17 - 25 of the Health Act 2006 – which include the functions and responsibilities of accountable officers (section 17 of the Health Act 2006). The powers were drawn broadly with implementation details defined in regulations. The provisions of the Health Act 2006 came into effect in England in January 2007 and Scotland in March 2007. The provisions have not been substantially amended since. The 2006 Regulations set out more detailed provisions in relation to ensuring the safe management and use of CDs in healthcare, and the current 2013 Regulations have followed the same principles.

The Gosport Inquiry

32. The findings of the Gosport Inquiry provide a reminder of the importance of having a robust system of governance around the management and use of CDs. Following concerns about the care of older patients in Gosport War Memorial Hospital ("Gosport") an Independent Panel, under the chairmanship of Bishop James Jones, was set up to review the evidence held across a range of organisations concerning the initial care of patients and the subsequent investigations into their deaths in Gosport War Memorial Hospital.

33. The Panel found that during the 1990s, there was a disregard for human life and a culture that resulted in the shortening of the lives of a large number of patients through the prescribing and administering of dangerous doses of a hazardous combination of CDs, including opioids and benzodiazepines, that were not clinically indicated or justified.

34. The full report was published on 20 June 2018[3], and the Government response to the report was published on 21 November 2018[4].

35. The findings of the Panel reinforce that the provisions set out in the 2006 and 2013 Regulations, subsequent to the Shipman Inquiry, are important to protect public and patient safety. The Government response to the Inquiry highlights that the governance systems enshrined in the 2013 Regulations are still needed to reduce the risk of harm to patients and the risk of illegal diversion of CDs. It also recognises, that while no system can ever completely prevent the mismanagement or intentional misuse of controlled drugs, the measures that have been put in place mean that the inappropriate use of opioids and other harmful CDs can be detected more quickly and stopped, so that protracted poor practice or criminal activity is less likely to continue unchecked.

Section 2 - The Controlled Drugs (Supervision of Management and Use) Regulations 2013

Overview

36. The 2013 Regulations were made by the UK Parliament on 14 February 2013, and came into effect from 1 April 2013. The 2013 Regulations have a sunset clause provision, setting an expiry date for the 2013 Regulations of 31 March 2020.

37. The 2013 Regulations incorporated the framework of the 2006 Regulations but adapted this to the new structure of the NHS. The primary provisions of the 2013 Regulations:

    a. designate particular organisations as “designated bodies” and/or “responsible bodies”. All “designated bodies” are required to appoint a CDAO

    b. define the role of the CDAO and the requirement to keep a national register of CDAOs – which falls to the CQC in England and HIS in Scotland;

    c. provide for the establishment of LINs, which facilitate information sharing between “relevant persons” who are engaged in activities that involve, or may involve, the management or use of CDs in the area covered by the LIN; and

    d. cover ancillary matters, such as carrying out inspections, and afford the CQC, HIS and the General Pharmaceutical Council (GPhC) the power to obtain information from particular persons engaged in relevant activities.

38. Alongside the introduction of provisions outlining the requirements around LINs, the 2013 Regulations also updated and simplified previous arrangements set out in the 2006 Regulations to:

    a. provide a clearer and more logical structure based on the three key areas of CDAOs, information sharing, and supplementary matters, reducing the number of regulations from 31 to 21;

    b. rebalance the emphasis on ensuring safe clinical practice as well as the security of CDs throughout the supply chain;

    c. remove several specific record-keeping obligations and clarify the information management obligations;

    d. simplify the list of activities and functions for which CDAOs must have standard written operating procedures in place;

    e. remove from independent hospitals and NHS hospital trusts the need to ensure that any sub-contractors that perform relevant activities have appropriate CD management and use systems in place, because the statutory responsibility already lies with the contractor to have such systems in place;

    f. remove some obligations on CDAOs in relation to securing relevant education and training;

    g. introduce new exemptions from the regulatory obligations for certain types of business;

    h. apply the regulatory scheme, for the first time, to the armed forces; and

    i. introduce a sun-setting provision so that these Regulations lapse in 2020 unless the Government of the day legislates to maintain the Regulations, in whole or in part, if it wished to retain them.

39. Further details of the Regulations are provided at Annex A.

40. The aim of these changes was to ensure that measures designed to help safeguard patients and the public are sufficiently robust and that both NHS and private providers share information and best practice, whilst at the same time facilitating a proportionate response to incidents and concerns relating to CD mismanagement or intentional misuse.

System and Professional Governance

41. The CQC in England and HIS in Scotland play a key role in overseeing and governing the safe management and use of CDs. Since the 2013 Regulations came into effect, the CQC has published an annual report on CD management in England – which includes information on the prescribing of CDs and the work of LINs, as well as recommendations for health and social care commissioners, providers, and staff in relation to the continuing safe management and use of CDs. The CQC also publishes, on their website, information on the 2013 Regulations and potential exemptions, and tools for self-assessment in relation to CD governance. HIS offers similar information on their website.

42. The 2013 Regulations do not contain any enforcement provisions. Professional regulators of healthcare in England and Scotland – primarily the General Medical Council (GMC), Nursing and Midwifery Council (NMC), GPhC and the Health and Care Professions Council (HCPC) – regulate the activity, behaviour and professionalism of healthcare professionals who manage and use CDs. The regulators provide help and advice for healthcare professionals and can take action to protect the public interest should a professional not be fit to practise.

43. Figure 1 presents a summary of the system landscape of CD governance in healthcare in England and Scotland to aid understanding of the roles that the different organisations play. Acronyms are defined in the abbreviations section at the end of this report.

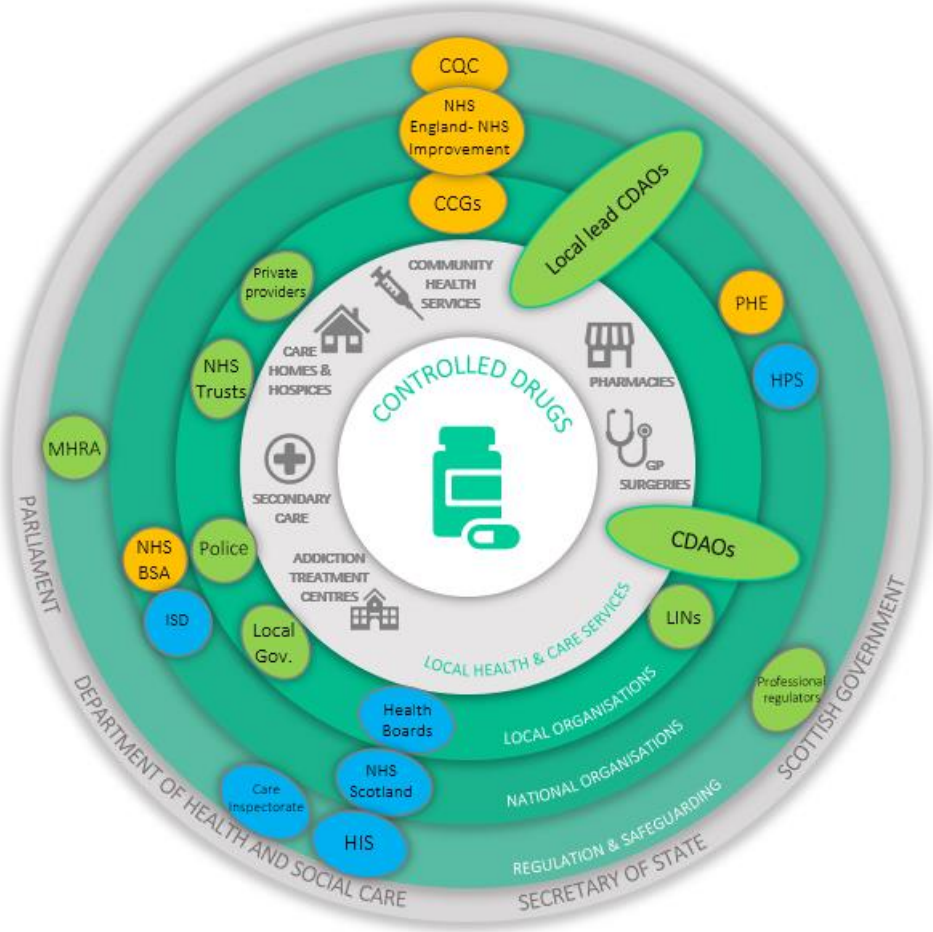


Figure 1 - System map of CD governance in England and Scotland. English-specific organisations outlined in red, Scottish-specific organisations outlined in blue and mutual organisations/persons outlined in green.

Section 3 - Review Methodology

44. The Department of Health and Social Care (DHSC) has taken a proportionate approach to the level of evidence gathered to inform this review, based on the scale of the 2013 Regulations, information and data available, and impact and cost to business.

45. Throughout this review of the 2013 Regulations, DHSC worked with officials in the Scottish Government to ensure the findings and recommendations represented the view of both countries fairly and equally.

Process Evaluation

46. This review includes a process evaluation drawing on qualitative and quantitative evidence to assess whether the Regulations have been implemented as intended. The review looks at what has worked well in practice and what has not; and whether the same objectives could be achieved in another way. The process evaluation focused on the four policy objectives relating to implementation:
    - maintain and, where possible, improve the system of good governance concerning the safe management and use of CDs in the healthcare system;
    - promote co-operation and information sharing between different local bodies and organisations;
    - enable effective mechanisms to monitor and audit the use of CDs as medicines; and

- enable adequate powers to investigate, and to take prompt and effective action where appropriate, when concerns are raised.

47. Evidence to inform this process evaluation was primarily gathered through engagement with key stakeholder groups in England and Scotland that are impacted by the 2013 Regulations. A questionnaire was developed to gather evidence on the implementation of the 2013 Regulations, including barriers to implementation. Other sources of evidence included:
    - meetings and workshops with main stakeholder groups;
    - discussions with key national organisations in England and Scotland; and
    - case studies provided by CDAOs describing how the Regulations had been implemented and real impact at a local level.

    Further description of these data sources is provided below.

Impact and Economic Evaluation

48. The costs and benefits of the 2013 Regulations, including measures carried over from the 2006 Regulations, are:
    - costs associated with statutory CDAO role, with some additional costs associated with the duty to share information and report incidents.
    - benefits of avoided patient and public harm from reducing inappropriate clinical use, criminal use and diversion of CDs.

49. To estimate costs, actual data was used on the costs of the CDAO role. These data were previously used in the 2013 Impact Assessment. These are the most detailed data available and remain relevant since the CDAO role has not changed since 2013 apart from a small number of NHS “local lead” CDAO roles. Costs were uprated to allow for wage growth and inflation. It was not considered proportionate to collect new detailed staffing data for this review.

50. Benefits to patients and the public of the Regulations have not been quantified or monetised because of inherent difficulties in establishing whether these have materialised. The primary aim of the Regulations is to prevent another serious case of wilful harm or institutional negligence (i.e. another case such as that of Harold Shipman or Gosport) that could lead to the loss of hundreds of lives and the costs of a major Inquiry. Based on two previous known events, it is not possible to estimate the risk of such events occurring or the impact of the Regulations in reducing this risk. Neither this review, the original 2006 Regulatory Impact Assessment nor the 2013 Impact Assessment have attempted to quantify this intended benefit.

51. There are also difficulties in quantifying reductions in more frequent cases of inappropriate clinical use of CDs. The 2013 Impact Assessment attempted to quantify these benefits in the following way:
    - It used data on the number and severity of self-reported patient safety incidents involving CDs.
    - It assumed that the CDAO role would prevent some fraction of incidents to quantify benefits.
    - It acknowledged that there was substantial under-reporting of incidents and adjusted estimates of benefits to account for this.

52. In practice, there are difficulties in establishing whether these benefits have materialised. Numbers of patient safety incidents reported via different reporting tools

have increased over time. It is widely recognised that the improvement in reporting is a positive indication that awareness has increased of requirements in relation to the safe management and use of CDs.

53. For these reasons, instead of quantifying and monetising benefits, this review has used the following sources of evidence to describe benefits:
    - Stakeholder views on perceived benefits collected via a Stakeholder Survey.
    - Case studies providing examples of actual local benefits provided by CDAOs.
    - Descriptions of the number, type and severity of reported incidents involving CDs.

Sources of Evidence

54. Stakeholder engagement by DHSC and the Scottish Government included meetings and workshops with a range of stakeholder groups. These are listed in Annex B. Discussions were structured around five key questions:
    - To what extent have the 2013 Regulations achieved the original policy objectives?
    - Do the objectives remain appropriate?
    - Have there been any unintended consequences?
    - What has worked well?
    - If the objectives remain appropriate, to what extent could they be achieved in another way which involves less onerous regulatory provision?

55. A stakeholder survey was used to gather detailed information on the implementation of the Regulations, informing the process evaluation, and practitioner views on its impacts, informing the impact evaluation. An online questionnaire was circulated to stakeholders inviting responses from all interested parties, running for four weeks between 23 April 2018 and 21 May 2018. It included questions on how the 2013 Regulations are working in practice and offered respondents the opportunity to express their views on the necessity, or not, of maintaining the 2013 Regulations as well as flagging areas for improvement in any future potential regulations. A total of 128 individuals responded to the survey either in an individual professional capacity or on behalf of their organisation. A summary of responses is provided in Annex C. Some questions were answered by subsets of respondents only (e.g. CDAOs, NHS lead CDAOs) and other questions were answered by all respondents. This variation may appear as inconsistencies in the results. To aid in understanding, the number of responses is also provided. A list of organisations responding to the questionnaire is provided at Annex D.

56. Case study evidence was collected to provide examples of how the Regulations have been implemented and how they have impacted patient and public health. Case studies were provided by a group of NHS local lead CDAOs, who described examples of CD incidents, how these had been handled locally and how provisions in the Regulations, such as information sharing or inspection powers, had been used.

57. To estimate costs, detailed survey data on CDAO staffing was used. These data were collected by the National Prescribing Centre in 2012 on behalf of a CD working group established by the then Chief Pharmaceutical Officer. The working group was made up of representatives from the NHS (including those involved in designing the future NHS structures), regulators, the independent sector and Scotland. The main task of the Group was to look at the role and functions of CDAOs and LINs and consider how the

2006 Regulations should be updated in 2013. The survey was distributed via a dedicated CDAO website for all CDAOs to complete. This allowed for development of reliable and robust cost estimates of CDAO staffing. With responses from over 200 individuals, the data cover the entire spectrum of CD AO working patterns and arrangements, including calculated average wages, full time equivalent (FTE) of CD AO working time, support staff and FTE of local lead CDAOs spent on LIN tasks.

58. To describe benefits, data on reports of patient safety incidents involving CDs were used from the National Reporting and Learning System (NRLS). The NRLS is a central database, run by NHS Improvement, containing records of all patient safety incident reports in England and Wales, including near misses and incidents that caused harm. On request from DHSC for this review, NRLS provided an extract from their database describing the number and severity of incidents where a CD was mentioned in the report during 2018 (based on the date when then incident occurred). Incidents involving CDs were identified based on a free text search of relevant fields for names of CDs. A similar extract was provided in 2013 for the 2013 Impact Assessment. There are several reasons why trends in reported CD-related incidents, and their reported severity, are not used to infer trends in the overall underlying number of CD-related incidents:
    - Although open to all organisations, only NHS Trusts are required to routinely report incidents, so many incidents occurring in private businesses are not captured.
    - One limitation is that some reported incidents involving CDs could be missed if the CD was not documented.
    - It is also widely recognised that this type of self-reported data underestimates the actual number of adverse events. NRLS data does not, and cannot, provide the definitive number of patient safety incidents occurring in the NHS; it only measures the number that are reported. The total number of reports has increased each year since its inception, reflecting an improved reporting culture.[5]
    - Incident classification, particularly reported degree of harm, can change as local investigations progress and incidents are updated.

59. A second source of more detailed data on reported CD incidents was used to describe recent trends in reporting. In 2017, the Greater Manchester CDAO and local area team developed the NHSE-I online CD reporting tool. The tool is now used nationally in England, apart from one region which is yet to adopt it. Private healthcare providers, as well as NHS organisations, are encouraged to use this reporting tool. This has led to improved reporting, in both volume and accuracy of reporting. Again, due to widely acknowledged under-reporting, these data are used to describe the number, types and severity of reported incidents but not infer trends in the underlying number of CD incidents.

60. Prescribing data covering the period January 2014 to December 2018 were provided for this review by NHS BSA Information Services Data Warehouse for England and NHS Scotland's Information Services Division (ISD) for Scotland. These data cover all dispensed prescriptions of CDs by schedule, prescribed in the NHS and privately and dispensed by community pharmacies. Again, these data are not used to directly evaluate the success of the Regulations in promoting safe and appropriate prescribing of CDs since there are wider factors that influence prescribing levels, such as the simultaneous increase in licensing and availability of CDs for a range of conditions and changing patient populations, including for patients with more complex health needs.

Section 4 – Process Evaluation

Policy Objectives of the 2013 Regulations

61. The following section assesses evidence as to the extent that the key policy objectives of the 2013 Regulations have been achieved, remain appropriate, and whether they could be achieved in a less onerous way. Each of the policy objectives describing the intended implementation of the Regulations are addressed in turn:

    - **Improve governance:** maintain and, where possible, improve the system of good governance concerning the safe management and use of CDs in the healthcare system.
    - **Promote information sharing**: promote co-operation and information sharing between different local bodies and organisations.
    - **Improve audit**: enable effective mechanisms to monitor and audit the use of CDs as medicines.
    - **Enable investigative powers**: enable adequate powers to investigate, and to take prompt and effective action where appropriate, when concerns are raised.

62. In considering each objective the analysis is based on maintaining the 2013 regulations, versus letting the Regulations expire (the counterfactual). If the Regulations expire it is assumed that businesses would rely on voluntary internal governance arrangements to meet other legal duties that apply to all healthcare providers, including the fundamental standards of care and maintaining patient safety. Private businesses with good standards of care would be expected to:

    - Have in place standard operating procedures to secure the safe management of CDs e.g. safe storage, record keeping etc.
    - Provide training for staff handling CDs
    - Encourage and share best practice
    - Monitor and audit the use of CDs
    - Record and investigate incidents concerning CDs, taking appropriate action and implement learning to prevent incidents reoccurring.

63. These all form part of what is considered good governance. Voluntary robust arrangements for the safe management and use of CDs would aim to minimise patient harm, misuse and criminality within their respective organisation. Failure to do this, or sub-standard governance arrangements would be expected to increase the risk to patients and the public as well as damage public confidence in the business and the health services they provide.

Improve Governance

"Maintain, and where possible, improve the system of good governance concerning the safe management and use of CDs in the healthcare system"

To what extent the objective has been achieved?

64. We can never be complacent concerning the safe management and use of CDs. Drugs that have a CD status are, by definition, substances that have a high potential to cause harm, be misused or diverted. The fact that we have not discovered another incident on the scale of Shipman or Gosport, does not mean that we can stop striving to improve

the safe use and governance of these drugs within the NHS or private healthcare system.

65. When asked whether, overall, the 2013 Regulations have met their objective to "maintain, and where possible, improve the system of good governance concerning the safe management and use of controlled drugs", 113 (89%) questionnaire respondents suggested they have met, or firmly met, the objective. 6 (5%) respondents suggested they have not met, or firmly not met, their objectives and 9 (7%) respondents had no view. Of those that suggested the Regulations have not met its objectives, comments related mainly to the need for the Regulations to keep pace with the changing structure of the NHS.

66. Furthermore, 40 (69%) respondents indicated that the 2013 Regulations have led to increased, or very increased, awareness of the requirements in relation to the safe management and use of CDs. 15 (26%) indicated there had been no change since the introduction of the 2013 Regulations; none indicated there had been a decrease in awareness; and 3 (5%) indicated they were unsure of any change.

67. This review subsequently finds that the regulatory objective to "maintain, and where possible, improve the system of good governance concerning the safe management and use of controlled drugs" and "protect patient and public health" has been broadly met by the 2013 Regulations.

68. The 2013 Regulations provide a statutory basis for the structures through which the safe management and use of CDs can be assured. Although this is the case, stakeholder engagement has suggested that not all organisations may be appropriately captured under the Regulations. This is primarily linked to the ongoing evolution of healthcare provision since the 2013 Regulations came into force. Any future amendments to the 2013 Regulations should ensure that they are updated to reflect new structures and organisations as appropriate, for example, new models of care; alternative providers of healthcare (such as non-NHS providers); integrated care systems; private clinics; and social enterprise companies and consider proportionality of the CD arrangements and whether the existing exemption for small businesses would/should continue to apply. In addition, any future amendments to the 2013 Regulations should reflect the ongoing restructuring of NHSE-I, and this review recommends that it would be more appropriate to review the Regulations once this is completed to ensure all organisations are properly captured.

69. Though it is reported that not all organisations may be appropriately captured under the 2013 Regulations, some providers of new models of care will already have a CDAO or be exempt under existing provisions. It should also be noted that healthcare providers are required to comply with the wider regulatory and legislative framework as appropriate and have legal obligations to achieve fundamental standards of care and maintain patient safety. Further information is provided in paragraph 27. Discussions with NHS Lead CDAOs have indicated that organisations who may not be captured by the 2013 Regulations are able to receive informal support and can report incidents through the NHS England online CD reporting tool.

70. The monitoring and reporting requirements embedded within the Regulations are explored further in paragraphs 101 - 113, including trends in prescribing and reporting of incidents concerning CDs.

Does the objective remain appropriate?

71. The lessons learned from the Shipman and Gosport Inquiries confirm that it remains appropriate to have mandatory national governance on the safe management and use of CDs. We cannot rely solely on internal and voluntary governance. Regional and national oversight and information sharing between organisations is important to identify and address misuse or diversion of CDs in the healthcare system. The evidence considered under this review indicates that the arrangements under the 2013 Regulations complement and sit alongside professional regulation, clinical best practice, and other initiatives concerning medicines safety to minimise the risk associated with CDs. No system can ever completely prevent the mismanagement or misuse of CDs. However, the measures in the 2013 Regulations mean that the inappropriate use of opioids and other harmful CDs can be detected more quickly and stopped, so that protracted poor practice, or criminal activity, is less likely to continue unchecked.

72. Engagement with stakeholders indicates continued support for the organisations designated in the Regulations to be required to appoint or nominate a CDAO (solely or in partnership with other organisations). This is supported by responses received via the stakeholder questionnaire, which found 119 (93%) respondents shared this view. It was however raised in some of the responses that CDAOs require appropriate time and resource to undertake their role effectively. Some respondents also suggested that the profile of the CDAO needs to be maintained or raised to reiterate the seriousness of the position and that there could be consideration of further seniority requirements for the role. This and the regulatory burden of maintaining the CDAO role is explored further below.

To what extent the objective could be achieved in another way?

73. As outlined above, in a situation where the Regulations were allowed to expire, it is expected that most private businesses/independent providers would continue to perform the statutory functions to a certain extent - at least in the short-term - on a voluntary basis. The main burden on business lies with the statutory functions and duties associated with the CDAO role and the statutory duty to share information about CD incidents. Full details of the CDAO duties are set out in Annex A.

74. When the Regulations were initially brought into force in 2013, there were 27 NHS England local lead CDAOs and associated local area teams. As the structure of NHS England has evolved, the number of NHS England local lead CDAOs has decreased to 13 in 2019 - although their responsibility in respect of the geography they cover has increased. There was concern expressed in interviews with CDAOs and in response to the survey that, as NHS England's structure has evolved, the full scope of the NHSE-I local lead CDAO role has not been recognised. As a result, the role and resources to support the role, have been subsumed into existing roles that some consider are already functioning near capacity.

75. National registers of CDAOs are held and maintained by the CQC and HIS. Table 2 summarises the number and location of CDAOs who are currently registered. Discussions with CQC have indicated that they are confident that the systems in place are such all organisations requiring a CDAO do have one in place and have notified CQC for them to be included in the CDAO register. In summary, of the total 1,016 CDAOs appointed in England and Scotland, 24% work in NHS organisations and 76% work in 'other' organisations (including private organisations and other organisations that fall under the 2013 Regulations, including social care providers).

Table 2 Number of CDAOs in England and Scotland by sector

	England		Scotland	
Sector	Number	%	Number	%
NHS	233	24.1%	17	35.4%
Other	735	75.9%	31	64.6%
Total	968	100.0%	48	100.0%

Source: CQC and HIS CDAO registers as of November 2019. Other includes independent healthcare organisations and organisations such as social care providers that fall within the designated body status.

76. At the end of December 2008, there were 1,049 CDAOs registered with the Healthcare Commission (now CQC)[6], 658 of which were in private business (independent healthcare organisations). The number of registered CDAOs has therefore remained stable since the introduction of the Regulations.

Small and medium business provisions

77. The 2013 Regulations currently provide an exemption to the requirement to appoint or nominate a CDAO where an independent hospital in England or Scotland has fewer than 10 employees, or an exemption has been requested and granted from the CQC or HIS on the grounds that requiring the organisation to appoint or nominate a CDAO would give rise to difficulties that would be disproportionate to the associated benefits. In 2018, only six organisations requested and were granted an exemption from the CQC. HIS received no requests in 2018.

78. Independent hospitals in England or Scotland which have fewer than 10 employees are automatically exempt from appointing or nominating a CDAO and do not have to notify the CQC or HIS of their automatic exemption. However, current practice and particular circumstances, such as staffing levels of an organisation changing, means that some organisations do submit exemption notifications. The notification system in place provides data for the total number of exemptions granted but does not indicate whether the exemption is based on size or on the grounds that appointing or nominating a CDAO would be disproportionate. Businesses applying for an exemption on the grounds of disproportionality must apply each year, but once an exemption is granted on the grounds of size no further applications are required unless their circumstances change. The total number of exemptions granted by CQC between 2013 and January 2020 is 46. In 2018, six organisations requested and were granted an exemption from CQC. The financial value of this exemption is described in paragraph 134. HIS received no requests in 2018 and has reported that it regulates no eligible businesses who have fewer than 10 employees.

79. This review concludes that this exemption remains appropriate and should be maintained to minimise the burden on small businesses and rely on system governance, professional regulation, and best practice. In addition, the CQC has agreed to update its notification system to collect information on the size of business, which will inform future reviews of the regulations.

Promote Information Sharing

"Promote co-operation and information sharing between different local bodies and organisations"

To what extent the objective has been achieved?

Local Intelligence Networks (LINs)

80. In England, NHS England local lead CDAOs held 33 NHS England LINs across the 14 NHS England areas in 2018. LINs primary function is to promote co-operation and the sharing of information. They are unique in their purpose and bring together a diverse range of organisations which may not otherwise interact on the issue of CDs. Membership comprises of a broad range of organisations, including NHS, independent sector, social care bodies, and the police.

81. In Scotland, a LIN is run by the local lead CDAO of each of the 14 Health Boards, covering the whole of Scotland. Reporting indicated that a total of 13 LIN meetings where held during 2017, and similarly to England, membership comprised of a broad range of organisations.

82. Engagement with stakeholders suggests that the general purpose and function of LINs are felt to remain appropriate. This is supported by responses received via the stakeholder questionnaire, which found 48 respondents (82%) suggesting that LINs are helpful or very helpful in ensuring the safe management and use of CDs.

83. Furthermore, feedback from stakeholders suggests that LINs promote co-operation and information sharing between LIN members; are an effective method of sharing information on the wider use and diversion of CDs in the area; and provide sufficient access to information that LIN members would otherwise be unable to obtain. Most responses to the stakeholder questionnaire agree with these views – with 54 respondents (93%) supporting the first point, and 47 respondents (81%) agreeing the second and third points.

84. Several key themes emerged regarding the points raised above during stakeholder engagement. It was suggested that although LINs promote co-operation, information sharing and learning – LIN groups can be too large and the engagement of some participants and sharing of information could be improved. Similarly, it was suggested by some that there is a need for more co-ordination and streamlining the use of analytics to enhance monitoring and pick up trends in CD incidents. To address concerns around the sharing of confidential information, some NHS England CDAOs have introduced secure conference style apps that allow LIN members to raise questions anonymously, and these have proved popular. As LINs grow in membership it is important that all members feel able to share concerns and contribute at the meetings.

Does the objective remain appropriate?

85. When asked whether there are any organisations that are not currently included in LINs that it would be useful to include more representation from, the following organisations were identified by respondents of the stakeholder questionnaire:

- Care homes
- Community pharmacies

- Counter fraud representatives
- Home Office (inspectors)
- Hospices
- Local authority representation (especially in relation to drug and alcohol teams)
- Out of hours service providers
- Pain management representatives
- Private clinics (i.e. slimming clinics and in vitro fertilisation clinics)

86. The function of LINs was set out in the 2013 Regulations to be flexible and allows for variation across the different regions of England and Scotland, in respect of membership and operation. This flexibility is to ensure that LINs are appropriate and useful to their specific members, and this generally appears to have been a valued feature which remains an effective way to share intelligence and learning in addition to providing valuable networking opportunities.

Information sharing

87. As alluded to above, most stakeholders agreed that the 2013 Regulations have contributed towards improving the sharing of information between relevant parties. When asked whether the 2013 Regulations have met their objective to promote co-operation and information sharing between different local bodies and organisations, 107 (84%) questionnaire respondents suggested they have met, or firmly met, the objective. 14 (11%) respondents suggested they have not met, or firmly not met, their objectives and 7 (5%) respondents had no view.

88. During engagement with stakeholders, it was highlighted by some that individuals are often reluctant to share patient-identifiable information, even when there is a risk of harm. Responses suggested that this relates to uncertainties around information sharing obligations of the 2013 Regulations and how they interact with other legal obligations relating to protecting patient confidentiality and ensuring data sharing is appropriate and correct. Indeed, in response to the stakeholder questionnaire, 10 (17%) respondents suggested they had experienced difficulties accessing information they felt they should have access to, when investigating when things went wrong.

89. In the Government's response to the Gosport Independent Panel report, NHSE-I lead CDAOs committed to reviewing the effectiveness of their LINs to share information of concern. In April 2019, CQC conducted a survey on behalf of NHSE-I inviting all LIN members to take part and received 481 complete responses. CQC and NHSE-I are currently analysing the survey results, which will contribute to an action plan to improve how LINs function. Although the interim findings are generally positive they show that the sharing of confidential information is a concern, particularly since the GDPR came in to force, which is cited as a perceived barrier to the effective sharing of information. In 2018 the 2013 Regulations were updated to reflect the coming into force of the GDPR. An exemption was introduced to the 2013 Regulations for CDAOs and other defined bodies which provides legal cover for the disclosure of personal data in the course of meeting statutory obligations required by the 2013 Regulations. However, the interim findings of the survey and the Department's own PIR survey indicate that awareness of the GDPR exemption provided by the 2013 Regulations could be improved. Both CQC and NHSE-I CDAOs continue to highlight the importance of speaking up and sharing information of concern to protect patients and the public.

90. The specific function and operation of LINs is not restricted by 2013 Regulations, which are drafted to provide flexibility for NHSE-I local lead CDAOs to arrange and manage

LINs to suit the requirements of their region. As such, based on the interim findings, discussions with the CQC and NHSE-I have indicated that it is not anticipated that results of survey CQC conducted on behalf of NHSE-I will require amendments to the 2013 Regulations or any other legislative action.

91. A group of NHSE-I local lead CDAOs, in looking to inform this review, provided qualitative information on some of the CD-linked activities that they encounter and deal with as local lead CDAOs. The following case studies are examples of incidents and information sharing related to provisions of the 2013 Regulations:

Case study 1:

92. *In one CD incident shared by lead CDAOs during this review, a palliative care patient died after bathing, whilst using a transdermal fentanyl patch. The death occurred due to a fentanyl overdose, with the heat of the bath likely causing an early onset release of fentanyl, via the fentanyl patch drug delivery system, into the patient – in turn causing opioid overdose. Several similar deaths were identified.*

93. *Action was taken to ensure that information was shared across the LINs and the wider healthcare system on the potential dangers and the MHRA and National Patient Safety Agency (whose role is now fulfilled by NHSE-I) were contacted regarding the issue and advised to review patient leaflets issued in conjunction with the medicine – to ensure that advice was included which recommends not bathing when the patches are on the skin.*

94. The sharing of information with others, including healthcare professionals and healthcare regulatory bodies, is an important way in which patient harm can be avoided in the future. This case study evidences that this sharing of information is taking place, and is directly linked to the provisions of the 2013 Regulations – with local lead CDAOs and LINs clearly playing an important role in safeguarding patients and the public against the dangers associated with CDs.

Case study 2:

95. *A GP erroneously prescribing a CD with incorrect dosage instructions. When the prescription was presented to the community pharmacist the error was noted and the GP alerted. A new prescription was subsequently written up for the patient.*

96. *An investigation identified that the prescribing doctor was distracted by a telephone call during the writing up of the prescription.*

97. *As a result of the incident, the practice raised the issue at their next practice meeting, where it was discussed. A behavioural change was agreed. Telephone calls would no longer be taken whilst prescribing a medicine. Learning was shared within the LIN.*

98. The above case studies demonstrate the importance and value of the LINs in sharing information and learning from medication errors. This has resulted in system improvements and decreases the likelihood of harmful or potentially harmful CD incidents occurring in the future.

To what extent the objective could be achieved in another way?

99. This review finds that the regulatory objective to "promote cooperation and information sharing between different local bodies and organisations" has been met. The 2013 Regulations provide a statutory support for organisations and individuals to share information and their concerns. This is primarily through the function of LINs – an element of the 2013 Regulations that most stakeholders indicate to be beneficial.

100. If the 2013 Regulations where to expire, the LINs is one of the main functions that could reasonably be expected to discontinue on a voluntary basis. As outlined in the section on impact to business above, the burden of arranging LINs is the responsibility of NHSE-I local lead CDAOs. As such, savings to independent hospitals and other non-NHS organisations from ceasing participating in LINs is estimated to be less than £0.6m, which when balanced against the benefits realised from attending the LINs, is negligible.

Improve Audit

"Enable effective mechanisms to monitor and audit the use of CDs"

To what extent the objective has been achieved?

Reporting of Controlled Drug incidents

101. When asked whether, overall, the 2013 Regulations have met their objective to "enable effective mechanisms to monitor and audit the use of controlled drugs" in relation to the safe management and use of CDs, 96 (75%) questionnaire respondents suggested they have met, or firmly met, the objective. 25 (19%) respondents suggested they have not met, or firmly not met, their objectives, and 7 (5%) respondents had no view.

102. 25 (43%) respondents indicated that the 2013 Regulations have led to increased, or very increased, reporting of incidents associated with the safe management and use of CDs. 26 (45%) indicated there had been no change since the introduction of the 2013 Regulations; 2 (3%) indicated there had been a decrease in associated reporting; and 5 (9%) indicated they were unsure of any change.

103. This review notes the role of the NHS England online CD reporting tool and the National Reporting and Learning System (NRLS) in allowing for incidents and concerns to be reported, and the level of associated harm to be noted. The NHS England online CD reporting tool presents a useful avenue through which patient and public health can be safeguarded - with CD incidents and concerns being reviewed and action taken by local lead CDAOs, as appropriate, to prevent and mitigate future occurrences. To relax regulation around the required reporting of incidents is likely to lead to a decrease in this occurring, and subsequently the health of patients and the public would be at increased risk.

104. When things go wrong in using or managing CDs, it is vital incidents are recorded and action is taken to address the incident and prevent it from happening again. CDAOs duties in this area are important and complement Medication Safety Officers and other post holders with responsibilities and duties to secure the safe management and use of all medicines. The review indicates that more can be done to improve systems of reporting and avoid duplication and the review recommends this should be subject to further consultation, encompassing work by NHSE-I to improve reporting and learning from medication errors and work underway to replace NRLS through the Development

of the Patient Safety Incident Management System (DPSIMS). This project will develop a new system to better support the NHS to learn about what goes wrong in healthcare and provide learning resources to support safety improvement. CDAOs have a keen interest in this work and can share their knowledge with respect to the report and learning from incidents involving CDs.

Prescribing of controlled drugs

105. CDAOs also have a duty to monitoring the prescribing of CDs, and the CQC has included prescribing trends of CDs in its annual reports on the safer management of CDs. Prescribing of CDs in England and Scotland has remained stable between 2014 and 2018. In this period there has been an increase in licensing and availability of CDs for a range of conditions and for patients with more complex health needs, but there has also been a drive to reduce prescribing of CDs and other potentially dangerous and/or addictive medicines.

106. Following reports of overprescribing of opioids leading to dependence and deaths in the USA, levels of opioid prescribing are now being monitored more closely by CDAOs, clinical commissioning groups and providers. A range of organisations are developing tools and guidance to support prescribers to promote best practice and reduce overprescribing and dependence on CDs.

107. For example, work has been undertaken by CDAOs and the CQC to inform prescribers of the potential dangers associated with CD prescribing and use - encouraging prescribers to consider alternative medicines. Public Health England has undertaken a review of the scale and distribution of prescription drug dependence and withdrawal, and the Medicines and Healthcare products Regulatory Agency (MHRA) has initiated a review of the benefits and risks of opioid medicines, including dependence and addiction. The NHS England East of England CDAO network has developed PrescQIPP, a prescribing support resources, metrics and tool to support providers review and tackle high dose opioid prescribing.

108. Further analysis of the prescribing of CDs and incident reporting is provided at Annex E.

Other CDAO reporting obligations

109. Local lead CDAOs, CQC, HIS and the Care Inspectorate may also request periodic declarations and self-assessments from providers of medical, dental, nursing or midwifery services. These must outline whether the provider uses CDs at any premises from which they provide healthcare, and if so how CDs are being managed and used at those premises. These aim to help identify poor practice within an organisation which can then be addressed and improved.

110. Engagement with stakeholders suggests that, overall, there is support for the provisions that allow local lead CDAOs and other organisations to request periodic declarations and self-assessments. 31 (72%) CDAOs indicated that they feel it is still appropriate to provide periodic declarations and self-assessments.

111. Responses suggested that some local lead CDAO teams are unclear on their value; that responsibility for requesting and assessing periodic declarations would better lie with the regulators and individual clinicians, unless regional teams are adequately resourced.

Does the objective remain appropriate?

112. This review finds that the regulatory objective to “enable effective mechanisms to monitor and audit the use of controlled drugs” has largely been met, although there are some aspects that could be improved. As outlined earlier in this review, the reporting of CD incidents and concerns could benefit from being streamlined and improved to more effectively assure the safe management and use of CDs. This review does however recognise that work is ongoing to improve the reporting of CD incidents and concerns in England via the NHSE-I England online CD reporting tool and replacement of the NRLS in relation to wider medicines safety and patient safety.

To what extent the objective could be achieved in another way

113. The 2013 Regulations currently provides a firm basis for the monitoring and auditing of CD use across healthcare settings. Removing regulation in this area would likely lead to a decrease in reporting and subsequent learning from incidents. As outlined in the section on impact, business costs savings from ceasing statutory reporting would be likely to be less than £100,000. When balanced against the benefits of reporting and subsequent learning, these costs are insignificant.

Enable Investigation

“Enable adequate powers to investigate, and to take prompt and effective action where appropriate, when concerns are raised”

To what extent the objective has been achieved?

114. When asked whether, overall, the 2013 Regulations have met their objective to “enable adequate powers to investigate, and to take prompt and effective action where appropriate, when concerns are raised” in relation to the safe management and use of CDs, 103 (80%) questionnaire respondents suggested they have met, or firmly met, the objective. 14 (11%) respondents suggested they have not met, or firmly not met, their objectives and 11 (9%) respondents had no view.

115. This review finds that the regulatory objective to “enable adequate powers to investigate, and to take prompt and effective action where appropriate, when concerns are raised” has been adequately met. The 2013 Regulations provide useful powers for CDAOs and others to investigate and act in respect of CDs, with the case studies included in this section acting as a prime example of the action taken in regard to securing the safe management and use of CDs.

Does the objective remain appropriate?

116. 101 (79%) respondents agreed that, generally, CDAOs have adequate powers to investigate and take prompt and effective action where appropriate in regard to securing the safe, appropriate and effective management and use of CDs. Some themes did emerge however during stakeholder engagement. Some respondents suggested that there could be more involvement of local counter fraud and security management specialists. Some suggested that in some circumstances powers of inspection are limited, and CDAOs should be given the powers to enter and investigate all premises subject to inspection by the CQC, for example, in relation to private practitioners.

117. The 2013 Regulations set out a requirement for CDAOs to take appropriate action with regard to well-founded concerns (which may relate to incidents) associated with CD

use. Furthermore, where there is a case that appears to the CDAO to signify concerns relating to performance, there must be arrangements in place for the CDAO to:

- request additional support, advice, training or mentoring for the relevant individual from an appropriate person;
- implement a procedure for dealing with serious untoward incidents;
- refer concerns to regulatory bodies, police forces, NHS Protect (now replaced by NHS Counter Fraud Authority (NHS CFA)), the Scottish Counter Fraud Services or an incident panel (which can be convened by a local lead CDAO, where the local lead CDAO is referring concerns); and
- where the CDAO is an NHS local lead CDAO, deal with matters arising from an incident panel, which can include ongoing monitoring of an individual, implementation of a procedure for dealing with serious untoward incidents, or referral of concerns to the bodies mentioned previously above.

118. The following case studies illustrate how CDAOs have taken prompt and effective action.

Case study 1:

119. *Sixty care homes in a local lead CDAO's area had been visited by Controlled Drug Liaison Officers. It was reported by some of the care homes that possible thefts by staff of oral liquid presentations of CDs were occurring.*

120. *Upon investigation by the CDLOs and local lead CDAO's team, it was ascertained that a district nurse, who had recently been dismissed from their position in an NHS Acute Trust, was responsible for the thefts. Following their dismissal, the nurse had gone on to gain employment at several of the care homes without disclosing the reason for their dismissal, and subsequently stolen CDs.*

121. *Following the investigation, the nurse was prosecuted and convicted They were also referred to the professional regulator – the Nursing and Midwifery Council.*

122. *The investigation also revealed deficiencies in record keeping and the need to ensure record entries are made promptly and signed by both staff members administering CDs. The learning from the incident was shared in the local lead CDAO's LIN newsletter.*

Case study 2:

123. *A care home manager stole a blank prescription pad and wrote prescriptions using the details of deceased residents to gain illicit access to CDs.*
124. *This incident was investigated by the local lead CDAO and local CDLOs, who inspected the care home's processes and prescribing patterns, and liaised with other organisations to identify action that had been taken. The manager was arrested and charged. Support was provided to the care home, as well as to staff and the patients' relatives – bringing in safeguarding and social services as required.*

Case study 3:

125. *Information on a member of the public impersonating clinicians to obtain CDs was shared by local lead CDAOs. In this case, a woman impersonated a nurse to access and illicitly divert CDs for pecuniary motives. Police were alerted, and the offender arrested and convicted following an investigation into their activity across local healthcare services.*
126. *During the incident, the local lead CDAO team were involved as was the local CDLO. Information was shared through the LIN, with organisations reminded of the importance of checking staff IDs when CDs are requested, following standard operating procedures, reporting suspicious activity and ensuring records and CD registers are kept up to date.*

To what extent the objective could be achieved in another way?

127. In order to investigate incidents in relation to the safe management and use of CDs, statutory powers are the only effective means to ensure there are no barriers to CDAOs carrying out their duties effectively. If the 2013 Regulations were to expire, reliance would fall to CQC and professional regulators to enter premises, investigate incidents concerning CDs and ensure the organisation's clinical governance and patient safety. These would be outwith regular inspections and require additional resource. Additionally, CQC and professional regulators are national bodies and do not have access to the local networks or local intelligence which is often needed to identify trends of inappropriate activity.

128. CDAOs are the only officers dedicated to investigating CD incidents and are uniquely qualified and connected to all bodies, including the police (CDLOs), involved in the safe management of controlled drugs. On this basis, the 2013 Regulations should not be allowed to expire and remain the best method for securing the safe management and use of CDs.

Section 5 - Impact and Economic Evaluation

129. This review provides quantitative estimates of the costs of the Regulations but not the benefits. Instead, a qualitative assessment is provided of the benefits based on a range of data sources. These are described below.

Costs of Regulations

130. For the 2013 Impact Assessment, a detailed assessment was made of CDAO working patterns and arrangements, including average salaries of staff performing these roles, FTE of working time and support staff. These were based on survey data collected for this exercise. An average cost of £36,102 per CDAO was estimated, with £10,892 attributed to the CDAO role and £25,210 for support staff. Because these remain the most detailed data on CDAO staffing and costs, we have used this original estimate and uprated it to allow for wage growth and inflation using the Office for Budget Responsibility (OBR) Average Earnings Index[7], giving an estimated average cost for 2019/20 of £41,517 (£36,102 x 1.15) per CDAO role. Further detail is given in Table 3.

Table 3 CDAO staffing costs - National Prescribing Centre survey of CDAOs 2012

CDAO and support staff	% CDAOs delegating tasks	% FTE dedicated to CDAO tasks	Mean FTE pay
CDAO	-	10.5%	£66,730
1st staff member	63.0%	48.8%	£46,900
2nd staff member	34.5%	30.9%	£42,600
3rd staff member	13.7%	33.8%	£38,900
4th staff member	6.3%	20.0%	£39,700
Total average CDAO costs[1]	-	-	£36,102
Uprated costs for 2019/20[2]	-	-	£41,517

Source: See the review methodology section for further description of these data.

1 Note that this figure includes 30% overheads added to support staff costs. It is not a weighted sum of the % delegating tasks, % FTE dedicated to role and salaries.

2 See paragraph 130 for details of calculation.

131. Applying this average CDAO cost of £41,517 per role to current numbers of CDAO posts described earlier in Table 2 gives a total cost of around £42m on CDAO staffing in England and Scotland (£41,517 per CDAO role x 1,016 CDAOs in England & Scotland). A breakdown is given in Table 4. This includes around £32m for non-NHS organisations and £10m for NHS organisations in England and Scotland.

Table 4 Total staffing costs of CDAOs in England and Scotland by sector

Sector	**England**	**Scotland**
NHS	£9.7m	£0.7m
Other	£30.5m	£1.3m
Total	£40.2m	£2.0m

132. However, these figures overstate the regulatory burden on business and any savings likely to be achieved if the Regulations were permitted to expire – as outlined in Table 1. As described in paragraph 22, if one in five organisations reduced their investment by half in the private sector, this would result in savings of just over £3m, although decreases in investment could lead to a potential increase in risk to patients. As described in more detail in paragraph 21, the savings from ceasing participation in LINs and ceasing reporting into national incident reporting systems would be likely to be low.

133. If a similar pattern of disinvestment occurred in the NHS, the savings would amount to £1m. However, we note that the disinvestment could be higher in the NHS if NHS Local Lead CDAO roles were discontinued altogether in the absence of the 2013 Regulations. This is due to their additional responsibilities, including work organising LINs and running national reporting systems. For example, the 2013 Impact Assessment estimated that the creation of new NHS Lead CDAO roles could cost up to £4m, although it acknowledged that this was likely to be an overestimate since some of the

roles would not be entirely new. Savings of between £1m and £4m therefore represent a range of realistic costs to the NHS.

134. The financial value of the exemption from appointing a CDAO for micro businesses and those granted an exemption in special circumstances is also likely to be less than the average CDAO cost of £41,517 per CDAO since all organisations concerned with the prescribing, supply, administration or disposal of controlled drugs must meet the requirements of relevant Misuse of Drugs legislation.

135. It is also acknowledged that there is wide variation across England in how local lead CDAO teams are funded and resourced, as well as variation across individual designated bodies in how they resource their nominated or appointed CDAO and in some cases associated team. Similarly, the level of delegation of CDAO responsibilities varies considerably across localities and organisations, and the prevalence and influence on resourcing of delegation has therefore not been considered as part of this review.

136. In discussing the resourcing of CDAO teams across England with a group of local lead CDAOs, it was flagged that in an ideal scenario each local lead CDAO team in England should have the necessary skill mix to allow local lead CDAOs the ability to flex the roles and responsibilities of staff depending on the local geography, knowledge of local issues and the number of healthcare organisations within their area. It was proposed that preferably a local lead CDAO team should comprise, at least, of a CDAO, a Controlled Drug Liaison Officer (CDLO), an investigatory team, a business analyst and administrative support.

Benefits of Regulations

Stakeholder views

137. When asked whether, overall, the 2013 Regulations have met their objective to “protect patient and public health” in relation to the safe management and use of CDs, 96 (75%) questionnaire respondents suggested they have met, or firmly met, the objective. 19 (15%) respondents suggested they have not met, or firmly not met, their objectives and 13 (10%) respondents had no view. For those of the view that the Regulations have not met or firmly not met, comments provided reflected that no system can ever entirely prevent intentional harm or misuse of CDs and that more could be done, particularly around opioid prescribing to reduce the harm to patients and the public.

138. Furthermore, 20 (35%) respondents indicated that the 2013 Regulations have led to decreased, or very decreased, levels of harm associated with the safe management and use of CDs. 15 (26%) indicated there had been no change since the introduction of the 2013 Regulations; 3 (5%) indicated there had been an increase in associated harm; and 20 (34%) indicated they were unsure of any change.

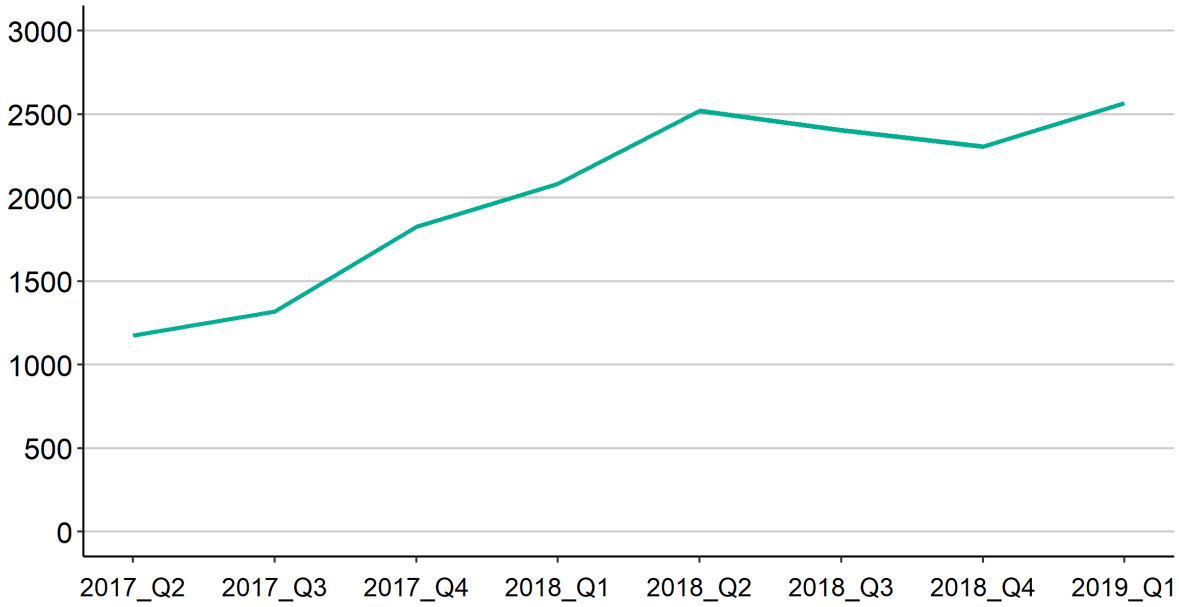
Reported patient safety incidents

139. In 2018/19, 9,793 CD incidents were reported via the NHSE CDAO reporting tool – see Figure 2. Although the level of reporting is still quite low, it is increasing over time. This is evidence of a culture of greater openness around CD incident reporting. This could be a positive sign, reflecting learning and improvement following any CD incidents.

140. We are have not drawn direct conclusions as to whether increased reporting has led to improvements in patient and public health. However, it is widely recognised that top performing health providers have higher levels of reporting of incidents and that higher reporting of incidents provides greater opportunity to learn and help prevent such incidents from reoccurring. Many respondents to the stakeholder survey also stated their view that the Regulations had led to increased or very increased learning from incidents (59% of respondents).

Figure 2 - Number of CD incidents reported via NHSE tool

England



Source: NHS England CD online reporting tool

141. Similarly, we have not used the incident report data to make inferences about changes in the underlying number of incidents or associated harm to patients. For example, NHS Improvement emphasise that the NRLS data is primarily collected and used for local learning from patient safety incidents, and the data is not comprehensive or reliable as a measure of the total number of incidents occurring. This is due to under-reporting, variations in perceptions of definitions and processes for reporting, and culture and awareness of patient safety. Consequently, it is not possible to evaluate the impact of the Regulations in reducing the prevalence of CD-related incidents and consequent harm to patients and costs.[89]

142. That said, there are some positive signs that the number of incidents, and associated harms to patients, have reduced since the 2013 Regulations were introduced. Comparing incidents reported to the NRLS in 2011 and 2018, the total number of reported incidents involving CDs increased from 16,287 to 25,040. However, this was driven by an increase in incidents that were rated as causing either “no harm” or “low harm”. In contrast, the number of incidents associated with “moderate harm” decreased from 571 to 345, the number associated with “severe harm” was 17 in both years, and the number connected with a death fell from 12 to 8. Although encouraging, these positive trends should not be over-interpreted. For example, the distinction between an incident that caused “low harm” (i.e. observation or first-aid only) versus “moderate harm” (i.e. additional healthcare) can be a matter of judgement and interpretation, so the reduction in incidents causing “moderate harm” could be due to changes in clinical judgement.[10] It is also worth restating that the NRLS does not generally capture incidents occurring in private healthcare settings

apart from some voluntary reporting. It is only NHS Trusts that are required to report to NRLS. Because of the complexity and limitations in these data, these have not been used to estimate the likely magnitude of any reduction in harm resulting from the Regulations.

Table 5 Patient safety incidents involving CDs reported in England to the National Learning and Reporting System (NRLS)[1]

Degree of Harm	2011		2018		Change in number of incidents
	number	%	number	%	
No harm	13,871	85.17	25,040	89.91	+11,169
Low harm	1,816	11.15	2,434	8.74	+618
Moderate harm	571	3.51	345	1.24	-226
Severe harm	17	0.10	17	0.06	0
Death	12	0.07	8	0.03	-4
Total	16,286	100.00	27,850	100.00	+11,564

1 https://improvement.nhs.uk/resources/national-quarterly-data-patient-safety-incident-reports/

2 Please note caveats surrounding these data. NRLS data does not, and cannot, provide the definitive number of patient safety incidents occurring in the NHS; it only measures the number that are reported. It largely excludes incidents occurring in private healthcare organisations.

Summary of Costs and Benefits

143. In summary, the annual costs of CDAO staffing are around £42m, of which £32m are in non-NHS organisations and £10m are in the NHS. However, much of the work performed by CDAOs and their support staff would need to continue in the absence of the Regulations. If for example, in the absence of the Regulations, a fifth of organisations reduced their investment in these activities by a half, the savings in staff costs would be around £4m (£3m in non-NHS organisations, £1m in the NHS).

144. The stakeholder survey provides strong support for the view that the Regulations have met their objective of protecting patient and public health. There are also positive signs from the overall improvement in reporting of incidents, alongside the decrease in the proportion of reported incidents resulting moderate to severe harm or death. However, for reasons explained in the review methodology section (Section 3), strong inferences cannot be drawn from these data. Finally, as summarised in Section 3, the case studies illustrate the real benefits of provisions in the regulations, such as enabling vital information to be shared on the dangers of incorrect administration of certain CDs such as fentanyl patches.

Section 6 - Recommendations

145. It is the overall recommendation of this review that the 2013 Regulations should not be allowed to expire on 31 March 2020. The evidence examined in this review demonstrates that they positively contribute towards achieving the policy intentions of protecting patients and the public from the harms associated with CDs, and helping to improve the governance, learning and co-operation associated with their use.

146. This review concludes that to let the safeguards in the 2013 Regulations expire would be a dereliction of duty of the Government to protect public and patient safety and harm public confidence in the healthcare system. 'Do nothing' is not considered a viable option. History has shown that voluntary measures cannot be relied on to prevent the events reported in the Shipman and Gosport Inquiries. The governance systems enshrined in the 2013 Regulations are still relevant and required to minimise the risk of harm to patients and the risk of illegal diversion of CDs.

147. The review also finds that the exemption for independent hospitals in England and Scotland with less than 10 members of staff, or bodies granted an exemption by the CQC or HIS, remains an appropriate approach to reducing the burden on businesses and recommends that it is maintained.

148. This review therefore finds that the current Government intervention remains the most appropriate way to achieve the original policy objectives. In order to maintain the 2013 Regulations, and in light of the urgency to amend the Regulations before the expiry date of 31 March 2020, it is recommended that a statutory instrument (SI) is laid to remove the statutory expiry clause from the 2013 Regulations. This SI should also update and make appropriate amendments to the definitions of the responsible bodies listed to reflect any updates made to names or functions of bodies since the 2013 Regulations came in to force. It is also recommended that this SI should insert a statutory review clause to comply with the Small Business, Enterprise and Employment Act 2015.

149. The evidence provided in this review indicates that there are some additional areas which warrant further consideration:
    - 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 governance system;
    - Following completion of the restructuring of 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 organisations of LINs;
    - Review and streamline as necessary the reporting of CD 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.
    - Review the level of awareness amongst CDAOs and other designated bodies regarding the GDPR exemption and legal cover provided by the 2013 Regulations to permit sharing on information to fulfil requirements of the statutory obligations of 2013 Regulations. Assess whether further action is required to increase awareness.

150. Should the 2013 Regulations be maintained these areas will be considered further and any proposed changes will be subject to further consultation. The impact of any changes will be assessed under the first statutory review of the Regulations (by March 2025).

Abbreviations

AIHO	Association of Independent Healthcare Organisations (now defunct)
CCG	Clinical Commissioning Group
CD	Controlled Drugs
CDAO	Controlled Drugs Accountable Officer
CDLO	Controlled Drugs Liaison Officer
CPPSG	Community Pharmacy Patient Safety Group
CQC	Care Quality Commission
DHSC	Department of Health and Social Care
DPSIMS	Development of the Patient Safety Incident Management System
ePACT	Electronic Prescribing and Analysis Costs Tool
GMC	General Medical Council
GPhC	General Pharmaceutical Council
HCPC	Health and Care Professions Council
HIS	Healthcare Improvement Scotland
HPS	Health Protection Scotland
HQIP	Healthcare Quality Improvement Partnership
ICS	Integrated Care System
IJB	Integrated Joint Board
LIN	Local Intelligence Network
MHRA	Medicines and Healthcare products Regulatory Agency
MoD	Ministry of Defence
MSO	Medication Safety Officer
NHS BSA	NHS Business Services Authority
NHSE-I	NHS England-NHS Improvement
NMS	Nursing and Midwifery Council
NRLS	National Reporting and Learning System
PCT	Primary Care Trust
PHE	Public Health England
PIR	Post Implementation Review
PRISMS	Prescribing Information System for Scotland
PSNC	Pharmaceutical Services Negotiating Committee
RPS	Royal Pharmaceutical Society
STP	Sustainability and Transformation Partnership
The 2006 Regulations	The Controlled Drugs (Supervision of Management and Use) Regulations 2006
The 2013 Regulations	The Controlled Drugs (Supervision and Management and Use) Regulations 2013

Annex A: Details of regulations

Regulatory Provisions: Definitions and Governance

151. The 2013 Regulations set out definitions and associated provisions in respect of the governance requirements of ensuring the safe and effective management and use of CDs. This includes the meaning of "English independent hospital", "Scottish independent hospital", "relevant persons", "responsible bodies" and "designated bodies" – all of which are outlined in further detail below. The 2013 Regulations also provide a requirement for designated bodies to appoint or nominate a CDAO for the purpose of securing the safe management and use of CDs, and a requirement for LINs to be set up and to cover the entire geography of England and Scotland – similarly outlined below.

English and Scottish Independent Hospitals

152. A body is determined to be an English or Scottish independent hospital if it runs a hospital in England/Scotland at or from which health care is provided to individuals and which is not a "health service hospital" within the meaning of the National Health Service Act 2006 and the National Health Service (Scotland) Act 1978. This is not the case however where fewer than 10 individuals work at the hospital or the body has requested, and been granted, a determination from the CQC/HIS that requiring the body to appoint or nominate a CDAO would give rise to disproportionate difficulties and they therefore are not required to do so.

Relevant Persons

153. An individual is determined to be a "relevant person" if they are a health care professional who provides health care services to patients on behalf of a local authority providing health services, or to private patients outside of an independent hospital, where doing so does or may involve activities relevant to the safe management and use of CDs. Furthermore, the determination applies to care home managers and people assisting them, and where an individual, not being a health care professional, is engaged with relevant activities carried on with or on behalf of a health care professional.

Designated Bodies

154. In England, a body is determined to be a "designated body" if it is regarded as:
    - an NHS Foundation Trust;
    - an NHS Trust;
    - an English independent hospital;
    - the NHS Commissioning Board (NHS England); or
    - the HQ in England of regular or reserve forces.

155. In Scotland, a body is determined to be a "designated body" if it is:
    - a Health Board;
    - a Scottish independent hospital;
    - the HQ in Scotland of regular or reserve forces; or
    - any of the following Special Health Boards –
        i. the Scottish Ambulance Service Board;
        ii. the National Waiting Times Centre Board; or
        iii. the State Hospitals Board for Scotland.

Responsible Bodies

156. A body is determined to be a "responsible body" if, in England or Scotland, it is:

- a regulatory body (as defined in the regulations);
- a local authority;
- a police force;
- a designated body; or
- a country-specific body, as named in the 2013 Regulations –
  i. in England –
     1. a clinical commissioning group (CCG),
     2. NHS Protect,
     3. Prescription Pricing Division of the NHS Business Services Authority (NHS BSA); or
     4. the Care Quality Commission.
  ii. in Scotland –
     1. the Scottish Counter Fraud Services,
     2. Common Services Agency (Information Services Division and Practitioner Services division),
     3. Healthcare Improvement Scotland; or
     4. the Care Inspectorate.

Regulatory Provisions: Controlled Drugs Accountable Officers

157. The 2013 Regulations require designated bodies to appoint and support a suitable CDAO, as outlined above. Designated bodies can "group together", and "share" a CDAO – although if this is the case all bodies must be in either England or Scotland.

158. Further to this, NHS England must appoint a suitable CDAO to lead each Local Intelligence Network (LIN) in England to share information and intelligence about the misuse and unsafe use of controlled drugs. The CDAO of each of the local Health Boards in Scotland must also lead a LIN for their area. The NHS England and Health Board CDAOs are described as local lead CDAOs in the 2013 Regulations, and NHS England local lead CDAOs can lead more than one LIN.

159. In order to qualify as a CDAO, several criteria must be met:

    a. the CDAO must be a senior manager of their respective designated body, or a senior manager of one of the jointly acting designated bodies if appropriate, or answerable to a senior manager who satisfies this condition;
    b. the CDAO must be an officer or employee of the designated body that appoints or nominates them, or one of the joint acting designated bodies if appropriate; and
    c. the CDAO does not, or does not exceptionally, prescribe, supply, administer or dispose of CDs as part of their duties as an officer or employee of their designated body, or one of the jointly acting designates bodies if appropriate.

160. In practice, the CDAO role is often an additional duty placed on the organisation's senior pharmacist or senior nursing officer. The regulations permit the CDAO to delegate some of the more day-to-day tasks to junior staff members but does not allow them to delegate responsibility.

161. The 2013 Regulations provide a requirement that designated bodies must provide their CDAO with funds and other resources necessary for enabling them to discharge their

responsibilities. These resources can include the use of information systems, accommodation and staff.

162. The 2013 Regulations also make it clear that some independent hospitals are exempt from the requirement to appoint a CDAO, as described above – i.e. if fewer than 10 individuals work at the independent hospital. Similarly, the CQC in England or HIS in Scotland can determine that requiring an organisation or body to appoint or nominate a CDAO would give rise to difficulties that would be disproportionate to the benefits to be derived from such an appointment or nomination and they therefore do not have to do so.

163. Additionally, the 2013 Regulations outline the requirement for the CQC and HIS to compile, maintain and publish from time to time, in such manner as it sees fit, a register of CDAOs of designated bodies in England[11] and Scotland[12]. This is supported by the requirement for each designated body in England and Scotland to appoint a CDAO and register that person's details with the CQC/HIS and notify of any change.

Regulatory Provisions: Information Sharing and Incident Reporting

164. The 2013 Regulations outline the requirement for LINs to be established and operated by NHS England and the Health Boards in England and Scotland, respectively. The aim of LINs is to facilitate co-operation and information sharing between responsible bodies, which include designated bodies, in the area as regards the safe and effective management and use of CDs and local cases or issues relating to this. The 2013 Regulations leave it to the discretion of the local CDAO as to how each LIN is operated.

165. LIN members, largely made up of representatives of responsible bodies, are required to co-operate with other members on issues relating to the identification of cases in which action may need to be taken, the consideration of issues relating to taking action, and the actual taking of action in respect to matters arising in relation to the management or use of CDs by individuals who are relevant persons as regards any member of the LIN.

166. Furthermore, the 2013 Regulations provide the power for local lead CDAOs, who operate and run LINs, to request periodic declarations and self-assessments from providers of medical, dental, nursing and midwifery services in the area, as regards their use and management of CDs. Local lead CDAOs can also request occurrence reports, on a quarterly basis or more frequently if warranted, that provide information relating to the concerns of the CDAO of a designated body in relation to the safe management and use of CDs by a relevant individual - or the absence of such concerns.

Regulatory Provisions: Ancillary Matters

167. The final part of the 2013 Regulations covers ancillary matters, such as further CD declaration requirements and information management provisions. In order to facilitate the auditing and investigation obligations of CDAOs, the 2013 Regulations also provide powers to CDAOs to enter "relevant premises" for the purpose of securing the safe, appropriate and effective management and use of CDs. These "relevant premises", in England and Scotland, include (subject to inspection by the relevant CDAO) premises of:

- In England –
    i. relevant persons, as regards NHS England, that are not subject to inspection by the CQC, the GPhC or a CDAO of a regular or reserve force;
    ii. an NHS foundation Trust;

iii. an NHS Trust;

iv. a regular or reserve force, or of members of that regular or reserve force; and

v. an English independent hospital and premises of a person engaged in relevant activities on the hospital's behalf.

- In Scotland –
  i. a Health Board;
  ii. any person or undertaking from which that person or undertaking provides a Health Board with services as part of the health service;
  iii. relevant persons, in the area of a Health Board, that are not subject to inspection by HIS, the Care Inspectorate or the GPhC;
  iv. of a regular or reserve force, or of members of that regular or reserve force;
  v. a Special Health Board, as previously referenced in this report; and
  vi. a Scottish independent hospital and premises of a person engaged in relevant activities on the hospital's behalf.

Annex B: List of stakeholders consulted

168. Discussions were held with key English groups/bodies who have an interest in the 2013 Regulations. These include:

- Association of Independent Healthcare Organisations (AIHO)
- Controlled Drug Liaison Officers
- NHS England
- NHS England - health and justice commissioning
- NHS England local lead CDAO group
- The CQC
- The Chief Pharmaceutical Officer for England
- The General Pharmaceutical Council
- The Home Office
- The Ministry of Defence (MoD)
- The Pharmaceutical Services Negotiating Committee (PSNC)

169. Officials in the Scottish Government also approached key Scottish groups/bodies with an interest in the 2013 Regulations:

- Health Boards
- HIS
- Care Inspectorate
- Royal Colleges
- Allied Health Professionals
- Scottish Independent Care Sector
- CDAO Group
- Scottish Ambulance Service
- Police Scotland

Annex C: Questionnaire distributed to key stakeholders and summary of responses

Questions inviting respondents to elaborate on answers are not summarised. In total,128 individuals completed the questionnaire in an individual capacity or on behalf of their organisation. Some sections were designed to be completed only by local lead CDAOs (n = 15), or by CDAOs (n = 43).

What is your name?

What is your email address?

What is your job title?

If you are responding on behalf of an organisation, what is that organisation's name?

In what context are you responding to this questionnaire? (n = 128)

	Number	%
As or on behalf of a "local lead" CDAO	15	11.7
As a CDAO	43	33.6
As a health and social care professional	32	25.0
On behalf of an organisation	28	21.9
Other	10	7.8

Which of the following best describes where you work?

Sector	Number	%
Ambulance Service	3	2.3
Care Home	1	0.8
Clinic (e.g. In Vitro Fertilisation)	2	1.6
CCG	11	8.6
Community Pharmacy	3	2.3
General Practice	2	1.6
Hospice	14	11.0
Independent Hospital (including Hospital Pharmacy)	17	13.3
NHS England	10	7.8
NHS Hospital (including Hospital Pharmacy)	29	22.7
Police Force or similar	7	5.5
Prison Healthcare	4	3.1
Professional/Representative Body	3	2.3
Regulatory Body	3	2.3
Scottish Health Board	1	0.8
Substance Misuse Organisation	4	3.1

Other	14	10.9

How many employees are there in your organisation?
(Please include all branches and subsidiaries)

	Number	%
Less than 10 (inclusive)	4	3.1
Between 11 and 49	8	6.2
Between 50 and 249	33	25.8
More than 250	71	55.5
Not applicable	9	7.0
I don't know	3	2.3

Who is your primary regulator, or who primarily regulates your organisation?

Sector	Number	%
Care Quality Commission (CQC)	73	57.0
General Pharmaceutical Council (GPhC)	12	9.4
Health and Care Professions Council (HCPC)	1	0.8
Healthcare Improvement Scotland (HIS)	2	1.6
Home Office (HO)	5	3.9
Other	22	17.2
I don't know	2	1.6
Not applicable	11	8.6

Which country do you work in?

	Number	%
England	120	93.8
Scotland	8	6.2

Section 1 - Controlled Drugs

Does your organisation interact with (e.g. hold/supply/manage) controlled drugs?

	Number	%
Yes	98	76.6
No	29	22.7
I don’t know	1	0.8

Do you work in an independent hospital that is exempt from the Regulations, due to having fewer than 10 individuals working at the hospital or through a determination of exemption?

	Number	%
Yes	2	1.6
No	123	96.1
I don’t know	3	2.3

Section 2 – Definitions and Governance

Are there any changes/amendments required to the definitions of "English and Scottish independent hospitals" in the 2013 Regulations?

	Number	%
Yes	21	16.4
No	66	51.6
No view	41	32.0

Are there any changes/amendments required to the definition of "relevant persons" currently outlined in in the 2013 Regulations?

	Number	%
Yes	19	14.8
No	88	68.8
No view	21	16.4

Are there any changes/amendments required to the definition of "designated bodies" currently outlined in the 2013 Regulations? Should any bodies be added or removed?

	Number	%
Yes	30	23.4
No	70	54.7
No view	28	21.9

Are there any changes/amendments required to the definition of "responsible bodies" currently outlined in the 2013 Regulations? Should any bodies be added or removed?

	Number	%
Yes	14	10.9
No	85	66.4

No view	29	22.7

We are aware that some new ways of working may now mean that not all appropriate health care models fall under the 2013 Regulation's definition of "designated bodies". What new ways of working do you think should be defined by the 2013 Regulations but currently are not?

Section 3 – The CDAO role

Does it remain appropriate for each designated body to nominate or appoint, or in a group with one or more other designated bodies jointly nominate or appoint, a fit, proper and suitably experienced person to be its CDAO?

	Number	%
Yes	119	93.0
No	5	3.9
No view	4	3.1

Do the duties of a CDAO, as outlined above, remain appropriate?

	Number	%
Yes	115	89.8
No	10	7.8
No view	3	2.3

Does it remain appropriate for CQC/HIS to compile, maintain and publish national registers of CDAOs?

	Number	%
Yes	116	90.6
No	4	3.1
No view	8	6.2

Are there any specific requirements in or omissions from the 2013 Regulations that limit your capacity to act as a CDAO and warrant further consideration? [CDAOs only]

	Number	%
Yes	15	25.9
No	39	67.2
No view	4	6.9

Are there any specific requirements in the 2013 Regulations that you feel are too onerous or unnecessary in your capacity to as a CDAO and warrant further consideration? [CDAOs only]

	Number	%
Yes	14	24.1
No	37	63.8
No view	7	12.1

Section 4 – Information Sharing (Local Lead CDAO only)

On average, how many LINs do you host a year? (local lead CDAOs only, n = 15)

	Number
1	2
2	3
3	3
4	3
5+	4

Do you feel this number is sufficient? (local lead CDAOs only, n = 15)

	Number
Yes	12
No	0
No view	3

How helpful do you think LINs are in regard to securing the safe management and use of controlled drugs? (local lead CDAOs only, n = 15)

	Number
Very helpful	5
Helpful	7
Neither helpful or unhelpful	1
Unhelpful	0
Very unhelpful	2

Do you think that LINs promote co-operation and information sharing between members, and learning from when things go wrong? (local lead CDAOs only, n = 15)

	Number
Yes	14
No	1
No view	0

Do you think that LINs provide sufficient access to information you would otherwise be unable to obtain / are an effective method of sharing information on the wider use and diversion of controlled drugs in the area? (local lead CDAOs only, n = 15)

	Number
Yes	11
No	3
No view	1

Do you think there are barriers that restrict the overall effectiveness of LINs? (local lead CDAOs only, n = 15)

	Number
Yes	8
No	5
No view	2

Do you think there are any organisations that are not currently included in LINs who would be useful to include? (local lead CDAOs only, n = 15)

	Number
Yes	10
No	3
No view	2

Have you ever experienced difficulties accessing information you feel you should have access to, when investigating when things go wrong? (local lead CDAOs only, n = 15)

	Number
Yes	6
No	7
No view	2

Section 5 – Information Sharing (CDAO)

Do you, or your organisation, attend Local Intelligence Networks (LINs)? (CDAOs only, n = 43)

	Number
Yes	42
No	1
I don't know	0

How many LINs do you, or your organisation, attend on average a year? (CDAOs only, n = 43)

	Number
1	2
2	18
3	10
4	8
5+	5

Do you feel this number is sufficient? (CDAOs only, n = 43)

	Number
Yes	38
No	3
I don't know	2

How helpful do you think LINs are in regard to securing the safe management and use of controlled drugs? (CDAOs only, n = 43)

	Number
Very helpful	15
Helpful	21
Neither helpful or unhelpful	5
Unhelpful	1
Very unhelpful	1

Do you think that LINs promote co-operation and information sharing between members, and learning from when things go wrong? (CDAOs only, n = 43)

	Number
Yes	40
No	2
No view	1

Do you think that LINs provide sufficient access to information you would otherwise be unable to obtain / are an effective method of sharing information on the wider use and diversion of controlled drugs in the area? (CDAOs only, n = 43)

	Number
Yes	36
No	5
No view	2

Do you think there are barriers that restrict the overall effectiveness of LINs? (CDAOs only, n = 43)

	Number
Yes	19
No	22
No view	2

Do you think there are any organisations that are not currently included in LINs who would be useful to include? (CDAOs only, n = 43)

	Number
Yes	2
No	25
No view	16

Have you ever experienced difficulties accessing information you feel you should have access to, when investigating when things go wrong? (CDAOs only, n = 43)

	Number
Yes	4
No	39
No view	0

Section 6 – Controlled Drugs Incident Reporting (Local Lead CDAOs only)

Do all controlled drugs incidents occurring in your LIN area get reported to you? (local lead CDAOs only, n = 15)

	Number
Yes	6
No	9

Does it remain appropriate to request quarterly controlled drugs occurrence reports from members of your LIN? (local lead CDAOs only, n = 15)

	Number
Yes	6
No	3
I don’t know	6

Does it remain appropriate to request periodic declarations and self-assessments from members of your LIN? (local lead CDAOs only, n = 15)

	Number
Yes	11
No	2
I don’t know	2

In your opinion, to what extent have the 2013 Regulations contributed to increased reporting of controlled drugs incidences? [Scale] (local lead CDAOs only, n = 15)

	Number
Very decreased reporting	0
Decreased reporting	1
No change	0
Increased reporting	7
Very increased reporting	4
I don’t know	3

In your opinion, to what extent have the 2013 Regulations contributed to the sharing of information and increasing the learning from controlled drugs incidences? [Scale] (local lead CDAOs only, n = 15)

	Number
Very decreased sharing and learning	0
Decreased sharing and learning	0
No change	1
Increased sharing and learning	6
Very increased sharing and learning	6
I don’t know	2

In your opinion, to what extent have the 2013 Regulations contributed to decreasing the level of harm associated with controlled drugs incidences? [Scale] (local lead CDAOs only, n = 15)

	Number
Very decreased level of harm	1
Decreased level of harm	7
No change	1
Increased level of harm	2
Very increased level of harm	0
I don't know	4

In your opinion, has there been an overall increase in the awareness of the requirements for the safe management and use of controlled drugs since the introduction of the Regulations in 2013? [Scale] (local lead CDAOs only, n = 15)

	Number
Very decreased awareness	0
Decreased awareness	0
No change	0
Increased awareness	9
Very increased awareness	2
I don't know	1

Beyond data regarding controlled drugs incidence/occurrence reporting, is there any of other data or evidence that you know of that could help inform our review of the 2013 Regulations? (local lead CDAOs only, n = 15)

	Number
Yes	8
No	7

Section 7 – Controlled Drugs Incident Reporting (CDAO)

How do you, or your organisation, report any controlled drugs incidents? (CDAOs only, n = 43)

Please tick all that apply.

	Number
Direct to Police Force / Controlled Drugs Liaison Officer	20
Direct to your chief pharmacist	25
Direct to your clinical leadership	22
Direct to your "local lead" CDAO	31
Direct to your Medication Safety Officer	11
Direct to your professional Regulator	15
Via the CD Incident Reporting Tool (www.cdreporting.co.uk)	18
Via a Datix reporting system	21
Via the National Reporting and Learning System (NRLS)	12
Other	13

Have you encountered any issues with the reporting of controlled drugs incidents to your "local lead" CDAO? (CDAOs only, n = 43)

	Number
Yes	3
No	40

Does it remain appropriate to provide a quarterly controlled drugs occurrence report to your "local lead" CDAO? (CDAOs only, n = 43)

	Number
Yes	30
No	9
I don't know	4

Does it remain appropriate to provide periodic declarations and/or self-assessments to CQC, HIS, the Care Inspectorate or the General Pharmaceutical Council at their request? (CDAOs only, n = 43)

	Number
Yes	31
No	3
I don't know	9

In your opinion, have the 2013 Regulations contributed to your reporting of controlled drugs incidences? (CDAOs only, n = 43)

	Number
Very decreased reporting	0
Decreased reporting	1
No change	26
Increased reporting	8
Very increased reporting	6
I don't know	2

In your opinion, have the 2013 Regulations contributed to increasing your learning from controlled drugs incidences? (CDAOs only, n = 43)

	Number
Very decreased learning	0
Decreased learning	0
No change	20
Increased learning	16
Very increased learned	6
I don't know	1

In your opinion, have the 2013 Regulations contributed to reducing the level of harm associated with controlled drugs incidences? (CDAOs only, n = 43)

	Number
Very decreased level of harm	0
Decreased level of harm	12
No change	14
Increased level of harm	1
Very increased level of harm	0
I don't know	16

In your opinion, has there been an overall increase in the awareness of the requirements for the safe management and use of controlled drugs since the introduction of the Regulations in 2013? (CDAOs only, n = 43)

	Number
Very decreased awareness	0
Decreased awareness	0
No change	12
Increased awareness	21
Very increased awareness	8
I don't know	2

Beyond data regarding controlled drugs incidence/occurrence reporting, is there any of other data or evidence that you know of that could help inform our review of the 2013 Regulations? (CDAOs only, n = 43)

	Number
Yes	8
No	35

Section 8 – Auditing and Investigations

Do the 2013 Regulations give CDAOs adequate powers to investigate, and take prompt and effective action where appropriate, when concerns are raised about the safe management and use of controlled drugs?

	Number	%
Yes	101	78.9
No	13	10.2
I don’t know	14	10.9

Do the “relevant premises” of the 2013 Regulations, outlined above, remain appropriate?

	Number	%
Yes	82	64.1
No	26	20.3
I don’t know	20	15.6

Section 9 – Objectives of the 2013 Regulations

To what extent do you think the 2013 Regulations have met their objective to “maintain and, where possible, improve the system of good governance concerning the safe management and use of controlled drugs” in relation to the safe management and use of controlled drugs?

	Number	%
Have firmly met	24	18.8
Have met	89	69.5
Have not met	4	3.1
Have firmly not met	2	1.6
No view	9	7.0

To what extent do you think the 2013 Regulations have met their objective to “protect patient and public health” in relation to the safe management and use of controlled drugs?

	Number	%
Have firmly met	22	17.2
Have met	74	57.8
Have not met	14	10.9
Have firmly not met	5	3.9
No view	13	10.2

To what extent do you think the 2013 Regulations have met their objective to “promote co-operation and information sharing between different local bodies and organisations” in relation to the safe management and use of controlled drugs?

	Number	%
Have firmly met	43	33.6

Have met	64	50.0
Have not met	12	9.4
Have firmly not met	2	1.6
No view	7	5.5

To what extent do you think the 2013 Regulations have met their objective to “enable effective mechanisms to monitor and audit the use of controlled drugs” in relation to the safe management and use of controlled drugs?

	Number	%
Have firmly met	21	16.4
Have met	75	58.6
Have not met	18	14.1
Have firmly not met	7	5.5
No view	7	5.5

To what extent do you think the 2013 Regulations have met their objective to “enable adequate powers to investigate, and take prompt and effective action where appropriate, when concerns are raised” in relation to the safe management and use of controlled drugs?

	Number	%
Have firmly met	26	20.3
Have met	77	60.2
Have not met	10	7.8
Have firmly not met	4	3.1
No view	11	8.6

How appropriate overall do you think the 2013 Regulations remain?

	Number	%
Very inappropriate	5	3.9
Inappropriate	7	5.5
Appropriate	74	57.8
Very appropriate	38	29.7
No view	4	3.1

How effective overall do you think the 2013 Regulations have been in meeting the five primary policy objectives outlined above?

	Number	%
Very ineffective	2	1.6
Ineffective	9	7.0
Effective	78	60.9
Very effective	28	21.9
No view	11	8.6

Do you think there have been any unintended consequences of the 2013 Regulations?

	Number	%
Yes	21	16.4
No	58	45.3
No view	49	38.3

Do you think the objectives of the 2013 Regulations could be achieved in another way which involves less onerous regulatory provision?

	Number	%
Yes	11	8.6
No	85	66.4
I don’t know	32	25.0

In your opinion, should the 2013 Regulations be replaced with similar measures when they cease to have effect in March 2020?

	Number	%
Yes	106	82.8
No	13	10.2
I don’t know	9	7.0

If the 2013 Regulations are not replaced with similar measures, what effect would this have?

Annex D: List of organisations which responded to the on-line questionnaire

Advisory Council on the Misuse of Drugs
Barts Health NHS Trust
BMI Healthcare
Bridgewater Community Healthcare NHS Foundation Trust
Central and North WestNorth-West London NHS Foundation Trust
Change Grow Live
Compton Care
Cornwall Foundation Trust
Country Durham and Darlington NHS Foundation Trust
Dispensing Doctors' Association
Edinburgh Marie Curie Hospice
Ellern Mede Ridgeway (Oak Tree Forest Limited)
Greater Manchester Health and Social Care Partnership
General Pharmaceutical Council
Guys & St Thomas's NHS Foundation Trust
Hospiscare
John Taylor Hospice
Lancashire Care NHS Foundation Trust
Leeds Community Healthcare NHS Trust
Livingstone House
London Centre for Aesthetic Surgery
Mastercall Healthcare
Mount Stuart Hospital
NHS Basildon and Brentwood CCG
NHS Bath and North East Somerset CCG
NHS Camden CCG
NHS East and North Hertfordshire CCG
NHS England
NHS England – Central Midlands
NHS England – Cumbria and North East
NHS England - (Health and Justice commissioning)
NHS Fylde and Wyre CCG
NHS Southampton City CCG
NHS Southern Derbyshire CCG
NHS Swale CCG
NHS Thurrock CCG
NHS West Kent CCG
Nightingale Hospital
North East Ambulance Service NHS Foundation Trust
Nottingham University Hospitals NHS Trust
Nottinghamshire Police
Queenscourt Hospice
Rowlands Pharmacy
Royal National Orthopaedic Hospital NHS Trust
Saint Francis Hospice
Scottish Controlled Drugs Accountable Officers' Network
South Central Ambulance Service NHS Foundation Trust
South West London and St George's NHS Trust
South Western Ambulance Service NHS Foundation Trust
Spectrum Community Health
Spire Bushey Hospital
Spire Little Aston Hospital
St Catherine's Hospice
St Oswald's Hospice
Suffolk Constabulary
Swanswell
Trinity Hospice and Palliative Care Services
Virgin Care
Vocare
West Midlands Police
West Yorkshire Police
Woodlands Hospice

Annex E: Controlled drugs prescribing and incident reporting

Prescribing

170. There are a range of factors other than the Regulations that affect levels of prescribing of CDs. Prescribing of CDs in England and Scotland has remained stable between 2014 and 2018. Increased licensing and availability of CDs for a range of conditions and for patients with more complex health needs has been balanced against a drive to reduce prescribing of CDs and other potentially dangerous and/or addictive medicines.

171. Following reports of overprescribing of opioids leading to dependence and deaths in the USA, levels of opioid prescribing are now being monitored more closely, by CDAOs, clinical commissioning groups and providers. A range of organisations are developing tools and guidance to support prescribers to promote best practice and reduce overprescribing and dependence on CDs.

172. For example, work has been undertaken by CDAOs and the CQC to inform prescribers of the potential dangers associated with CD prescribing and use - encouraging prescribers to consider alternative medicines. Public Health England has undertaken a review of the scale and distribution of prescription drug dependence and withdrawal, and the Medicines and Healthcare products Regulatory Agency (MHRA) has initiated a review of the benefits and risks of opioid medicines, including dependence and addiction. The NHS England East of England CDAO network has developed PrescQIPP, a prescribing support resources, metrics and tool to support providers review and tackle high dose opioid prescribing.

173. Tables 6 and 7 show the number of prescribed CDs dispensed by community pharmacies in England and Scotland each year from 2014 to 2018. In England, the number decreased slightly from 63.9m to 61.3m, whereas in Scotland it increased slightly from 7.8m to 8.5m. This is in the context of over a billion items prescribed annually in England[13], and just over 100m prescribed in Scotland[14], with only small increases in prescribing since 2014 (annual increases ranging from 0 to 1.8%).

174. In England, prescribing of more tightly controlled Schedule 2 and 3 medicines such as morphine, buprenorphine and temazepam, has decreased from 21.7m to 20.5m, a decrease of around 6%. In contrast, prescribing of Schedule 2 and 3 medicines has increased in Scotland between 2014 and 2015 from 2.2m to 2.7m, an increase of nearly a fifth, but then stabilised. These trends cannot be used to evaluate the success or not of the Regulations in ensuring safe and appropriate prescribing of CDs, since levels of prescribing are also affected by the increase in the licensing, availability of CDs and changing patient populations.

Table 6 Number of controlled drugs dispensed by community pharmacies in England

Millions of items

Year	Schedule 2/3	Schedule 4/5	Total
2014	21.7	42.3	63.9
2015	21.5	42.4	64.0
2016	21.6	42.4	64.0
2017	21.1	41.6	62.8
2018	20.5	40.7	61.3

Sources: NHS BSA Information Services Data Warehouse.

Table 7 Number of controlled drugs dispensed by community pharmacies in Scotland

Millions of items

Year	Schedule 2/3	Schedule 4/5	Total
2014	2.2	5.7	7.8
2015	2.7	6.0	8.7
2016	2.7	6.0	8.7
2017	2.7	6.0	8.6
2018	2.6	5.9	8.5

Sources: NHS Scotland's ISD.

175. The vast majority of CDs dispensed by community pharmacies are prescribed by GPs; accounting for around 95% of prescribed items in England. Amounts of prescribing by non-medical prescribers, including nurses, pharmacists and paramedics, remain low but have increased between 2014 and 2018 from around 1.5% to 3.5% of prescribed items. Similarly, there has been an increase in prescribing of CDs by nurses in Scotland, although the rate also remains very low at around 1.5% of prescribed items.

176. The presented increase in CD prescribing by non-medical prescribers in England and Scotland is a result of work undertaken within the healthcare sector to utilise the healthcare workforce more effectively and efficiently. Through affording powers to healthcare professionals such as nurses and pharmacists, as well as others such as podiatrists and radiographers and paramedics, to prescribe medicines, there are great benefits that can be attained. There are also potential risks, although work has been undertaken by the healthcare regulators and wider to ensure these are mitigated as fully as possible. This includes the setting of professional standards and competency frameworks, such as those produced by the Royal Pharmaceutical Society[15], and the introduction and use of clinical governance and risk management strategies.

Additional information on reported incidents involving Controlled Drugs

177. Systems to report CD incidents and concerns play an important role in facilitating learning and good practice in the management and use of CDs. They allow CDAOs and local lead CDAOs to have oversight of the number and type of CD incidents occurring in their locality. The 2013 Regulations mandate the reporting of CD incidents and

concerns to a relevant local lead CDAO. As such, a CDAO is statutorily required to report CD incidents and occurrences to their local lead CDAO.

178. Table 8 and 9 describe the types and severity of incidents reported via the NHS England CDAO tool. The most common category was patient related (e.g. wrong dose or wrong medicine administered or dispensed) (35.1%), with 13 (0.1%) indicating that a death has occurred, although not necessarily linked to the CD incident.

Table 8 Number of CD incidents reported to the NHS England online CD reporting tool in 2018, by category of incident.

Category	Number	%
Patient Related	3,439	35.1%
Unaccounted for losses	2,648	27.0%
Record Keeping	1,091	11.1%
Accounted for losses	920	9.4%
Patient and the public	742	7.6%
Governance	596	6.1%
Professional individuals of concern	170	1.7%
Death	13	0.1%
No Category	174	1.8%
Total	9,793	100.0%

Source: NHS England online CD reporting tool

179. The online tool also helps CDAOs to standardise the level of risk and determine the level of harm and likelihood of reoccurrence to help identify any system failures and enable effective learning. Over half of incidents were categorised as no or low risk and just 9 (0.1%) were categorised as extreme risk (Table 9 below) (extreme typically meaning a death has occurred - although not all deaths are due to the CD incident).

Table 9 Number of CD incidents reported to the NHS England online CD reporting tool in 2018, broken down by category of incident.

Level of risk	Number	%
No Risk	50	0.5%
Low	4,640	47.4%
Moderate	3,092	31.6%
High	2,002	20.4%
Extreme	9	0.1%
Total	9,793	100.0%

Source: NHS England online CD reporting tool

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