Title:	Impact Assessment (IA)
Controlled Drug Accountable Officers and "The Controlled Drugs (Supervision of Management and Use) Regulations 2006"	**Date:** 15/01/2013
IA No: 6077	**Stage:** Final
Lead department or agency: Department of Health	**Source of intervention:** Domestic
Other departments or agencies:	**Type of measure:** Secondary legislation
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Summary: Intervention and Options

RPC Opinion: Green

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£48.3m	£0m	£0m	Yes	Zero Net Cost

What is the problem under consideration? Why is government intervention necessary?

Controlled drugs (CDs) are essential to modern healthcare but have the potential for misuse or diversion, which gained national notoriety because of the activities of Harold Shipman. The Fourth Shipman Inquiry (2004) recommended strengthening the arrangements for the management of CDs. The function of CD Accountable Officers (AO) was established under the Health Act 2006, including for NHS Primary Care Trusts (PCTs). Under the Health and Social Care Act 2012, PCTs will cease to exist from April 2013. Therefore, a decision has to be made before then as to whether the PCT AO functions continue afterwards, and, if so, how best they can be delivered in order to minimise CD diversion and misuse.

What are the policy objectives and the intended effects?

The policy objectives are to (a) maintain and, where possible, improve the system of good governance concerning the safe management and use of controlled drugs; (b) to protect patient and public health; (c) to promote co-operation and information sharing between different local bodies and organisations; (d) to enable effective mechanisms to monitor and audit the use of controlled drugs; and (e) to enable adequate powers to investigate, and to take prompt and effective action where appropriate, when concerns are raised. The intended effect is to prevent increase in patient harm and criminal diversion and misuse of controlled drugs, while keeping the regulatory burden to a minimum.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing – rely on voluntary compliance;
Option 4.1: Require compliance through regulation, with the current PCT roles located in the NHS Commissioning Board;
Option 4.2: Require compliance through regulation, with the current PCT roles located in the Clinical Commissioning Groups

Option 4.1 is the preferred option. It meets all policy objectives and delivers highest Net Present Value, as evaluated against the do-nothing scenario. The underlying assumptions used in calculating the benefits (avoided patient harm) and costs (additional AO roles) are considered to be prudent and are shown to be robust in the sensitivity analysis.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 04/2018

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded: N/A**	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: ***Earl Howe*** Date: ***21st January 2013***

Summary: Analysis & Evidence

Policy Option 4.1

Description: Require compliance through regulation, with the current PCT roles located in the NHS Commissioning Board

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: 48.3**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		3.87	**33.18**

Description and scale of key monetised costs by 'main affected groups'

Main cost of average £3.87m per annum (£33.18m 10-year NPV) accrues to NHS Commissioning Board, where the current PCT Controlled Drug Accountable Officer functions would be located.
This can be broken down into the average annual cost of the Accountable Officer at £1.17m per annum, and the cost of support staff, estimated at £2.70m per annum.

Other key non-monetised costs by 'main affected groups'

Continuation of good CD management can lead to a possible initial increase in acquisitive crime (resulting from prevented worsening of CD management). This effect has not been quantified. Over time, good CD management should reduce the total number of people with a drug misuse problem. As a result, the initial increase in acquisitive crime should reverse over time as the total number of drug users decreases.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		8.83	**81.49**

Description and scale of key monetised benefits by 'main affected groups'

The main monetised benefits accrue to patients in the form of avoided increase in negative health outcomes related to improper CD management and use, which can be mitigated by the actions of CD Accountable Officers. The health benefits are estimated at average £8.47m per annum with additional £0.35m per annum in saved NHS treatment costs.

Other key non-monetised benefits by 'main affected groups'

Benefits stemming from reduced probability and faster detection of any wilful patient harm resulting from criminal CD diversion.
Reduction in criminal activity, social cost of crime and NHS treatment costs resulting from fewer people, including healthcare professionals, developing drug addictions.
Saved costs of not having to create AO posts in small organisations currently overseen by PCT CDAOs.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

A discount rate of 1.5% is used for direct health (QALY) impacts. Health impacts are based on EQ5D, NHS reference costs and literature-based assumptions, thus they present a subjective assessment. It is assumed that the NHS Commissioning Board will create 100 Accountable Officer roles to deliver the current PCT functions. Improvement of patient health outcomes, when set against the do-nothing, has been assumed to equal 5% of current Patient Safety Incidents.

BUSINESS ASSESSMENT (Option 4.1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	Yes	Zero net cost

Summary: Analysis & Evidence

Policy Option 4.2

Description: Require compliance through regulation, with the current PCT roles located in the Clinical Commissioning Groups

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: 11.2**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		8.21	**70.33**

Description and scale of key monetised costs by 'main affected groups'

Main cost of average £8.21m per annum (£70.33m 10-year NPV) accrues to NHS Clinical Commissioning Groups, where the current PCT Controlled Drug Accountable Officer functions would be located.
This can be broken down into the average annual cost of the Accountable Officer at £2.48m per annum, and the cost of support staff, estimated at £5.73m per annum.

Other key non-monetised costs by 'main affected groups'

Continuation of good CD management can lead to a possible initial increase in acquisitive crime (resulting from prevented worsening of CD management). This effect has not been quantified. Over time, good CD management should reduce the total number of people with a drug misuse problem. As a result, the initial increase in acquisitive crime should reverse over time as the total number of drug users decreases.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		8.83	**81.49**

Description and scale of key monetised benefits by 'main affected groups'

The main monetised benefits accrue to patients in the form of avoided increase in negative health outcomes related to improper CD management and use, which can be mitigated by the actions of CD Accountable Officers. The health benefits are estimated at average £8.47m per annum with additional £0.35m per annum in saved NHS treatment costs.

Other key non-monetised benefits by 'main affected groups'

Benefits stemming from reduced probability and faster detection of any wilful patient harm resulting from criminal CD diversion.
Reduction in criminal activity, social cost of crime and NHS treatment costs resulting from fewer people, including healthcare professionals, developing drug addictions.
Saved costs of not having to create AO posts in small organisations currently overseen by PCT CDAOs.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

A discount rate of 1.5% is used for direct health (QALY) impacts. Health impacts are based on EQ5D, NHS reference costs and literature-based assumptions, thus they present a subjective assessment. It is assumed that the NHS Clinical Commissioning Groups will create 212 Accountable Officer roles to deliver the current PCT functions. Improvement of patient health outcomes, when set against the do-nothing, has been assumed to equal 5% of current Patient Safety Incidents.

BUSINESS ASSESSMENT (Option 4.2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	Yes	Zero net cost

Evidence base (for summary sheets)

A. Policy background

A.1. General

1. Controlled drugs (CDs) are an essential part of modern healthcare but have the 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).
2. CDs are controlled under Home Office legislation - the Misuse of Drugs Act 1971. Access to CDs for healthcare is regulated under the Misuse of Drugs Regulations (MDR) 2001. The main purpose of the Act is to prevent the misuse of CDs. It does so by imposing a complete ban on the unlawful possession, supply and manufacture of CDs. The MDR further govern the legitimate clinical use of CDs. They divide CDs into five Schedules according to the level of control they need. Schedule 1 CDs have the strictest controls while Schedule 5 CDs have the least stringent controls.
3. CDs include medicines such as morphine and diamorphine and are used in a wide variety of clinical treatments e.g. for the relief of acute and chronic pain, end-of-life treatments or the treatment of substance misuse. Other medicines such as anxiolytics, sleeping pills, steroids and growth hormones are also designated CDs, albeit these are subject to less stringent controls.
4. The potential for criminal misuse of CDs gained national notoriety during the late 1990s because of the activities of Doctor Harold Shipman.

A.2. The Shipman Inquiry

5. Chaired by Lady Justice Janet Smith, a High Court judge, the Shipman Inquiry reported on the activities of GP and serial killer Dr Harold Shipman. The police became aware of the activities of Dr Shipman during 1998. Following conviction, he was sentenced to life in prison in 2000. He committed suicide in January 2004.
6. The inquiry began in 2001 and released its findings in a series of 6 reports published between July 2002 and January 2005. While Dr Shipman was convicted of 15 murders, the Inquiry established that he probably committed 250 murders in total but the true number is thought to be higher. The cost of the Inquiry is estimated at approximately £21 million[1].
7. The Fourth Shipman Inquiry report of 2004 concerned the management and use of CDs. It made 32 recommendations. In its response to the Inquiry's recommendations, the previous Government accepted the need to strengthen the arrangements for the management of CDs, and to do so in a way which did not hinder patients from accessing the treatment they needed.
8. The previous administration took the necessary powers in sections 17 - 25 of the Health Act 2006. These include the functions and responsibilities of Accountable Officers (section 17). The provisions were drawn broadly and left implementation of the requirements to regulations. These were duly laid in 2006 and came into effect in England in January 2007. They have not been substantially amended since.

A.3. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (2006 regulations)

9. The 2006 regulations stipulate that designated bodies such as PCTs, NHS Trusts and independent healthcare providers in England and Scotland must appoint and resource a Controlled Drugs Accountable Officer (CDAO).

[1] See House of Commons Hand Written Answers, 24th February 2005: http://www.publications.parliament.uk/pa/cm200405/cmhansrd/vo050224/text/50224w12.htm

10. The 2006 Regulations derive from the Health Act 2006. The relevant provisions of that Act were drawn in broad terms, permitting but not requiring regulations and leaving the detail of governance schemes to such regulations. No changes to that Act for England were identified as needed to take account of the recent Health and Social Care Act 2012.

11. The 2006 Regulations provide a three-part framework for CD governance. First, they designate the bodies which must appoint a specific individual as CDAO and set out their duties and powers. Second, they provide the necessary powers for PCT CDAOs to enter premises and carry out inspections. Third, they introduce a duty on designated "responsible" bodies (such as PCTs, local authorities, the police and regulators) to co-operate in sharing information where there are concerns about local CD practice and for PCT CDAOs to create Local Intelligence Networks (LINs) for this purpose.

12. The CDAO has been assigned particular responsibilities such as to:

    a. Ensure adequate and up-to-date Standard Operating Procedures are in place in relation to the management and use of CDs

    b. Ensure the safe and effective use and management of CDs within their own organisations and by any body or person providing services to their organisation

    c. Ensure adequate destruction and disposal arrangements for CDs

    d. Ensure monitoring and auditing of the management and use of CDs

    e. Ensure relevant individuals receive appropriate training

    f. Maintain a record of concerns regarding relevant individuals

    g. Assess and investigate concerns

    h. Take appropriate action if there are well founded concerns

    i. Establish arrangements for sharing information

    j. Produce quarterly reports of their CD occurrences and give them to the CDAO leading the Local Intelligence Network of which their organisation is a member.

A.4. Who can be a CDAO?

13. To reflect the importance of the CDAO post, the 2006 regulations require appointed CDAOs to be of a sufficiently senior position in the organisation (e.g. a director or member of the management committee or someone reporting to such a person), and have little or no involvement with CD use in their organisation. 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.

A.5. PCT CDAOs

14. PCT CDAOs have a wider remit and dual roles – first, ensuring local CD governance arrangements across their area, and second, local co-ordination and intelligence gathering and sharing and taking appropriate action. PCT CDAOs therefore ensure overall CD governance within those organisations without designated CDAOs, such as GP practices, pharmacies and voluntary sector organisations, social enterprise organisations, community health services or further education establishments.

15. PCTs CD Accountable Officers have additional responsibilities to establish LINs. These bring together local CDAOs with others such as regulatory bodies, the police and local authorities. LINs are responsible for sharing information about local CD matters and concerns and considering what action to take. Investigations, inspections etc. are the responsibility of the PCT CDAO.

16. LINs are normally established on the basis of a health community, and may include more than one PCT. PCT CDAOs duties include:

    a. Convening incident panels. It is a requirement on PCT CDAOs that the LIN has a process for establishing an incident panel if serious concerns are raised. The process should outline the responsibilities of key individuals and how the panel should be called together;

b. Analysing NHS and private prescribing of CDs using electronic Prescribing Analysis and Cost (ePACT) data;

c. Requesting a periodic declaration and a self assessment from a general medical practitioner on the PCT's medical performers list regarding their CD management and use;

d. Ensuring their organisation operates arrangements for periodic inspections of premises used in connection with management or use of CDs which may not be subject to inspection by Care Quality Commission (CQC) or General Pharmaceutical Council (GPhC);

e. The PCT leading a LIN must take steps to protect patients and the public if there are concerns about inappropriate or unsafe use of CDs by a person who is not providing services for any designated body, but who lives or provides services in the LIN area.

A.6. External Monitoring

17. No formal review of the impact of the 2006 regulations has been conducted. The previous Government appointed the Care Quality Commission (CQC) (when it was the Healthcare Commission) to monitor progress on implementation of these requirements and overall compliance. The CQC publish annual reports and since the first report in 2007 it has tracked continual improvements in CD governance arrangements. Overall, it has found that safer CD management and use has become embedded in organisational healthcare practice.

B. The underlying problem

B.1. Consequences of the Health and Social Care Act 2012

18. Under the Health and Social Care Act 2012, PCTs will cease to exist from April 2013. The current regulations require PCTs first to ensure safe governance of CDs amongst a range of smaller providers and organisations (e.g. GP practices, hospices) that are not required to appoint a CD Accountable Officer, and second, to co-ordinate effective action where concerns are raised locally through the Local Intelligence Network. The Government therefore needs to explore and decide before April 2013 whether these functions should continue afterwards, and, if so, how best they can be achieved. If the current regulations are not amended, in England, the LINs will have no legal underpinning by virtue of PCTs being abolished, and many local organisations will have to appoint their own CD Accountable Officers.
19. Because no significant changes to NHS structures are expected to take place in Scotland, this Impact Assessment focuses solely on England.

C. Policy objectives and desired outcomes

C.1. Maintaining safe management and use of controlled drugs

20. The objectives are to:

a. protect patient and public health;

b. maintain and, where possible, improve the system of good governance concerning the safe management and use of controlled drugs across a range of healthcare providers and in the community;

c. to promote co-operation and information sharing between different local bodies and organisations concerned with controlled drugs;

d. to enable effective mechanisms to monitor and audit the use of controlled drugs; and

e. to enable adequate and uniform powers to investigate, and to take prompt and effective action where appropriate, when concerns about controlled drugs are raised.

C.2. Regulatory burden

21. The system should also ensure that any burdens placed on business are kept to the minimum necessary to deliver the policy objectives; are expedient and proportionate; and take account of comments received on these Regulations as part of the recent Medicines Red Tape Challenge[2], which ran from March - April 2012.

D. Options

22. The options presented below were developed and considered by a CD Working Group (CDWG). In December 2011, DH Ministers agreed to establish the CDWG under the chairmanship of the Chief Pharmaceutical Officer, Dr Keith Ridge. 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 can be updated to reflect current best practice and to identify any areas where non-regulatory solutions would be appropriate. The aim of the Group was to remove any unnecessary burdens and improve operational procedures, whilst at all times ensuring that the necessary safeguards are in place to protect the public and patients. Consultation on proposals took place in autumn 2012. For more information, please see paragraph 122.

D.1. Consideration of long-listed Options

Option 1: Do nothing – rely on voluntary compliance

23. The Health and Social Care Act 2012 has a significant impact on the role of the PCT Drugs Accountable Officer (PCT CDAO). However, simply removing references to the PCT CDAO from the 2006 Regulations without making other amendments would create considerable gaps and inconsistencies and lead to confusion for the remaining CDAOs, as well as the independent sector, in terms of their regulatory duties and functions. In this situation, both the NHS and independent healthcare providers could agree to a voluntary self-regulating governance regime. However, this risks poor or incomplete compliance unless all providers universally agree to such a scheme and follow it. In addition, providers could simply decline co-operation with any investigation or inspection should a local CD incident occur (for which there would be no regulatory back-up).

Option 2: Require compliance through professional standards

24. Replacing the 2006 Regulations with professional standards would remove some of the regulatory burdens on the NHS and independent sector CDAOs. However, without defined regulatory powers and functions, there would be no nationally applicable standards for local CD governance common to all designated bodies. This could potentially lead to organisations stopping or reducing current CDAO governance systems and other actions to address local concerns. Not all CDAOs are registered health professionals and would therefore lie outside any universal professional standards. There would also be no power to ensure the independent sector complies adequately with governance requirements.

Option 3: Require compliance through contracts

25. Current CDAO functions and duties across NHS bodies might be transposed (for example, using Secretary of State's mandate to the NHS Commissioning Board, or using the powers in Section 20 of the 2012 Act to impose, under regulations, requirements (known as "standing rules") on the Board and CCGs) to deliver adequate CD governance arrangements. However, this would still leave the independent hospital sector outside future arrangements and, as now, other types of independent or charitable organisations that offer only private healthcare.

Option 4: Require compliance through regulation

26. A regulatory regime provides nationally applicable standards for local CD governance common to all designated bodies. It also requires the same standards in the independent sector. Without

[2] See website at: http://www.redtapechallenge.cabinetoffice.gov.uk/themehome/medicine/

Regulations in place, organisations may see an opportunity to divert funds and resources away from CD governance, which would impair the overall effectiveness of any national governance system. The most important advantage of a regulatory system is that it permits sharing of “soft” and “hard” information and intelligence about local CD concerns amongst LIN members without risking breach of the Data Protection Act 1998 (which generally requires personal data to be protected from unwarranted disclosure). The other options do not offer this protection.

Table 1 – Assessment of options against policy objectives (where ✗ indicates an objective not being met, ✓ / ✗ indicates a partially met objective and ✓ indicates a fully met objective).

POLICY OBJECTIVE	**OPTION 1** (voluntary compliance)	**OPTION 2** (professional standards)	**OPTION 3** (contracts)	**OPTION 4** (regulation)
Maintain and, where possible, improve the system of good governance of controlled drugs.	✓ / ✗	✓ / ✗	✓ / ✗	✓
Protect patient and public health.	✗	✓ / ✗	✓ / ✗	✓
Promote co-operation and information sharing between different local bodies and organisations.	✗	✗	✗	✓
Enable effective mechanisms to monitor and audit the use of controlled drugs.	✓ / ✗	✓ / ✗	✓ / ✗	✓
Enable adequate and uniform powers to investigate and to take prompt and effective action where appropriate when concerns about controlled drugs are raised.	✗	✗	✗	✓

27. Based on the above Option examination, Options 1, 2, and 3 are ruled out from further analysis. This is predominantly due to the risk of breaching the Data Protection Act, incomplete compliance, unequal coverage between the NHS and the independent sector, and lack of any official mandate for inspections, incident investigation, and general enforcement.

D.2. Regulatory objectives

28. The regulatory objectives are to:

    a. secure appropriate delivery of the current PCT CDAO functions;

    b. ensure sufficient separation from local interest groups and sectors (i.e. minimal conflict of interests and clear accountability);

    c. maintain local presence allowing for gathering knowledge and co-ordinating actions locally;

    d. continue provision of uniform oversight across NHS and the independent sector;

    e. deliver above objectives without creating excessive NHS and private resource pressures and allow delivery within required timelines;

Option 4.1: Require compliance through regulation, with the current PCT roles located in the NHS Commissioning Board

29. The Commissioning Board will have responsibility for supporting CCGs' commissioning and direct responsibility for commissioning NHS primary care and other services. The Board would be sufficiently separated from local interest groups and sectors, but at the same time close enough to gather knowledge and co-ordinate action locally. The Board is proposing to form Local Area Teams (LATs), which will be responsible for e.g. primary care commissioning. However, the Board will not be responsible for commissioning hospital services and may have less direct relations and involvement with the independent sector and other types of providers.

Option 4.2: Require compliance through regulation, with the current PCT roles located in the Clinical Commissioning Groups

30. CCGs are expected to have experience of and dealings with both NHS and other healthcare providers. The PCT CDAO role requires support from an experienced senior pharmacist with links to GPs' fitness to practice (which CCGs will have) and to pharmaceutical service commissioning arrangements (which CCGs will not). However, CCGs could access adequate pharmaceutical advice through the emerging commissioning support organisations. If the co-ordination role were to transfer to CCGs, they would also need to have strong accountability lines to ensure, where the CCG leads are GP principals, conflicts of interests or allegations thereof are avoided.

Option 4.3: Require compliance through regulation, with the current PCT roles located in a new independent inspectorate

31. This recommendation from the Shipman's Fourth Report was previously rejected, as it would have required new primary legislation and in 2006 was estimated to cost between £18 to £20 million per annum. The same disadvantages remain today and it would not be possible both to legislate and to establish such an inspectorate in time for the expected changes in April 2013, even if resources permitted.

Table 2 – Assessment of sub-options against regulatory objectives (where ✗ indicates an objective not being met, ✔ / ✗ indicates a partially met objective and ✔ indicates a fully met objective).

REGULATORY OBJECTIVE	**OPTION 4.1** (Commissioning Board)	**OPTION 4.2** (Clinical Commissioning Groups)	**OPTION 4.3** (independent inspectorate)
Appropriate delivery of the current PCT CDAO functions.	✔	✔	✔ / ✗
Sufficient separation from local interest groups and sectors (i.e. minimal conflict of interests and clear accountability).	✔	✔ / ✗	✔
Local presence allowing for gathering knowledge and co-ordinating actions locally.	✔	✔	✔ / ✗
Provide uniform oversight across NHS and the independent sector.	✔ / ✗	✔ / ✗	✔
Does not present excessive NHS and private resource pressures and allow delivery within required timelines.	✔	✔	✗

D.3. Refinement of short-listed Options

32. The above analysis illustrates that only Options 4.1 and 4.2 are capable of meeting all the policy objectives timely, reliably and consistently. Option 4.3 is ruled out based on resource and delivery time constraints associated with establishing an independent inspectorate.

33. As a result, the following two options are considered for quantification in this Impact Assessment:

Option 4.1: Require compliance through regulation, with the current PCT roles located in the NHS Commissioning Board

Option 4.2: Require compliance through regulation, with the current PCT roles located in Clinical Commissioning Groups

E. Costs and benefits

34. In line with Impact Assessment guidance, this section looks at the marginal costs and benefits of Options 4.1 and 4.2 relative to Option 1, the do-nothing option. As a result, Option 1 is presented as having no costs and benefits, as the other policy Options are assessed as marginal changes against the do-nothing baseline. Relevant costs and benefits of Option 1 are therefore considered implicitly in the following analysis.

35. In light of the above, it is important to briefly outline the consequences of Option 1 when compared against the outcomes of the current arrangements. In particular, the following outcomes are expected:

- Lower regulatory burden resulting from the discontinuation of the PCT CD AO role. Under the do-nothing scenario, current CD AO roles across 152 PCTs (corresponding to 50 PCT clusters) cease to exist, resulting in staff cost savings. However, it is important to note that some of the local AO roles would have to be re-established in order to ensure smaller organisations (currently excluded from the requirement to appoint an AO due to the oversight provided by PCT CDAOs) have adequate CD governance systems.
- Lower level of CD system oversight (as evidenced by the disappearance of functions described in paragraphs 14-16) leading to the risk of increased diversion, and ultimately of increased criminal behaviour (both wilful patient harm, as well as pecuniary motives) and negative health impacts from improper CD use and management.

36. It is against these outcomes that Options 4.1 and 4.2 are valued, where the estimates of:

- the **benefits** focus on improved health outcomes, resulting from a **prevented increase in patient harm**[3]; and
- the **costs** predominantly relate to the regulatory burdens imposed by the CD Regulations, resulting from the **creation of additional CD AO roles**.

37. The quantified benefits of Options 4.1 and 4.2 are considered to be of much lower magnitude than the unquantified benefits identified in this Impact Assessment, but are based on robust estimates and assumptions.

38. In this analysis the financial costs and benefits to the NHS have not been adjusted to reflect the full opportunity cost of NHS funds.

E.1. One-In, One-Out

39. The regulations considered in this Impact Assessment consolidate, update and reform the Controlled Drugs (Supervision of Management and Use) Regulations SI 2006/3148. They cover England and Scotland. Northern Ireland and Wales have separate but equivalent legislation.

[3] Please note that these benefits represent the marginal impact that arises in relation to the continuation of the current PCT CDAO roles in the new NHS architecture that would otherwise not continue under the do-nothing option, and do not reflect the benefits that arise from the wider legislative provisions outlined in paragraph 2.

40. As discussed in paragraph 70, the proposed measures are expected to place no additional burden on the private sector. The only additional burdens identified fall on the Commissioning Board (under Option 4.1) or Clinical Commissioning Groups (under Option 4.2) and relate to additional Accountable Officer posts created to ensure continuation of good CD governance amongst those organisations not required to appoint a CDAO and of the Local Intelligence Network coordination and information sharing functions. The organisation-level CDAO function requirements are identical under all three options. The regulatory burden placed on business and civil society organisations is the same, irrespective of where these functions are located (see paragraph 70). However, as explained in paragraph 35, if CDAO functions have to be created under the do-nothing option by small organisations to replace current PCT CDAO oversight, then the burden of complying with regulations would fall on these small organisations. These costs to the third sector are avoided under the preferred option, as explained in paragraph 70. As a result, and in line with the One-In, One-Out (OIOO) Methodology guidance, this measure has a zero net impact on business and civil society organizations.

E.2. Option 4.1

E.2.1. Benefits

41. A national standard for local CD governance common to all designated bodies would provide the highest level of compliance, as well as improved overall effectiveness of any national governance system. Numerous studies[4] provide the justification for a system-wide approach, which covers all the aspects of CD use. Without such consistency and uniformity of approach, risks are likely to concentrate in less-regulated parts of the wider system. Compared to the do-nothing option, an effective and uniform CD regulatory system, which can only be ensured by re-establishing current PCT CDAO roles outlined in paragraphs 14-16, should therefore lead to:

- a prevented increase in CD diversion (both by patients and by staff), resulting in:
  - prevented increase in patient adverse health events (prevented increase in wilful harm), leading to health gains and saved NHS treatment costs;
  - prevented increase in diversion for pecuniary motives or to feed own drug addiction, leading to fewer drug addictions by staff and better health outcomes, reducing costs to society and the NHS;
- a prevented increase in inappropriate clinical use of CDs, resulting in:
  - avoided deterioration in patient health outcomes, leading to patient health gains and saved NHS treatment costs;

42. The level of prevented risk increase described above has to be valued marginal to existing systems that could potentially prevent diversion of CDs in the absence of the Regulations. Under the do-nothing option, with the PCT CD Accountable Officer role and Local Intelligence Networks being discontinued, the following safeguards will continue to limit misuse and mismanagement of Controlled Drugs:

- Professional regulation;
- Misuse of Drugs Act 1971;
- Misuse of Drugs Regulations 2011;
- Care Quality Commission (CQC) regulatory framework;
- current regulatory regime becoming enshrined in local systems as best practice, leading to diminishing benefits of further regulation.

43. As a result of the above, removal of the current Regulations would result in risk profiles that are significantly lower than the pre-Regulation risk levels observed prior to 2006. At the same time, this effect is expected not to be uniform across all areas of CD usage (i.e. supply chain, prescribing,

[4] See, for example: Fountain, J., Strang, J., Gossop, M., Farrel, M. and Griffiths, P. (2000), Diversion of prescribed drugs by drug users in treatment: analysis of the UK market and new data from London. Addiction, 95: 393–406. doi: 10.1046/j.1360-0443.2000.95339310.x

storage, etc.). Because diversion can take place in any one part of the wider area[5], it is important to account for the particularly damaging risk concentration that may follow from an incomplete system of oversight.

44. In light of the above, the marginal benefit of continuing the PCT CDAO roles in the new NHS structures (as compared to the do-nothing option where these functions are discontinued) stems from maintaining the risk-mitigating roles of AOs relating to LINs and their oversight of smaller organisations that otherwise do not appoint AOs, as outlined in paragraphs 14-16. Therefore, any benefits identified in this Impact Assessment result from preventing increase in CD diversion and in inappropriate clinical use of CDs. For further discussion of the marginality of these benefits, see Annex C.

E.2.2. Prevented increase in patient adverse health events

Appropriate use and management of CDs – prevented increase in patient health loss

45. Patient harm incidents can be defined by a health loss metric, as measured in terms of frequency of occurrence, severity, and duration of a given adverse health outcome. Some of these events are unavoidable, and therefore cannot be mitigated against. On the other hand, risk profiles of other incidents can be influenced by the safe use and management of CDs. Therefore, it is expected that the continuation of PCT CDAO functions could prevent increases in all three aspects of these avoidable hazards. In order to quantify the resulting avoided health loss, as well as the associated prevented increase in NHS treatment costs, a risk-based approach is used. This approach considers the risks that occur as a result of CD use and management and the extent to which Regulations can mitigate them.

Prevalence of adverse health events

46. The data obtained from the National Patient Safety Agency (NPSA)[6] of self-reported Patient Safety Incidents (PSIs) to the National Reporting and Learning Systems (NRLS) allow for desegregation of CD-related health events by cause and severity of health loss. It is important to acknowledge that this type of self-reported data often underestimates the actual number of adverse events. Barber (2005)[7] estimated the proportion of spontaneously [or self-] reported medication incidents at less than 1% of the total underlying number of incidents. Levels of reporting evidenced in more recent prevalence studies[8] can be estimated at approximately 2.5-3.5% of actual events. This level of under-reporting (circa 100-fold for Barber (2005) and 40- to 29-fold for wider literature estimates) requires caution when extrapolating from such a small data sample, particularly regarding the split between different severity categories. Furthermore, this creates a need to adjust for the level of under-reporting (see below). Being aware of the data limitations, with no alternative sources easily available, sensitivity analysis undertaken in paragraph 85 shows the results to be robust.

47. In order to develop conservative benefit estimates, the reporting level is assumed to represent 7% of the total CD-related Patient Safety Incidents. CD-related incidents are more likely to be reported, as compared to general medicine-related PSIs, resulting in an estimated 2-fold increase of the highest literature estimates of reporting levels (2 * 3.5% = 7%). This suggests that for every reported incident, there are approximately 14.3 incidents that were not reported and therefore are not captured in the NPSA data. As explained above, if the true level of reporting is approximately 1-3%, this analysis would understate the quantified benefits by 2- to 7-fold, depending on the reliability of

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[5] See: Fountain, J., Strang, J., Gossop, M., Farrel, M. and Griffiths, P. (2000), Diversion of prescribed drugs by drug users in treatment: analysis of the UK market and new data from London. Addiction, 95: 393–406. doi: 10.1046/j.1360-0443.2000.95339310.x

[6] National Patient Safety Agency Submission to the Controlled Drugs Accountable Officers Review, March 2011. Figures revised October 2011 (reduced from initial 32,744 to 16,286 PSIs for calendar year 2011) following a refinement of search methodology of the NRLS dataset. This reflects removal of double-counted incidents and better-defined search terms used in data retrieval (such as specific drug names, etc.). The reduced dataset is seen as more robust and therefore is used as the basis for the final analysis.

[7] Barber N, Dean Franklin B, Cornford T, Klecun E, and Savage I. Piloting Technology Evaluations to Reduce Medication Errors. Report to the Patient Safety Research Programme (England), 2005.

[8] See, for example (1) Classen DC, Pestotnik SL, Evans RS et al. Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. JAMA. 1997;277:301-6.
(2) Bates DW, Leape LL, Petrycki S. Incidence and preventability of adverse drug events in hospitalized adults. Gen Intern Med.1993; 8:289-94.
(3) Bates DW, Cullen DJ, Laird N et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA. 1995; 274:29-34.
(4) Kanjanarat P et al. Nature of preventable adverse drug events in hospitals: a literature review. Am J Health-Syst Pharm. 2003;60:1750-9.

the estimates. According to the NPSA patient harm categorisation, it is possible to distinguish between the following adverse patient health outcomes:

- no harm – no treatment required,
- low harm – requiring only first-aid level treatment; example: rash resulting from an adverse reaction to medication,
- moderate harm – can range from an extra consultation to several weeks in intensive care; example: a patient being given out-of-date medication,
- severe harm – resulting in permanent lessening of bodily functions; example: a patient being provided the wrong dose or formulation of medication;
- death – for example, resulting from administering the incorrect medication or severely excessive dosage (such as a multiple of 10).

Table 3 – National Patient Safety Agency NRLS Patient Safety Incidents reports involving controlled drugs by severity category[9] (CD-related Patient Safety Incidents in the calendar year 2011 = 16,286).

Hazard Severity	Description	Representative Condition	Number of Reported Incidents	Assumed Total Number of Incidents	Share of Incidents [10]
No Harm	No treatment or follow-up required;	Lack of signature on a prescription;	13,871	198,151	85.17%
Low Harm	Requires only first-aid level treatment;	Examination, reassurance;	1,816	25,939	11.15%
Moderate Harm	Harm that requires extra healthcare investigation, observation or treatment, but does not lead to permanent disability;	Application of out-of-date medication leading to emergency admissions;	571	8,153	3.50%
Severe Harm	Event that causes permanent lessening of bodily functions;	Wrong dose or formulation of medication leading to permanent disability;	17	239	0.10%
Death	Harm leading to patient death;	Incorrect medication or dosage;	12	175	0.075%

Severity and duration of adverse health outcomes

48. The NPSA classification of adverse health outcomes allows for the aggregation of severity levels across various causes of health loss. The available data do not allow a more granular approach. As a result, a single heading, such as low harm events, incorporates more than just one possible health outcome, as described in paragraph 47. For the purpose of this analysis, the severity and duration of individual health outcome categories have been developed based on the representative condition presented in Table 3.

49. Discussions with experts from the CD Working Group informed the formation of likely health impact scenarios, which were then translated into specific Quality-Adjusted Life Year (QALY[11]) loss. For a detailed discussion of the scenarios and mapping methodology of representative conditions to a QALY value, please see Annex B.

[9] Cousins D, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over six years (2005 – 2010). British Journal of Clinical Pharmacology. 2011.

[10] The share of incidents was derived from a 5-year dataset (2005-2011) consisting over 72,000 PSIs, which was then used to extrapolate underlying numbers of PSIs in each severity category for the 16,286 reported PSIs in 2011. Th2 72,000 dataset was judged more robust in depicting the true underlying split by severity categories.

[11] QALY is a measure combining life expectancy and the quality of remaining life-years.

50. As above, the aggregation of health states into the NPSA severity categories leads to the development of an average duration approach, i.e. on average how long an adverse event is expected to last. Once again, assumptions used here were developed taking into account input from the CD Working Group.

51. More severe adverse events are expected to result in life-long health loss, as defined by the NPSA severity categories[12]. Based on the NRLS data, the age of an average adverse health outcome sufferer is approximated to 54[13] years for no-, low-, moderate-, and severe-harm incidents, and 70[13] years for death. According to 2010 ONS data, life expectancy of a 54 year-old is 28.05 years and that of a 70 year-old is 15.10 years. This is equivalent to a quality-adjusted life expectancy of 20.45 and 11.77 respectively, after accounting for the fact that quality of life decreases with age.

Table 4: Severity and duration assumptions of patient harm incidents

Hazard Severity	**Average QALY Loss (i.e. severity)**	**Average Duration**
No Harm	0	N/A
Low Harm	0.1207	1 week
Moderate Harm	0.255	1 month
Severe Harm	0.6781	20.45[14]
Death	1[15]	11.77[16]

Saved NHS treatment costs

52. Most adverse events are directly associated with NHS treatment costs. Therefore, in addition to the health (QALY) benefits identified above, a prevented increase in adverse events can result in avoided NHS treatment costs. Even in the case of events that caused no lasting harm (such as low harm health outcomes), there is a likelihood of further consultations and additional costs on the NHS that could be avoided.

53. Average treatment costs for each severity category are developed using data from the Unit Cost of Health and Social Care 2011[17]. Figures from both data sources are then inflated to reflect 2012/13 prices. The treatment costs are then assumed to increase in line with the GDP deflator, resulting in no change in the real price of NHS treatment over the appraisal period. The representative treatment assumptions are outlined in Table 5 below.

[12] http://www.npsa.nhs.uk/corporate/news/npsa-releases-organisation-patient-safety-incident-reporting-data-england/ and http://its-services.org.uk/silo/files/npsa-guide-to-root-cause-analysis-glossary.doc

[13] Approximated using data from the NRLS providing average age by severity category – exact average age of non-death PSIs was 54.12 years and death PSIs average was 70.43 years.

[14] Quality-adjusted life expectancy at 54 years of age

[15] Reflects a fall of QoL to zero. Note, that shorter duration adjusts for lower initial QoL, reflecting the correct health loss resulting from death

[16] Quality-adjusted life expectancy at 70 years of age. It is probable that individuals suffering death resulting from CD-related incident can have life expectancy below that of an average 70 year-old. However, with no data available to model this assumption, the marginal change associated with this uncertainty is addressed in sensitivity analysis.

[17] http://www.pssru.ac.uk/pdf/uc/uc2011/uc2011.pdf and the 2010-2011 NHS reference cost data, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_ 131140

Table 5: NHS treatment cost by severity of patient harm

Hazard Severity	Representative Treatment	Reference Cost Look-up	Average Total Cost
No Harm	No treatment or follow-up required;	N/A	£0
Low Harm	Additional consultation with a General Practitioner.	N/A	£44.50[18]
Moderate Harm	Non-elective short hospital stay, averaged across 1200 various conditions.	TPCTNEI_S	£1,300
Severe Harm	Summation of two factors: (i) Multiple trauma diagnoses (score 33 - 50 with interventions, score >=45); and (ii) annual follow-up aggregated over the course of remaining life years (28 years is the life expectancy of an average PMC patient).	Multiple trauma diagnoses (score 33 - 50 with interventions, score >=45) – VA15C Follow-up – PA57Z	£39,242
Death[19]	Approximately corresponding to the average of an emergency hospital admission and non-elective long hospital stay.	TPCTNEI_L	£3,000

Regulatory risk mitigation and resulting benefits

54. The extent to which regulations can reduce the overall impact of the adverse events identified above predominantly depends on: (1) how regulations add to existing CD management mechanisms that will be in place under the do-nothing scenario, and (2) the nature of the risks in question (i.e. if risks are avoidable and can therefore be mitigated).

55. Addressing the latter point, based on a random sample of 100 CD-related Patient Safety Incidents from the NRLS dataset after examining both the current role of AOs and the nature of reported PSIs (i.e. the harm minimisation aspect of AO roles), it has been concluded that between 20 and 45% of PSIs can be assumed to have a direct CDAO (or support staff) involvement[20]. This involvement is not reported in the NRLS dataset itself, as the data represent only a snapshot in the natural progression of a Patient Safety Incident before the involvement of the AO. As a result, AO involvement can be implied only from the interaction of the underlying cause of the PSI and the role of an AO. Based on the above range of possible AO involvement:

- no-, low-, and moderate-harm incidents are assumed to involve an AO in 20% of cases; and
- severe-harm and death incidents should command 45% involvement (see the table below for a summary of the above).

Table 6: Accountable Officer involvement in Patient Safety Incidents

Hazard Severity	Number of Reported Incidents (2011)	Assumed Total Number of Incidents	Assumed AO involvement rate	Number of Incidents with AO involvement
No Harm	13,871	198,151	20%	39,630
Low Harm	1,816	25,939	20%	5,188
Moderate Harm	571	8,153	20%	1,631
Severe Harm	17	239	45%	108
Death	12	175	45%	79

[18] Approximate cost of a GP consultation.

[19] Please note that the cost of death in this analysis is assumed additional to that of an average NHS expenditure per death of a member of the general population.

[20] It is possible that 100% of severe harm and death PSIs would require AO involvement, but the currently assumed 45% level of involvement is considered prudent, avoiding possible over-estimation of benefits. This is addressed in sensitivity testing at the end of the cost-benefit analysis.

56. In order to address the concerns regarding the relative lack of NRLS reports of CDAO involvement in Patient Safety Incidents (i.e. lack of documented connection between AO roles and PSIs), a survey was sent after consultation had ended to a random sample of over 100 CDAOs in order to gather more information on the extent of their clinical oversight and governance. 15 responses were received These results are not sufficiently robust to give a firm indication of the proportionate split between the "audit" and "clinical" functions that CDAOs undertake. Nonetheless, of those who responded, all reported a significant proportion of their time being spent on, amongst other things, investigations of PSIs, training of staff in regards to the use of CDs and ensuring clinical audits are performed. As such, they provide adequate evidence to link the roles of CDAOs with clinical outcomes and give an indication of their part in mitigating risks through their engagement in incident investigations which can lead to amendments of Standard Operating Procedures, staff training etc.

57. Paragraphs 42 and 43 outline the marginality of additional regulatory oversight as having proportionately diminishing effect, especially in light of numerous parts of the regulatory system becoming best practice and continuing under the do-nothing scenario. Following this reasoning, based on CQC's findings in "The Safer Management of Controlled Drugs" annual reports[21], it is assumed that the minimal prevented increase in patient harm, when compared to the do-nothing option, should amount to no less than 5% of adverse patient incidents (for an illustrative derivation, please see Annex C). Implicitly, this assumption suggests that under the do-nothing scenario, due to the discontinuation of CDAO functions, the likelihood, severity, and duration of patient safety incidents (adverse health outcomes) would increase by 5%. This increase is expected to be prevented by continuing the PCT CDAO roles in the new NHS structures under the preferred option. Due to the incremental nature of behavioural changes, this effect is then expected to spread over a 3-year period, with uniform year-on-year increments, arriving at 5% increase in year 3 (i.e. an increase of 1.67% of the initial figure for 3 consecutive years). After this 3-year period, the level of prevented adverse health events is assumed to remain stable (and increase only in line with use of CDs, as explained in paragraph 60). This effect, is presented in the table below:

Table 7: Prevented patient harm time distribution (% increase of year 1 patient safety incidents)

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Prevented patient harm	1.67%	1.67%	1.67%	0%	0%	0%	0%	0%	0%	0%

58. Please note that, as explained in paragraphs 34-36, the above table corresponds to an assumed increase of patient harm under the do-nothing option, which would be mitigated under Options 4.1 and 4.2. In essence, this implies that the discontinuation of the PCT CDAO roles under the do-nothing option would lead to an increase in CD-related Patient Safety Incidents. The benefit of continuing these roles under the preferred option is the prevented increase in patient harm.

59. It is assumed that a one person-year in full health, or Quality-Adjusted Life Year (a QALY) is worth £66,000[22] (in 2012/13 prices) to society. Based on the above, it is possible to quantify:

- the expected avoided health loss using the following calculation[23]: Benefits = A x B x C x D x £66,000, where:
  - A = Number of adverse events,
  - B = severity of adverse event (in QALYs),
  - C = duration of adverse event (in years),
  - D = reduction through Regulation. See footnote for illustrative calculation.

[21] Reports can be found at: http://www.cqc.org.uk/organisations-we-regulate/special-reviews-and-inspection-programmes/controlled-drugs

[22] Based Department for Transport research showing a QALY being worth £60,000 in 2008/09 prices, uplifted to 12/13 prices using HMT's GDP deflators (see http://www.hm-treasury.gov.uk/data_gdp_fig.htm for historical figures and forecast)

[23] Illustrative calculation for moderate harm for year 2012/13:
A x B x C x D x £66,000 = 571 x 0.255 x 1/12 x 1.67% x £66,000 = £13,350

- the expected benefits of avoided NHS treatments costs using the following calculation[24]: Cost savings = E x F x G, where:
  - E = Number of adverse event,
  - F = reduction through Regulation,
  - G = saved treatment cost to the NHS. See footnote for illustrative calculation.

60. Based on the above assumptions, Table 8 summarises annual benefits over the 10-year evaluation period. Because the prescription volumes of CDs are expected to increase at approximately 3% annually[25], the same scaling is applied to the annual benefits (i.e. patient harm is expected to be proportionate to the level of CD use). Please note that this quantified benefit is perceived to be of significantly lower magnitude than the unquantified benefits of Options 4.1 and 4.2.

Table 8: Summary of benefits from reduction in patient adverse health events, Option 4.1

Benefits (£, 000s)	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**
Patient Health[26]	2,725	5,614	8,590	8,848	9,113	9,387	9,668	9,958	10,257	10,565
NHS Treatment Cost Savings	114	235	359	370	381	392	404	416	429	442
Total	2,839	5,849	8,949	9,218	9,494	9,779	10,072	10,374	10,686	11,006
Discounted	2,839	5,758	8,673	8,795	8,918	9,043	9,171	9,300	9,431	9,564
Present Value	**81,492**									

E.2.3. Avoided increase in CD diversion by staff and patients

Pecuniary motives – staff and patients

61. As explored by Fountain et al., 2000[27] in their research report on the diversion of prescribed drugs, a number of key facts can be identified in relation to the diversion of prescribed drugs:
    a. Drug users in treatment are the primary diverters;
    b. Reports of doctors and other health workers being involved in diversion are less frequent;
    c. The main motives for drug diversion appear to be:
       - Dissatisfaction with prescribed drugs by drug users in treatment (i.e. selling prescribed drugs to then purchase other, usually stronger, drugs);
       - Drug users in private treatment raising money to pay for prescriptions and dispensing fees (i.e. raising money to fuel own habit, as above);
       - Alcoholics selling benzodiazepines to buy alcohol;
       - Healthcare professionals selling drugs for pecuniary motives or diverting them for personal use.
    d. Drug users in treatment who sell their prescribed drugs are less likely to commit other acquisitive crimes to fund their addiction, but are also more likely to be unsuccessful in the treatment.

[24] Illustrative calculation for moderate harm for year 2012/13:
E x F x G = 571 x 1.67% x £1,300 = £12,372

[25] Assumption developed based on 2009-2010 increase, CQC CD annual report:
http://www.cqc.org.uk/sites/default/files/media/documents/controlled_drugs_annual_report__2010_final_web_201108184636.pdf

[26] In line with standard health valuation practice, the quantified value of health benefits is assumed to increase in line with the GDP growth, resulting in a lower discount rate of 1.5% (as compared to 3.5% discount rate applied to all other impacts).

[27] Fountain, J., Strang, J., Gossop, M., Farrel, M. and Griffiths, P. (2000), Diversion of prescribed drugs by drug users in treatment: analysis of the UK market and new data from London. Addiction, 95: 393–406. doi: 10.1046/j.1360-0443.2000.95339310.x

62. Reduced ease of CD diversion may result in fewer drug addictions. This would be predominantly due to decreased availability of diverted prescription drugs, making it more difficult to obtain illegal substances in general, and lower addiction rates among healthcare professionals. Moreover, this should also lead to an increase in success of drug addiction treatments in that patients would be more likely to follow the course of treatment, rather than focus on diverting the drugs. Ultimately, this should lead to reduced level of criminal activity associated with acquisitive crimes for funding a drug habit. An initial increase in acquisitive crime is possible, albeit it should decrease over time as the total number of drug users decreases.

63. The above benefits have not been quantified due to the uncertainty regarding the exact behavioural changes relating to drug abuse. The overall effect is expected to be positive, albeit of an unknown magnitude.

Wilful patient harm

64. Preventing wilful patient harm (i.e. a Shipman-like event) is one of the main objectives of the CD regulatory framework. The safety net provided by the role and functions of the Accountable Officer and Local Intelligence Networks allows for a faster detection of any illegal behaviour and serves as a deterrent to risk clustering in less-regulated pockets of the wider system. Averting a Shipman-like incident would not only potentially save hundreds of lives[28], but would also result in saved costs of a possible inquiry.

65. Regulatory oversight and the coordination function provided by LINs provide an assurance framework that mitigates the probability of another Shipman-like event occurring. Quantification of the risk is very difficult in that the underlying probability of wilful patient harm is unknown, resulting in a possibility of large under- or over-estimation of said benefits. As a result, this benefit has not been quantified, albeit it is perceived to be the largest benefit of a uniform CD regulatory system[29].

66. Of significant importance is also the effect of a serious incident on patient trust for NHS staff and the doctor-patient relationship. Lack of trust may have negative impacts on medicine adherence as well as the willingness to make first contact leading to delayed diagnosis, ultimately leading to negative health outcomes and increased NHS treatment costs.

E.2.4. Costs

E.2.5. Regulatory burden – Accountable Officer role and supporting staff

67. The regulatory burden imposed on all the parties involved has to be considered as a marginal increase in relation to the level of 'regulatory' burden present under the do-nothing option (i.e. even with no regulatory regime in place, certain processes will continue generating burdens). Specifically, the do-nothing scenario assumed that the CD AO posts across all PCT clusters would be discontinued, whereas all the remaining non-PCT CD AOs would continue in their roles. Some smaller organisation CDAO roles may have to be re-established under the do-nothing option – see paragraph 70 for details. For the purpose of this Impact Assessment, a reduction in regulatory burden is defined as releasing resources (monetary and/or human), which can be diverted to other uses. Sources of regulatory burden include:
    - monitoring and inspections,
    - audit trail,
    - training and development, and
    - enforcement.

Current PCT CD AOs – function transfer

68. On behalf of the working group, a survey was undertaken by the National Prescribing Centre via their dedicated Controlled Drugs Accountable Officer website for all CDAOs to complete. This allowed for development of reliable and robust cost estimates. With responses from over 200 individuals, the data cover the entire spectrum of CD AO working patterns and arrangements. The

[28] According to the Shipman Inquiry's 6th Report, Harold Shipman may have been responsible for approximately 250 deaths in total. http://webarchive.nationalarchives.gov.uk/20090808154959/http://www.the-shipman-inquiry.org.uk/6r_page.asp?id=3445

[29] Arguably, a Shipman-like event represents unacceptable risk, the avoidance of which might command a higher risk-aversion premium when compared against a standard valuation of a QALY.

table below summarises the survey findings, including calculated average wages, full time equivalent (FTE) of CD AO working time, support staff and FTE of PCT CD AOs spent on Local Intelligence Network tasks.

69. It is important to note that the cost averages developed below are used for calculation of AO and support staff costs across all options, regardless of AO role allocation in the new NHS structures. In particular, no differentiation is made between the organisational structures that AOs are allocated into and the cost per AO post is assumed the same for the Commissioning Board (Option 4.1) and the Clinical Commissioning Groups (Option 4.2). This is predominantly due to:

- the uncertainty created by the independence of structuring the delegation of AO roles to support staff, as well as
- the rigidity of AOs themselves having to be of a certain minimum seniority within the respective organisations, which is expected to limit the cost differentials between the two options.

Table 9 – National Prescribing Centre survey results summary

Type of organisation	Primary Care Trust – 17%	NHS Trust – 12%	Foundation Trust – 15%	Independent Hospital – 31%	Other – 24% (Hospices)
Average AO Full Time Equiv. pay	£66,730				
FTE dedicated to AO responsibilities	0.105				
FTE dedicated to running LINs (PCT AOs only)	0.02				
Are the day-to-day tasks delegated?	Yes – 63%	No – 27%			
% of AOs delegating to:	1 staff member – 63%	2nd staff member – 34.5%	3rd staff member – 13.7%	4th staff member – 6.3%	
FTE dedicated to supporting AO	1st staff – 0.488	2nd staff – 0.309	3rd staff – 0.338	4th staff – 0.200	
Average support staff pay	1st staff – £46,900	2nd staff – £42,600	3rd staff – £38,900	4th staff – £39,700	

70. As explained in paragraphs 34-36, compared to the do-nothing option where the current PCT CDAO roles cease to exist, any additional CDAO roles created under Option 4.1 or 4.2 are considered a marginal cost, which for the purpose of this analysis is implicitly overstated for both Options 4.1 and 4.2. Where PCT CDAOs currently ensure CD governance in smaller organisations, certain local AO functions (and what follows, costs) would have to be re-established under the do-nothing scenario by these smaller organisations. These costs arise only under the do-nothing scenario. Continuation of CDAO roles at LAT or CCG level under Options 4.1 and 4.2 would provide CD governance for smaller organisations, ultimately leading to marginal cost savings as compared against the do-nothing scenario. Exclusion of these considerations from the cost calculations, due to the uncertainty regarding re-establishing of these functions locally, leads to an over-statement of costs under both Options 4.1 and 4.2 (i.e. cost estimates presented in this analysis may significantly overstate the general costs, as they do not account for cost savings to smaller organisations). The survey results in table 9 represent the additional cost of creating CD AO roles under Options 4.1 and 4.2, which would otherwise not exist under the do-nothing option, not accounting for the local small organisation considerations discussed above.

71. Based on average CD AO earnings and reported full time equivalent (FTE) work allocation to CD monitoring, as well as the number, pay band and FTE split of supporting staff, the following formula has been used to arrive at the average CD AO cost: (H + I) x J + [K] x [L], where:

    - H = FTE dedicated to AO role,
    - I = FTE dedicated to running LINs,
    - J = AO pay,
    - K = a matrix of individual support staff FTE dedicated to supporting an AO,
    - L = corresponding matrix of individual support staff pay. This is then uplifted by 30% to account for various associated on-costs.

    Using this methodology, an average cost of £36,102 per Accountable Officer is arrived at, with £10,892 attributed to the Officer and £25,210[30] for supporting staff[31].

72. During consultation, it was highlighted that the additional number of Accountable Officers at the proposed 27 Commissioning Board Local Area Teams (LATs) does not have to correspond 1-for-1 to the number of LATs (i.e. there may be more than one CDAO post per LAT). In order to reflect the uncertainty regarding the exact design of LAT CDAO structures, a more general costing approach was developed, where the future LAT CDAO costs are assumed not to exceed total current PCT CDAO costs. As a result, when compared to the do-nothing scenario where PCT CDAO posts cease to exist, continuation of these functions at LATs would lead, in the worst case, to mimicking of current PCT costs. No further training or transition costs are assumed to be incurred, as most of the expertise is assumed to be transferable from PCT structures. Current annual PCT CDAO costs are calculated by applying average AO cost to the assumed number of AOs in the PCT structures, which is estimated at 100 AOs across 50 PCT clusters (i.e. 100 x £36,102 = £3.61m p.a.). This costing methodology would imply that every LAT would establish, on average, 3.7 AO posts with AO and support staff costs derived in line with CDAO survey results presented in Table 9. The year-on-year cost is then uplifted by 1.54%[32] in order to reflect real annual wage inflation (i.e. wage inflation minus 2% inflation rate), which is developed based on 10-year average of Office of National Statistics pay inflation data.

Table 10 – Commissioning Board costs

Costs (£, 000s)	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Comm. Board AOs	3,610	3,666	3,722	3,780	3,838	3,897	3,957	4,018	4,080	4,143
Discounted	3,610	3,542	3,475	3,409	3,344	3,281	3,219	3,158	3,098	3,039
Present Value	33,176									

Impacts on small organisations

73. As explained in paragraphs 14-16, PCT CDAOs currently ensure CD governance within small organisations without designated CDAOs. Under the current Regulations, as a result of the discontinuation of the PCT CDAO roles, the majority of small organisations (such as NHS GPs, pharmacies, etc.) would have to create CDAO functions in order to assure adequate CD governance, or cease to use CDs if said assurance was not established. The preferred option proposes that these functions currently carried out by PCT CDAOs are instead continued by the NHS Commissioning Board. This will remove the need for, and consequently any burden on, those small businesses and civil society organisations currently overseen by PCT CDAOs to ensure any additional CD governance functions. Moreover, it is assumed that of the approximately 1,000 local CDAOs located in NHS Trusts and independent healthcare providers, all will continue in their current roles. This is based on the requirement in the regulations for the Care Quality Commission in

[30] An alternative more aggregated cost derivation method using same survey results arrived at support staff costs of approximately £23k. The higher cost figure was used in order to arrive at conservative NPV value.

[31] For illustrative purposes, we have assumed that for the current 152 PCTs there are an estimated 100 CDAOs covering around 50 PCT clusters, resulting in estimated costs of £3.6m p.a. (100 x £36,102).

[32] See ONS website at: http://www.ons.gov.uk/ons/rel/lms/labour-market-statistics/june-2012/dataset--labour-market-statistics.html

England and Health Improvement Scotland in Scotland to maintain a CD AO register, with whom all organisations, who are required to appoint a CDAO, have to register. As a result, no additional net burden is expected to be generated for business or civil society organizations[33], when compared to the do-nothing option. The preferred option is in fact cost-saving, when compared to the do-nothing option, as it avoids small organisation costs (i.e. having to choose between setting up their own Accountable Officer functions, individually or by clustering, or discontinuing their use of CDs) by locating AOs (and associated costs) within NHS structures.

Other non-quantified costs

74. The allocation of CD AO roles to the NHS Commissioning Board LATs may result in initial transition costs relating to AO training (such as familiarising with guidance) and other administrative burdens (e.g. recruitment of support staff, adaptation of LIN structures, etc.). In light of the recent establishment of the CB, and the still-fluid design of its structures, it is reasonable to assume that any such burdens would be spread across other areas. Moreover, due to the nature of AO roles (and that of support staff), few new staff members are expected to be recruited only to perform AO-related functions. It is more likely that administrative costs would be absorbed into current work areas without additional direct monetary impacts, with existing staff taking on additional responsibilities. As a result, it is assumed that there are no further transition costs that need to be accounted for. Sensitivity testing in paragraph 85 shows the main recommendation of this Impact Assessment to be not sensitive to this assumption.

75. Continuation of good CD management can lead to a possible initial increase in acquisitive crime (resulting from prevented worsening of CD management). This effect has not been quantified. Over time, good CD management should reduce the total number of people with a drug misuse problem. As a result, the initial increase in acquisitive crime should reverse over time as the total number of drug users decreases, as explained in paragraph 62. No additional unquantified costs have been identified. This Impact Assessment is viewed to account for the full real cost of implementation of Option 4.1.

E.2.6. Cost and benefit summary for Option 4.1

76. As explained in paragraphs 36 and 60, the quantified benefits of Option 4.1 are considered to be of the lowest magnitude amongst the identified benefits, whereas the monetised costs are expected to overstate the true cost of this option. As a result, the net benefits reported in this Impact Assessment are expected to be significantly lower than the true benefits. Nonetheless, the analysis presented here suggests that the quantified benefits alone justify the additional regulatory burden imposed by the CD AO roles and the LIN functions.

77. The table on the following page summarises the monetised costs and benefits identified under Option 4.1.

[33] It should be noted that the new Regulations propose that the armed forces in England and Scotland appoint CDAOs. This is included at the request of healthcare professionals at the Ministry of Defence in order to promote better liaison and co-operation between armed forces personnel, the NHS and other local interested organisations when CD issues or concerns arise. No significant impacts are expected to arise for the armed forces as a result of this new requirement. CDAO functions and responsibilities will be absorbed within senior armed forces personnel's existing duties.

Table 11: Summary of costs and benefits under Option 4.1

Option 4.1	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Benefits (£, 000s)										
Prevented increase in diversion (pecuniary motives)	UNQUANTIFIED									
Prevented increase in wilful harm (Shipman)	UNQUANTIFIED									
Prevented Impact on Smaller Organisations	UNQUANTIFIED									
Prevented Reduction in Patient Health	2,725	5,614	8,590	8,848	9,113	9,387	9,668	9,958	10,257	10,565
Prevented increase in NHS Costs	114	235	359	370	381	392	404	416	429	442
Total	2,839	5,849	8,949	9,218	9,494	9,779	10,072	10,374	10,686	11,006
Discounted	2,839	5,758	8,673	8,795	8,918	9,043	9,171	9,300	9,431	9,564
PV Benefits	81,492									
Costs (£, 000s)										
Transition	UNQUANTIFIED									
Comm. Board AOs	3,610	3,666	3,722	3,780	3,838	3,897	3,957	4,018	4,080	4,143
Discounted	3,610	3,542	3,475	3,409	3,344	3,281	3,219	3,158	3,098	3,039
PV Costs	33,176									
Net Present Value	**48,316**									

E.3. Option 4.2

E.3.1. Benefits

78. The benefits identified under Option 4.1 are assumed to be unchanged under Option 4.2. This assumption is based on a lack of evidence for any different effectiveness in the delivery of the current PCT CD AO coordination functions. Under both Options 4.1 and 4.2, the majority (bordering on the entirety) of the identified benefits are realised through the functions delivered by LINs. The increased resources required under Option 4.2, as identified below, do not contribute to improved LIN function delivery or efficiency. In other words, once established and meeting the optimal operational human resource requirements, the benefits of information sharing through LINs do not increase in line with staff levels. As a result, the additional staffing requirements and costs under Option 4.2 are assumed to not create any additional benefits.

E.3.2. Costs

79. Building on the assumptions outlined in paragraphs 67-75, the scenario developed under this option assumes that each CCG would create a separate CD OA role with the corresponding support staff. This would create burden equivalent to 212 PCT AOs positions, estimated at £7,65m (i.e. 212 x £36,102). As explained in paragraph 69, there is insufficient evidence to justify an alternative costing

methodology for Option 4.2 than the one employed for quantification of Option 4.1. The table below outlines these costs.

Table 12: Summary of costs under Option 4.2

Costs (£, 000s)	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Clinical Comm. Groups	7,654	7,771	7,891	8,013	8,136	8,261	8,389	8,518	8,649	8,782
Discounted	7,654	7,792	7,644	7,500	7,358	7,218	7,082	6,948	6,816	6,687
Present Value	70,332									

E.3.3. Cost and benefit summary for Option 4.2

80. The conclusions developed for Option 4.1 (see paragraph 76) are also true for Option 4.2. The difference in net present value between the two quantified options is due to the higher regulatory burden associated with a larger number of CD AOs under Option 4.2, which amounts to £37.2m (equivalent to the unit cost per AO role, £36,102, multiplied by the differential in number of AO roles between the two options, i.e. 212 – 100 = 112).

81. The table below summarises the monetised costs and benefits identified under Option 4.2.

Table 13: Summary of costs and benefits under Option 4.2

Option 4.2	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Benefits (£, 000s)										
Prevented increase in diversion (pecuniary motives)	UNQUANTIFIED									
Prevented increase in wilful harm (Shipman)	UNQUANTIFIED									
Prevented Impact on Smaller Organisations	UNQUANTIFIED									
Prevented Reduction in Patient Health	2,725	5,614	8,590	8,848	9,113	9,387	9,668	9,958	10,257	10,565
Prevented increase in NHS Costs	114	235	359	370	381	392	404	416	429	442
Total	2,839	5,849	8,949	9,218	9,494	9,779	10,072	10,374	10,686	11,006
Discounted	2,839	5,758	8,673	8,795	8,918	9,043	9,171	9,300	9,431	9,564
PV Benefits	81,492									
Costs (£, 000s)										
Transition	UNQUANTIFIED									
Comm. Board AOs	7,654	7,771	7,891	8,013	8,136	8,261	8,389	8,518	8,649	8,782
Discounted	7,654	7,792	7,644	7,500	7,358	7,218	7,082	6,948	6,816	6,687
PV Costs	70,332									
Net Present Value	**11,160**									

F. Summary, sensitivity testing, and conclusion

82. As recognised in paragraph 32, both Option 4.1 and 4.2 are viable mechanisms to deliver upon the policy objectives. This impact assessment has demonstrated that, based on the available evidence, Option 4.1 has a higher NPV and is estimated to be more likely to deliver better value for money.

83. In line with the considerations mentioned in paragraph 38, it is important to ensure not only that the preferred option has a positive NPV, but also that it justifies redirecting NHS resources away from alternative uses. In particular, because this analysis identifies NHS as the only body bearing any additional costs, it has to be shown that the identified benefits exceed the costs by a margin equal to or greater than the opportunity cost of NHS funding. For Option 4.1, with £81.5m benefits and £33.2m costs, each £1 spent generates £2.46 of benefits (i.e. a benefit-to-cost ratio of 2.45 to 1). For Option 4.2, the ratio is 1.16 to 1. For both options a positive benefit to cost ratio is expected, however the potentially large scale of unquantified benefits should result in either option meeting the minimum benefit to cost ratio threshold.

Sensitivity Testing

84. The main assumptions underpinning the analysis, as examined in this section, are thought to be prudent. Sensitivity testing presented below reaffirms the robustness of the overall results and recommendations of this Impact Assessment.

85. The benefits of continuing the PCT CDAO functions by establishing CDAO responsibilities at the Commissioning Board LATs would outweigh the costs associated with this policy option in each of the scenarios considered below.

- The level of prevented increase in patient harm is currently assumed at 5% of the current number of Patient Safety Incidents (PSIs). As explained in Annex C, this is considered as a robust assumption. The preferred option remains value-for-money even if the prevented increase in patient harm was reduced by 60% from 5% to 2%.
- Because of the inherent under-reporting evident in self-reported data (such as the NRLS dataset used in this analysis), it is essential to correct for underreporting to arrive at the true magnitude of the effect in question. As explained in paragraphs 46-47, current reporting levels are assumed at 7% of actual events - two times higher than highest literature estimates. If the proportion of the true number of all incidents was as high as 17%, this would reduce the likely benefits achievable from 81.5m to £33m, i.e. then the NPV would be zero.
- Based on the proportion of PSIs from a randomly selected sample, the analysis currently assumes 20-45% CDAO involvement in PSIs, depending on their severity (higher involvement rate in more serious incidents). In line with the consultation responses and the results of the second AO survey concerning the clinical governance and oversight of CDs, it may be argued that the current involvement rates are too low and should be increased up to 100% for the most serious PSIs (severe harm and death). If this were the case, the NPV would increase almost 3-fold to £144m.
- There is a risk that the current analysis over-states the Quality-Adjusted Life Expectancy of those who die, as it is based on the population-wide average life expectancy adjusted for age (70 years for those who die). A large number of individuals suffering death as a result of a CD-related PSI are probably below the population-average life expectancy at the age of 70. Taking this assumption to the extreme, we may suggest that these individuals would have died even without a serious incident. If the death category is eliminated from the analysis, the preferred option remains value-for-money with an NPV of £18.85m.
- Some consultation responses suggested that the average cost approach developed in this analysis may under-state the true underlying costs of AO and support staff posts. Even with the suggested 2-fold increase in costs, the preferred option remains value-for-money with an NPV of £15.1m.
- The above considerations are summarised in the table below:

Table 14: Break-point analysis

	Option 4.1			Option 4.2		
Assumption Tested	Currently Assumed	Break-Even Point (NPV = 0)	% Change Needed for NPV < 0	Currently Assumed	Break-Even Point (NPV = 0)	% Change Needed for NPV < 0
Prevented Increase in Patient Harm	5%	2%	60%	5%	4%	20%
Level of Under-Reporting	7%	17%	143%	7%	8%	114%
Proportion of CDAO Involvement	20-45%	Up to 100%	N/A (increases NPV)	20-45%	Up to 100%	N/A (increases NPV)
QALY for Death Sufferers	11.77	N/A (NPV always > 0 for all values)	N/A	11.77	7.31	38%
Average AO Post Costs	£36k	£88k	145%	£36k	£42	16%

86. The above analysis suggests that the policy recommendation is relatively independent of the sensitivities surrounding the main assumptions. Please note that due to the higher underlying Net Present Value of Option 4.1 over 4.2, none of the sensitivities and assumptions tested above suggest that Option 4.2 would become more beneficial than 4.1. As a result, the sensitivity testing reinforces the recommendation presented in this Impact Assessment of Option 4.1 being more beneficial than Option 4.2. For Option 4.2 to command a higher NPV than Option 4.1, its benefits would have to increase by almost 50% (i.e. by £40m), with the benefits of Option 4.1 remaining unchanged.

Annex A

Specific Impact Tests

87. The Department has identified the following specific impacts in relation to the proposals concerning the safe management and use of controlled drugs.

Equality assessment

88. This is published separately to the Impact Assessment.

89. However, no specific impacts on the equality duty have been identified nor as a result of consultation.

Health Impact Assessments (HIA)

Will the proposal have a direct impact on health, mental health and wellbeing?

90. Yes. These impacts are discussed in the background and explanatory text of the Impact Assessment.

Will the policy have an impact on social, economic and environmental living conditions that would indirectly affect health?

91. None has been identified beyond what has been described in the analysis above.

Will the proposal affect an individual's ability to improve their own health and wellbeing?

92. Yes, indirectly. These are discussed in the background and explanatory text of the Impact Assessment. For example, action to ensure good governance and best practice in the clinical use and management of controlled drugs can be expected to yield beneficial results for individuals who use or require access to such medicines. By carrying forward the current governance arrangements, health professionals with addiction problems may be offered help more quickly where problem misuse gives rise for concern locally.

Will there be a change in demand for or access to health and social care services?

93. No significant change is anticipated.

Will the proposal have an impact on global health?

94. None has been identified.

Sustainable Development/Carbon Assessment

95. No specific impact has been identified.

Small Firms Impact Test and Competition Assessment

96. The proposed regulations will, as now under the current regulatory regime, continue to apply to both the private and voluntary sector where they provide services from facilities that are designated in the regulations as required to appoint a Controlled Drugs Accountable Officer (CDAO). The principal type of facility affected is a hospital. This includes some facilities which may be run by independent, voluntary or other organisations but which provide respite and/or palliative care for patients or other types of clinical services but nonetheless fall within the definition of a "hospital" as set out in Regulations 3 and 4. Some of these will be small or medium-sized enterprises.

97. The requirement to appoint a CDAO applies to all such facilities which fall within the definition of a "hospital" and carry forward an existing requirement from the 2006 Regulations. This is set out in regulations 3 and 4.

98. Representatives from the independent and voluntary sectors were members of the Working Group which helped draw up the current draft regulations.

99. It was recognised that this current requirement may impose undue burdens on those facilities which are, for example, small, or where the use of controlled drugs does not represent a significant part of the facility's activities.

100. Regulations 3(3) and (4) and 4(2) and (3) now provide that the English and Scottish bodies responsible for maintaining a list of all CDAOs (the Care Quality Commission – CQC, Health Improvement Scotland - HIS) may, on application, agree that the facility can dispense with the need not to appoint and to register a CDAO.

101. This dispensation will apply where CQC or HIS decides the facility is to be exempt from the requirement to appoint a CDAO. This means CQC or HIS is satisfied that there would be disproportionate difficulties for the facility if it was required to appoint a CDAO. The criteria CQC and HIS will take into account in reaching such a decision are:

- The number of staff;
- The usual level of controlled drug activity at the facility; and
- Any difficulties, in relation to its overall business size, that the facility would have in appointing a suitable individual to be the CDAO.

102. CQC and HIS may review their determinations and renew or rescind them.

103. This new measure is expected to substantially ameliorate the need for SMEs to appoint a CDAO and offers CQC and HIS the opportunity to review, on application, existing SME facilities that have appointed a CDAO under the 2006 Regulations.

104. Otherwise, it is not expected that independent and voluntary sectors firms will incur any significant additional costs as a result of these proposals – and therefore there is no reason to expect any disproportionate cost impact for small businesses.

Competition Assessment

Would the proposal directly limit the number or range of suppliers?

105. The proposals are not expected to have a direct impact on the number or range of providers of healthcare or related services.

Would the proposal indirectly limit the number or range of suppliers?

106. The proposals are not expected to have an indirect impact on the number or range of providers of healthcare or related services.

Would the proposal limit the ability of suppliers to compete?

107. The proposals are not expected to have an impact on the ability of potential providers of healthcare or related services to compete.

Would the proposal reduce the incentives of suppliers to compete vigorously?

108. The proposals are not expected to have an impact on incentives for providers of healthcare or related services to compete.

Local Authority Burdens

109. No new burden has been identified. Local authorities are already included as a statutory member of the Local Intelligence Networks currently run by PCT CDAOs. This requirement continues under the new Regulations.

One In One Out (OIOO)

110. These regulations consolidate, update and reform the Controlled Drugs (Supervision of Management and Use) Regulations SI 2006/3148. They cover England and Scotland. Northern Ireland and Wales have separate but equivalent legislation. As set out in paragraphs 40 and 70, we estimate a zero net impact on business and civil society organisations.

Micro Enterprise Exemption from Regulation

111. No new burdens are proposed for micro or start-up enterprises which aim to provide health care services that involve the use of controlled drugs.

112. We are exempting in the final Regulations all micro and start-up enterprises with fewer than 10 employees from the requirement to appoint a CDAO in England and Scotland. The NHS CB and Health Board CDAOs will have responsibility for ensuring such enterprises adopt good CD governance systems where they provide NHS services.

113. In addition, the measures described in paragraphs 100 et seq above will substantially mitigate any such burdens for larger start-up enterprises by enabling, on application, CQC and HIS not to require them to appoint CDAOs where they meet the criteria set out in paragraph 101. Nonetheless, if such larger start-up enterprises choose to set up facilities where the use of controlled drugs forms a significant part of the activities of the enterprise or of individual health professionals engaged there, it is prudent that the CQC and HIS, as appropriate, should be able to determine whether such enterprises need to ensure good governance in that facility by appointing a CDAO.

Sunset Provisions

114. The Regulations contain a sunset provision of 2020. This is on the assumption that the Governments of the day will wish formally to review the working of these Regulations prior to that date and determine whether they should continue, in part or in full, or whether they should lapse.

115. Such a review is expected to test the evidence that the independent, voluntary and NHS sectors demonstrate good governance and compliance, such that the need for regulations to require these bodies to appoint CDAOs is no longer necessary.

116. Such a review is also expected to consider how inspections and investigations, and the sharing of relevant information within local intelligence networks (LINs) might be secured once these Regulations lapsed. Currently, for example, the ability of LINs to share sensitive or confidential information about individuals without risking breach of the Data Protection Act 1998 is best secured through legislation.

Privacy Impact Assessment

117. This policy involves the processing of personal information by LINs to the extent described in paragraph 116 above. As such, this is permitted under the Data Protection Act 1998 because of the need for a range of local bodies to be able to share through LINs information and concerns about the possible misuse of controlled drugs locally as set out in the regulations.

Environmental and sustainability impacts

118. None has been identified.

Human Rights

119. No significant impact on human rights has been identified.

Justice system

120. No significant impact has been identified. However, it should be noted that no right of appeal against a decision by the CQC or HIS requiring (or not requiring) an organisation to appoint a CDAO is proposed. However, this is not expected to generate a significant increase in workloads for the justice system.

Rural proofing

121. The policies proposed here will apply equally in rural and non-rural areas. No significant impact has been identified concerning rural communities or those who live there.

Consultation

122. The 2006 Regulations formed part of the Medicines Theme of the 'Red Tape Challenge' which ran from 8th March to 12th April 2012. Comments received to that Challenge and the Department's proposed response were included as part of the formal public consultation documents on the

proposed reforms to the 2006 Regulations which ran from 27th September to 15th November 2012. 93 further comments were received and the Department is publishing a summary of those comments and its response alongside the final 2013 Regulations. The majority of respondents had no comments on the consultation Impact Assessment. Where comments were received, these concerned primarily (a) the derivation of the assumed 5% prevented increase in patient risk, and (b) a possible under-estimation of LAT costs under Option 4.1. We have accepted and amended the final Impact Assessment in order to reflect these. In particular, for (a), Annex C provides an illustrative derivation of the level of prevented patient harm, and, for (b), the cost calculations in Option 4.1 have been adjusted to reflect a potentially larger number of AO posts (and therefore higher costs) that the NHS Commissioning Board may decide to appoint as set out in paragraph 72.

Annex B

Adverse health outcomes – EQ-5D analysis

1. The EQ-5D framework[34] developed by EuroQol is used to measure the severity of the hazards outlined in Table B1. The model is designed to give an estimate of how individuals rate their quality of life using a questionnaire with five independent domains: mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Each of these domains is rated using a discrete scale between 1 (representing no problems) and 3 (representing severe problems). Scores are then translated into a quality-of-life score using regression analysis, in order to give a continuous value between 1 (representing someone in perfect health) and -0.594 (representing someone with considerable and severe problems). Death is associated with a health state of zero.

Table B1 – National Patient Safety Agency NRLS Patient Safety Incidents by severity category

Hazard Severity	Description	Representative Condition
No Harm	No treatment or follow-up required;	Lack of signature on a prescription;
Low Harm	Requires only first-aid level treatment;	Examination, reassurance;
Moderate Harm	Harm that requires extra healthcare investigation, observation or treatment, but does not lead to permanent disability;	Application of out-of-date medication leading to emergency admissions;
Severe Harm	Event that causes permanent disability;	Wrong dose or formulation of medication leading to permanent disability;
Death	Harm leading to patient death;	Incorrect medication or dosage;

2. To derive the severity of adverse incidents, representative health states and corresponding answers to the EQ-5D questionnaire have been developed, taking into account input from the CD Working Group and the NPSA. These are assumed to be illustrative of an individual experiencing each of the hazards identified in Table B1. For instance, a severe health loss may be described by an EQ-5D score of 11231 (indicating some problems with usual activity and severe pain/discomfort), which translates into a 40% reduction in one's quality of life. Table B2 summarises the EQ-5D severity assumptions, together with examples of health states in each category.
3. In line with the NRLS data, the average patient is estimated to be 54 years old, with patients suffering death having a higher average age of 70 years. Therefore, the initial patient health state should reflect the average quality of life score for the representative age group. Using figures derived in the Illness Atlas for EQ-5D (Macran and Kind, 2005), it is estimated that the average patient's health state corresponds to a Quality of Life (QoL) score of 0.845[35] (as opposed to a score of 1 for a perfectly healthy person).
4. Accounting for the above considerations, the absolute health loss derived from the EQ-5D model is lower than for a perfectly healthy person suffering from the same adverse event. For example, an incident bringing down a patient's QoL to 0.705 is not treated as bringing it down by 0.295, but rather by 0.14 (= 0.845 - 0.705). However, it is acknowledged that such a reduction in one's QoL is proportionately more severe for individuals starting out from a lower health state. Thus, the severity of the above health loss adjusted to represent proportionate decline in health, compared to the initial QoL, arriving at 0.166 (health loss divided by initial health state = 0.14 / 0.845). The assumptions used to develop the ratings are compiled in Table B2[36].

[34] For a detailed explanation of the EQ-5D model, please see: http://www.euroqol.org/eq-5d/what-is-eq-5d.html

[35] The QALY adjustment for the death sufferers, who have a much higher average age, is reflected in their reduced Quality-Adjusted Life Expectancy reported in Table B2.

[36] Not accounting for the proportionality of health decline results in an approximate £7.6m reduction in NPV of both options, arriving at an NPV of £40.7m and £3.6m for Options 4.1 and 4.2 respectively.

Table B2: EQ-5D assumptions by severity of patient harm

Hazard Severity	EQ-5D Scoring Assumptions	Average QALY Loss	Average Duration
No Harm	21211	0	N/A
Low Harm	21212	0.1207	1 week
Moderate Harm	Midpoint between: 21212 and 22222	0.255	1 month
Severe Harm	Midpoint between: 22222 and 33311	0.6781	20.45[37]
Death	N/A	1[38]	11.77[39]

[37] Quality-adjusted life expectancy at 54 years of age

[38] Reflects a fall of QoL to zero. Note, that shorter duration adjusts for lower initial QoL, reflecting the correct health loss resulting from death

[39] Quality-adjusted life expectancy at 70 years of age

Annex C

Marginality of benefits

1. As explained in section A.5 of the IA, current PCT CDAOs, whose functions would cease to exist under the do-nothing option, are responsible for both (1) running the Local Intelligence Networks, and (2) providing CD oversight in small organisations that otherwise do not appoint their own CDAOs (see paragraphs 14-16). In effect, if the PCT CDAO roles were not replicated in the new NHS structures, both of these benefits would disappear. The local oversight of small organisations may not disappear completely if some of the AO functions become re-established locally – for a fuller discussion of this issue see paragraphs 35, 40, and 70.
2. In particular, paragraphs 42 and 43 discuss the marginality of risk increases in the absence of PCT CDAO roles. The resulting risk mitigation provided by replicating PCT CDAO functions, as discussed in paragraphs 53-55, is established against a baseline of local CDAOs retaining their current functions. This is why the prevented risk increase is assumed at 5% of the total Patient Safety Incidents, rather than a much higher proportion that would reflect discontinuation of all CDAO roles.

Illustrative derivation of prevented patient harm (5%)

3. In order to arrive at an illustrative derivation of prevented patient harm, the current level of Patient Safety Incidents that can be mitigated by all CDAOs has been estimated (see paragraph 54) and then a simple proportion that could be attributed to PCT CDAO roles and functions calculated. For simplicity, if removal of all Accountable Officers would increase the level of patient harm in the system by 50% and each non-PCT CDAO was assumed to contribute to risk mitigation equally, then PCT CDAOs should mitigate 50% x 100/1112 = 4.5% of patient risks (proportion of total risk mitigation x number of PCT CDAOs / total number of CDAOs). Because PCT CDAOs also establish and run LINs, their contribution is expected to be proportionately larger than that of an 'average' AO. Assuming a 50%[40] higher risk mitigation associated with each PCT CDAO, the 4.5% becomes 6.45% (50% x (100 x 150%) / (1112 + 100 x 50%)).
4. It is important to note that the Local Intelligence Network coordination function that PCT CDAOs carry out corresponds to benefits that are proportionately larger than non-PCT CDAOs organisation-level functions. Therefore, the estimated 6.45% prevented increase in the number of PSIs calculated above almost certainly under-estimates the true effect of discontinuing the PCT CDAO roles. This coordination function would cease to exist under the do-nothing option, even with all the non-PCT CDAOs maintaining their functions.
5. As a result of the above, the assumed 5% risk increase used in the IA, resulting from the discontinuation of PCT CDAOs, is viewed as being conservative, therefore underestimating the prevented patient harm and the benefits of Options 4.1 and 4.2 relative to the do-nothing option.

[40] This is only illustrative and almost certainly underestimates the importance of the LIN-oriented PCT CDAO roles.