

Red Tape Challenge

The Controlled Drugs (Safe Management and Use) Regulations 2006

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Summary

Controlled drugs (CDs) are essential to modern clinical care and include medicines such as diamorphine that are used in a wide variety of clinical treatments. CDs are controlled under Home Office legislation - the Misuse of Drugs Act 1971. The main purpose of the Act is to prevent the misuse of CDs. It does so by imposing a complete ban on unlawful possession, supply and manufacture of CDs. Therefore, access to CDs for healthcare is regulated under the Misuse of Drugs Regulations (MDR) 2001. The MDR govern the legitimate clinical use of CDs.

Following the Fourth Shipman Inquiry report of 2004, the previous Government accepted the need to strengthen the arrangements for the use and management of CDs in the community, and to do so in a way which did not hinder patients from accessing the treatments they need. The Government of the day therefore took necessary powers set out in sections 17 - 25 of the Health Act 2006. These powers include the establishment, functions and responsibilities of Controlled Drugs Accountable Officers (CDAOs). These provisions were drawn broadly and left detailed implementation to regulations. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 ("the 2006 Regulations") came into force in England in January 2007 and Scotland in March 2007. The Regulations have not been amended substantially since.

The 2006 Regulations were part of the Medicines Theme regulations scrutinised under the Red Tape Challenge (RTC). The RTC is a public review of all domestic secondary regulations affecting business, civil society organisations or citizens in England. It is hosted by the Cabinet Office. The Regulations were posted on the RTC website from 8th -March – 12th April 2012 for the public, citizens, businesses, charities to comment. Subsequently, DH consulted on amendments to the 2006 Regulations. Consultation ran from 27th September – 15th November 2012. DH is publishing a summary response to that consultation alongside this final response to the RTC.

The comments received under the Medicines Theme are arranged into 8 sections based on common themes. Given the close links with Home Office CD legislation, these have been shared, and the responses agreed, with the Home Office.

Comments in sections 1 and 2 concern the continuation and future roles of CDAOs in the new NHS structure under the Health and Social Care Act 2012 and what impact this may have on organisations. These include suggestions to reduce the burdens that the 2006 Regulations place on professionals, the need for reform to take account of NHS changes and to simplify future regulations. In addition, comments were received on how the role and functions of the CDAO should be simplified and applied more consistently across the country. Comments received in sections 3 to 8 primarily concern Home Office legislation, although they are relevant to CDAO matters. They include comments on the prescribing of CDs, safe CD storage requirements, including storage of expired stock, record-keeping and destruction of CDs.

Department of Health, Medicines Pharmacy and Industry

Home Office, Drug Legislation Team

February 2013

1. Comments concerning the 2006 Regulations

Comment	DH Response	Home Office Comments
<p>1.1 The 2006 Regulations sit on top of the original Misuse of Drugs Act 1971 and the Misuse of Drugs (Safe Custody) Regulations 1973. In adding to these regulations rather than causing them to be reviewed, they perpetuate out of date regulations and cement rigid process and procedure rather than applying a flexible and responsive approach in the patient interest. In essence the regulations do not work for the following reasons:</p> <ul style="list-style-type: none"> • Out of date regulations that have been in existence since early 70s • Overbearing and unnecessary duties; CDAOs have been made responsible for overseeing every aspect of CD prescribing, usage and administration within their trust. In addition, to right of pharmacy inspection that is over and above the GPhC's [General Pharmaceutical Council's] inspections. • Adding burden and bureaucracy such as SOPs [Standard Operating Procedures]. <p>In conclusion, the 2006 Regulations do not add to patient safety, nor prevent another Shipman disaster but add significantly to the burden of administration for community pharmacies. In</p>	<p>We appreciate the sentiment set out here. However, it is important to note that the legislative systems referred to have fundamentally different objectives.</p> <p>Controlled Drugs (CDs) are governed by Home Office legislation - the Misuse of Drugs Act 1971 and the Misuse of Drugs (Safe Custody) Regulations 1973 as amended. Their primary purpose is to prevent the unauthorised supply and use of certain drugs which are, under the UN Convention on Narcotics to which the UK is a signatory, deemed dangerous and which have the potential to be misused and/or to cause harm.</p> <p>However, recognising the important place that many controlled drugs have in patient treatment, access to CDs for healthcare is regulated under the Home Office's Misuse of Drugs Regulations (MDR) 2001. These govern the legitimate clinical use of CDs in the UK.</p> <p>The 2006 Regulations governing the safe management and use of controlled drugs, for which the Department of Health is responsible, were introduced under the previous administration in response to recommendations made in the Fourth Shipman Inquiry Report.</p> <p>The 2006 Regulations provide a three-part</p>	<p>The Home Office works closely with the Department Health to keep provisions under the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") under review. Both the Home Office and the Department of Health are committed to ensuring that controlled drug regulations provide an effective framework which enables access to controlled drugs whilst minimising the risk of diversion and misuse.</p> <p>The Home Office consults its independent experts, the Advisory Council on the Misuse of Drugs (ACMD), for their recommendations for reform of the legislative framework on controlled drugs.</p> <p>The Department of Health will continue to support Home Office action to review and, wherever possible and provided this does not compromise patient or public safety, streamline and simplify the 2001 regulations and the associated administrative requirements.</p> <p>The Home Office will consider proposals for change where there is a clear and compelling professional and/or policy need to act, as happened with recent changes to enable the independent prescribing of controlled drugs by qualified pharmacist and nurse independent prescribers.</p> <p>The Home Office consulted on proposals to</p>

the short term, the regulations need to be streamlined and then for a full review of the Misuse of Drugs Act resulting in the Department of Health having the responsibility for the Act rather than the Home Office.

framework for CD governance.

First, they designate the bodies which must appoint a specific individual as a Controlled Drug Accountable Officer (CDAO) and set out their duties and powers.

Second, they provide the necessary powers for NHS Primary Care Trusts' (in Scotland, Health Boards') CDAOs to enter premises and to carry out inspections.

Third, they introduce a duty on designated "responsible" bodies (such as PCTs, Health Boards, local authorities, the police and regulators) to co-operate in sharing information where there are concerns about local CD practices and for PCT and Health Board CDAOs to create Local Intelligence Networks (LINs) for this purpose.

Their primary purpose is to strengthen and improve the governance arrangements for CDs, in order to reduce the risks to patient safety and of their inappropriate use.

Monitoring of and compliance with the requirements of the 2006 Regulations is carried out in England by the Care Quality Commission (CQC) in the form of annual reports to Government. Overall, the CQC has found that the safer management and use of CDs have now become embedded into most organisations' structures.

The Department considers that the role of the

consolidate and review specific provisions under the 2001 Regulations in late 2011. When implemented, these proposals will lighten the burden on healthcare professionals and providers, including removing burdens associated with requisitions on specific healthcare organisations, providing authority for NHS ambulance trusts to possess and supply controlled drugs to healthcare professionals employed by the trust and streamlining the processes used by midwives to acquire and use controlled drugs.

Drug misuse is one of the key drivers of crime in the UK. The Home Office has responsibility for policing and crime policy in the UK. It is therefore important that the responsibility for drug legislation continues to sit with the Home Office to ensure a consistent approach to tackling crime and one of the major causes of crime.

	<p>CDAO has raised and strengthened the organisational governance concerning the use of CDs. The CQC has found in their annual reports that these roles have reduced the opportunity for poor CD management practices to prosper. The CQC has also highlighted examples of improving practice in their most recent annual report for 2011. Their reports are available at www.cqc.org.uk</p> <p>The Department agrees that it is questionable whether governance systems, such as the current regulatory model, would ever entirely eliminate the risk of a determined individual diverting CDs for serious criminal use, as was the case with Harold Shipman. However, the evidence to date indicates that the current arrangements offer a greater degree of protection for patients and have reduced the scope for CD diversion than existed before.</p> <p>Nonetheless, the Department considered that there was considerable scope to review and simplify the 2006 Regulations. With this aim, the Department established a small multi-disciplinary Working Group in early 2012 to undertake this work and to make recommendations to DH Ministers, including on how best the functions of PCT CDAOs might continue once new NHS structures in England take effect from April 2013. The Group considered the responses received to the Red Tape Challenge and completed its work in July 2012. Earl Howe, the Minister of State for Quality, accepted in full the Group's</p>	
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	<p>recommendations. Scottish Government Ministers also agreed similar proposals for reform of the 2006 Regulations concerning Scotland.</p> <p>The Department and Scottish Government therefore consulted on the Group's final proposals. This ran from 27th September to 15th November 2012.</p> <p>As a result, DH and Scottish Government Ministers have confirmed that revised and improved Regulations are to come into force from 1st April 2013 to reflect the new NHS structures in place in England from that date. DH is publishing a summary response to the consultation alongside these Regulations.</p>	
<p>1.2 This legislation will need to be revised with the impending abolishment of PCTs. With the changes to the NHS, more organisations are being formed that are not currently required to have a CD accountable officer. This should be corrected.</p>	<p>We agree the need to revise the 2006 Regulations. It has been necessary to decide how best existing CDAO responsibilities and functions can most effectively be deployed within new NHS organisational arrangements in England. CDAOs need to be able to work efficiently and flexibly across a variety of clinical settings, from large hospitals to smaller community settings, to fulfil their functions and duties. However, we do not believe all such new and emerging organisations should be required to appoint CDAOs in future. For example, new micro-business and start-up enterprises in England and Scotland with fewer than 10 employees should not be required to appoint CDAOs. The amendment Regulations also confirm that the regulators, CQC and Health Improvement Scotland, can, on application,</p>	

	<p>exempt organisations with larger workforces from the requirement to appoint a CDAO, subject to certain criteria. Please also see the response in Section 1.1 above.</p>	
<p>1.3 Too much of a problem, which again just puts blame on pharmacists. Have regulations that pharmacists can choose to apply rather than enforced on them. Give pharmacists opportunities to apply knowledge gained. Let us not be imposed with such regulations that were initiated by the wrongdoing or errors of other professions.</p>	<p>The Working Group referred to in Section 1.1 above found that the interpretation of the 2006 Regulations by some CDAOs had focused too heavily on securing the safety and security of CDs rather than optimising their safe clinical use. It therefore recommended that this balance should be re-dressed, placing equal emphasis and focus on the safe clinical use as well as the security of CDs. This is reflected in the amendment Regulations. However, it is important that regulatory requirements are applied consistently and uniformly. To that extent, the Regulations do not admit a greater element of professional discretion as to whether or not to apply them. Nonetheless, we will continue to seek ways in which undue bureaucratic burdens can be removed or reduced, to offer non-regulatory solutions as appropriate and to promote the application of professional knowledge and skills to reflect current best practice.</p>	
<p>1.4 The CD Regulations have to be simplified to deliver the contract and not scare the pharmacist or make them nervous. It is time to make them simple, friendly and less manpower intensive.</p>	<p>We agree. Please see the response in Sections 1.1 - 1.3 above.</p>	
<p>1.5 Regarding Controlled Drugs, currently many multiples operate by an unofficial policy</p>	<p>The Department wishes to promote a culture of openness and learning from which all health</p>	

<p>of presumed guilt. The number of incidents involving CDs could possibly be attributed to a culture of blame created by employers, so that some pharmacists are known to have tried changing CD balances or tried other creative ways to cover up mistakes.</p>	<p>professionals can learn. At the same time, we cannot condone any system which attempts to “cover up” mistakes concerning CDs or any other medicine from which valuable lessons for all health practitioners can be drawn.</p> <p>The Medicines and Healthcare products Regulatory Agency, which regulates medicines in the UK, is exploring how best to review the current penalties and sanctions in medicines legislation (including those relating to dispensing errors), taking into account the respective roles of medicines legislation and professional regulation. The Royal Pharmaceutical Society is continuing work to support a “just culture” where mistakes are made.</p>	
<p>1.6 Furthermore, the enforcement of CD regulations is not always equal. Many of us have received scripts that have been incorrectly written. This of course creates all sorts of problems, legal and clinical, yet pharmacists are treated with a much heavier hand for breach of CD regulations. The importance of these regulations should be reinforced to prescribers as well, either through education or by other means.</p>	<p>We sympathise with the views expressed here. Please see the response to Sections 1.1 - 1.5 above.</p>	
<p>1.7 The CD regulations are burdensome, but I don't see any way in which they could be simplified.</p>	<p>Please see the responses to Sections 1.1 - 1.5 above.</p>	
<p>1.8 Controlled drugs legislation needs to be</p>	<p>We agree. Please see the responses to Sections</p>	

<p>simplified. At the moment, it is more about the bureaucracy of having certain pieces of information filled in rather than safeguarding the public. More emphasis should be on a pharmacist's professional judgment rather than making a pharmacist have to send a prescription back to a prescriber for small errors.</p>	<p>1.1 - 1.5 above.</p>	
<p>1.9 The regulations need a review as currently a disproportionate amount of time and effort is spent making and keeping records that will not support an investigation should another Shipman come along.</p>	<p>We agree. Please see the responses to Sections 1.1 – 1.5 above.</p>	
<p>1.10 The red tape regarding CDs that came in after the Shipman case seemed to be something to appease the general public – it certainly would not prevent a repeat of the previous situation. It complicates the process unnecessarily and creates all kinds of problems. The only issues that ever seem to occur with CDs are balance discrepancies, which are constantly being investigated, ALL the time. Nobody is ever caught at the end of these (although usually it was just a mistake – but that's exactly the point, why did somebody else have to go through weeks of stress due to some enquiry and visits from senior management figures who took them through a series of interviews – at the end of which it transpires that everything was just an innocent mistake).</p>	<p>Please see the response to Sections 1.1 - 1.5 above.</p>	<p>Matters concerning CD registers, running balances, record keeping and storage come under Home Office legislation. Please see the response in Section 1.1 above and Sections 2 and 3 below.</p>


How is this benefitting the public? It isn't. How is it ACTUALLY preventing theft/abuse in pharmacies? How is it preventing future Shipmans doing what he did?

All it is doing is:

- 1) adding useless bureaucracy
- 2) increasing stress for pharmacists constantly looking over their shoulders
- 3) increasing costs and resources within pharmacy, including time taken to complete registers, do CD balance checks weekly, perform costly enquiries etc.

It seems like there is someone with a roll of red tape in his hand who is slapping it down everywhere and anywhere he pleases, just for the sake of total randomness. If there was some kind of clear benefit I would advocate regulations but these regulations arrived just because of politics and now we have accepted them as a necessity of life.

How can we change them? I have no idea. I'm too tired and worn out by the way pharmacy as a whole is going and I have little hope in it moving in a positive direction where patient help is the driving force and not money. Hence, I have other sources of income which I have ventured into over the last few years. If pharmacy was my sole source of income I

<p>would sit down and think of a good solution but I do have options so I will not – it's too big a job, there's too much to change, and 99% of the profession simply go with the flow – I have accepted the fact that pharmacy rules and regulations will be directed by Corporate Power – it's just the world we live in, everything is eventually overrun by corporations.</p>		
<p>1.11 The CD regulations were tightened following the Shipman affair, partly with the intention of stopping another Harold Shipman. The current regulations will not do this. It is still possible for a GP to "remove for safe keeping/destruction" CDs from a deceased patients house, not make any record, and use them nefariously with little chance of being found out.</p> <p>I note that the pharmacist who regularly dispensed Shipman's prescriptions highlighted concerns to the appropriate authority - who took no action!</p>	<p>Please see the response to Section 1.1 – 1.5 above.</p>	
<p>1.12 In one small group I work for, the CD SOP is 35 pages long and this is just one of about 54 SOPs. They are just too detailed. When I get around to signing the new ones, I will probably append the following: "This SOP applicable only in matters over which I have control or influence and which impinge upon my normal daily duties as a pharmacist. The professional decisions of the pharmacist to override all</p>	<p>Please see the responses to Sections 1.1 - 1.5 above. The Working Group sympathised with the concerns expressed about a pharmacist's responsibility for different employers' standard CD procedures, and the degree and complexity to which these vary. The Group agreed that the current list of SOPs stipulated in regulation 9(3) of the 2006 Regulations was unnecessary and over-bureaucratic. A simplified requirement for CDAOs</p>	

SOPs when deemed appropriate by the pharmacist.” I think a rubber stamp will be necessary!!

to ensure they have relevant standard operating procedures is included in Regulation 11(3) of the final Regulations.

2. Comments on the role and function of the Controlled Drug Accountable Officer (CDAO)

Comment	DH Response	Home Office comments
<p>2.1 Are accountable officers of use or benefit? They seem to vary enormously in what they think their remit is. The [County] accountable officer seems to be much more of a law enforcement officer than the [neighbouring County] equivalent, often deeming "good practice" recommendations legal obligations.</p>	<p>Please see the responses to Sections 1 above. The final Regulations aim to provide a comprehensive and consistent framework which enables the safer use and management of CDs. At the same time, the Working Group recommended a number of ways in which the requirements can be better structured and simplified. Importantly, these are designed to achieve a better balance between promoting safe clinical practice and the security of CDs.</p>	<div style="background-color: #cccccc; height: 20px; width: 100%;"></div>
<p>2.2 Overbearing and unnecessary duties; CDAOs have been made responsible for overseeing every aspect of CD prescribing, usage and administration within their trust. In addition, the right of pharmacy inspection is over and above the GPhC's [General Pharmaceutical Council – the pharmacy regulator for Great Britain] inspections.</p> <p>Adding burden and bureaucracy such as SOPs.</p>	<p>Please see the response to Sections 1 and 2.1 above.</p> <p>The General Pharmaceutical Council is responsible for regulating pharmacists and pharmacy premises. The role of the CDAO is more limited and different as described in Section 1.1 above.</p>	



<p>2.3 There should be no need to have an Accountable Officer, as these duties should be undertaken by the Police and law enforcers.</p>	<p>There is a clear need for the police to be involved in enabling the safer management and use of CDs locally, for example, in sharing information about local CD concerns. However, it would not be appropriate to assign the full monitoring or governance functions and duties of the CDAO to local police as this lies beyond their experience and skills.</p>	<p>The police Controlled Drugs Liaison Officer and the CDAO both have a role to play in ensuring that the governance arrangements for CDs in the community are effective. However, the role of a CDAO goes beyond that of enforcement. The police cannot be burdened with the duties of the CDAO as they do not have the resource or expertise that the CDAO brings to the role.</p>
<p>2.4 Pharmacies are required to report controlled drug recording errors to the PCT. Accountable Officers at PCTs often change, making it time consuming for pharmacies to identify who the report should be sent to. Each PCT has its own methodology for reporting and there is a lack of consistency amongst Accountable Officers when dealing with reports.</p>	<p>Accountable Officers have a legal obligation, under regulation 10 of the 2013 Regulations to notify the Care Quality Commission (in Scotland, Health Improvement Scotland - HIS) of their appointment and of any subsequent changes. The CQC holds and publishes an up-to-date list of CDAOs on their website at http://www.cqc.org.uk/organisations-we-regulate/special-reviews-and-inspection-programmes/controlled-drugs/accountable-off</p> <p>HIS maintains a similar list for Scotland.</p>	<p></p>

3. Comments on the destruction of Controlled Drugs (CDs)

Comment	DH Response	Home Office comments
<p>3.1 The destruction arrangements for out of date CD stock causes some pharmacies problems with separate storage while awaiting the AO agent. Consideration should be given to the impact of relaxing this requirement to allow pharmacists to destroy in the same way as patient returned CDs, while maintaining adequate governance, to minimise risk to the public through inadequate storage facilities.</p>	<p>The storage and destruction of controlled drugs is governed by the Home Office Misuse of Drugs Regulations (MDR) under Regulations 27 and the Misuse of Drugs (Safe Custody) Regulations 1973.</p> <p>We sympathise with the problem set out here and elsewhere in this Section. The MDR require that when a controlled drug is destroyed, details of the destruction must be recorded including the signature of an authorised person who witnessed the destruction and the professional destroying it (i.e. two signatures).</p> <p>While awaiting destruction of expired controlled drugs, these drugs should be segregated and clearly marked “date-expired” stock to prevent them being issued in error to patients.</p> <p>Controlled Drugs Accountable Officers should ensure they have sufficient authorised witnesses to avoid build-up of expired or unwanted stock.</p>	<p>Please see the responses to Section 1.1 above and Section 5 below (storage), which apply to the whole of this Section.</p>
<p>3.2 If pharmacists are trusted to destroy patient-returned CDs, why not out-of-date CDs?</p>	<p>Please see the response in Section 3.1 above.</p>	
<p>3.3 Destruction of out of date controlled drugs should also be allowable without supervision of “accountable officers”. To suggest a qualified, registered professional pharmacist is incapable of destroying out of date stock when</p>	<p>Please see the response in Section 3.1 above.</p> <p>Regulation 27(1)(a) of the Home Office’s Misuse of Drugs Regulations 2001 states that CDAOs should not witness the destruction of controlled drugs.</p>	

<p>patient returned medications of the same category is perfectly acceptable is ludicrous. Counter-signing of the destruction by another registered technician or pharmacist would easily be adequate.</p>	<p>CDAOs who oversee community pharmacy and dispensing practices need to ensure they have sufficient authorised witnesses to avoid build-up of expired or unwanted CD stock in pharmacy and dispensing premises.</p>	<p>[Redacted]</p>
<p>3.4 Retention of out of date CDs increases likelihood of dispensing errors even when stock is segregated. The Responsible Pharmacist can destroy patient returned CDs with a witness present so why not out of date stock? The RP should be empowered to deal with these aspects of CD management. Pharmacists should be trusted enough to dispose of out of date CD stock</p>	<p>Please see the response in Section 3.1 above.</p>	<p>[Redacted]</p>
<p>3.5 Controlled drug regulations relating to destruction of stock are particularly unwieldy and time consuming, with the added possibility of unforeseen errors occurring in registers where out of date stock must be recorded alongside usable stock. We should be allowed to destroy out of date stock in the same way as patient returns, after all this often involves the exact same drugs.</p>	<p>[Redacted]</p>	<p>[Redacted]</p>
<p>3.6 Destruction of CDs is an area where there is an unnecessary burden with out of date stock having to be retained alongside viable stock (increasing opportunity for dispensing or accounting errors) while awaiting destruction by an accountable officer. These rarely actually destroy CDs but get pharmacists to do it then countersign the record in the register. Most</p>	<p>Please see the response in Section 3.1 above.</p>	<p>[Redacted]</p>


<p>accountable officers have no pharmaceutical qualifications and little relevant experience (most are appointed by large multiples who see this role as purely clerical). Pharmacists are professional people and should be allowed to destroy out of date stock more efficiently/quickly, at a time to suit themselves and their patients with destruction witnessed and recorded appropriately, as already happens for patient-returned CDs.</p>		
<p>3.7 Destruction of CDs is an area where there is an unnecessary burden with out of date stock retained alongside viable stock while waiting to be destroyed by an accountable officer. There are safety issues with out of date stock being held for considerable amounts of time. Pharmacists should be allowed to destroy stock more efficiently with destruction witnessed and recorded appropriately.</p>	<p>Please see the response to Section 3.1 above.</p>	
<p>3.8 The one thing that I would like change is for pharmacists to be allowed to destroy out of date controlled drugs in the same way as patient returned medicine. This would prevent build-up of useless medicines that have to be accounted for while waiting until there are enough to make it worthwhile calling an authorized person to come and witness destruction. I had to wait two weeks for the authorized person to be able to come. A patient returned medicine could be destroyed at any time convenient to myself.</p>	<p>Please see the response to Section 3.1 above.</p>	

<p>3.9 Why am I not allowed to have a pharmacist colleague countersign destruction of out of date CDs rather than wait for months (years) for a Home Office appointed person to come and destroy the stock? It takes up space in the cupboard, still has to be counted each week until destroyed and having any out of date stock around is always a risk that it could be supplied to a patient.</p>	<p>Please see the responses to Sections 3.1 and 3.3 above.</p>	
<p>3.10 It is ridiculous that pharmacies are required to keep such detailed records when often prescribers do not similarly control the collection of the prescription in the first place. The issues around destruction of out of date CDs are a costly burden to the NHS. Why cannot one pharmacist separate stock for destruction that another pharmacist could then destroy? Why increase the risks of incidents by having out of date CDs awaiting destruction in the cabinets?</p>	<p>Please see the responses to Section 3.1 and 3.3 above.</p>	
<p>3.11 Controlled drugs cupboards are often full and space at a premium. Most pharmacies have a bag or two of out of date CDs and have to wait for the appropriate officer to destroy them. Stock audits are conducted every 2 weeks and this out of date stock has to be counted every time, adding to the burden and difficulty of the task. We presently are in the position that we need to phone the local drug liaison officer to make a special visit to perform this simple task – this is not a great</p>	<p>Please see the response in Sections 3.1 and 3.3 above.</p>	

<p>use of police time. If a sensible protocol could be established that allowed pharmacist managers to destroy out of date CDs, maybe with a double witness requirement, this could save a great deal of time all round and ensure 'clean and clear' operational storage conditions.</p>		
<p>3.12 Why can't a pharmacist dispose of small amounts of out of date CD provided they record expiry date and batch numbers and get a member of staff to witness? It would be less bureaucratic. Safeguard could be not more than 2 original packs in a 30-day period.</p>	<p>Please see the responses in Sections 3.1 and 3.3 above.</p>	
<p>3.13 I think it is criminal that unopened, unused controlled drugs have to be disposed of in Care Homes when the patient either dies or no longer needs it. If a national or localised piece of research was instigated to measure this, the public and the money holders will realise how ludicrous this policy is. It is a national disgrace; this money and resource waste when our health service is under threat.</p>	<p>We appreciate the concern that it might be wasteful to destroy a patient's medication if it is no longer needed. However, the medication that has been prescribed remains in the possession of that individual. If a patient dies or no longer needs their CDs, the person in whose possession they happen to be as a consequence of that event, can only continue possession of the CDs for a lawful purpose such as giving the unused CDs back to a doctor, nurse or pharmacist for their safe disposal. Care Home staff can only continue to possess a CD that has been dispensed in circumstances permitted under their Home Office Licence. The Care Home will need to demonstrate that they are supplying the CD back to authorised people for their destruction.</p> <p>Whilst we are concerned about wastage from unused medicines, we cannot promote the reuse</p>	

	<p>of returned medicines from patients. For reasons of hygiene and safety, medicines returned to a pharmacy from a patient's home or a nursing or residential home must not be supplied to any other patient. Recycling of medicines is both unethical and unsafe.</p>	
<p>3.14 When the new regulations came into force I had to write to the [County] accountable officer a report as to why one branch of our [County] pharmacies had odd numbers of Diamorphine ampoules (all out of date) in stock, and why were there different batches in the same box. This in a branch with 2 jammed full CD cabinets and GPs regularly prescribing three ampoules (they come in boxes of 5) All to get some very out of date old stock destroyed. A complete waste of my time, and I am sure only the accountable officer either over-exerting their authority or trying to find a crime where none existed.</p> <p>Destruction of CD stock - we are allowed to destroy patient returns, on our own, although good practice says get a witness. Could not an independent pharmacist witness the destruction of expired stock, so that it can be disposed of little and often, rather than having to collect enough to make it worth while to call in the drugs squad policeman to do it?</p>	<p>We sympathise with the views expressed in relation to the build-up of CD stock. Please see section 3.1 and 3.3 with regard to the destruction of CDs.</p>	

4. Comments on record keeping of Controlled Drugs (CDs)

Comment	DH Response	Home Office comments
<p>4.1 CD Regulations need to be simplified and made less laborious. Pharmacy should not need to duplicate entries in CD Registers especially when they have been recorded within the Patients PMR [Patient Medication Record] Record. Prescription requirements need to be removed such as handwriting requirements or “Words and Figures”. Storage requirements need to be relaxed for Temazepam.</p>		<p>Please see the response to Sections 1 and 3. above and Section 5 below which applies to the whole of this section.</p> <p>The record keeping requirements under the Misuse of Drugs Regulations 2001 are in place to ensure an adequate audit trail exists for drugs that have a high risk of diversion and are considered dangerous and harmful when misused. It is also important, when a pharmacist dispenses these specific controlled drugs, that they do so in accordance with the clear instructions of the prescriber, hence the need to ensure the prescriber’s instructions are clearly stated. The Home Office, as owner of the legislation, has a responsibility not only to ensure legitimate access to these drugs but also to protect the public. The burden placed on pharmacies under the legislative framework, in our view, is reasonable in the circumstances to prevent diversion and misuse and to protect the public from the harm posed by these drugs.</p>
<p>4.2 The CD register- Very cumbersome and takes up a lot of time and space to keep the register and we have not seen any benefit to patients or the pharmacy operation or safety. We have ended up with three large and thick</p>	<p>Please see the response to Section 4.1 above.</p>	

<p>folders for our CD register; whereas we used to have the whole register in one much smaller book. It was faster to fill in and patients received a better and faster service.</p>		
<p>4.3 CD records should also be automated so that the register does not have to be kept by hand and is kept on the pharmacy computer instead.</p>	<p>The use of an automated electronic CD Register may be used. However, the Misuse of Drugs Regulations 2001 require that entries made in computerised registers must be attributable and capable of being audited. Electronic CD registers must also be capable of being printed or displaying the name, form and strength of the drug in such a way that the details appear at the top of each display or printout to comply with the requirements.</p>	

5. Comments on storage of Controlled Drugs (CDs)

Comment	DH Response	Home Office comments
<p>5.1 Storage of ‘unusable’ drugs with those intended for dispensing creates the situation of a disaster waiting to happen.</p>	<p>The Home Office’s Misuse of Drugs (Safe Custody) Regulations 1973 governs the storage of schedule 1, 2 and 3 CDs.</p> <p>Section 11 of “A guide to good practice in the management of controlled drugs in primary care (England)” produced by the National Prescribing Centre (NPC) which is now part of the National Institute for Clinical Excellence sets out how to deal with a range of storage matters. This is available at:</p> <p>www.npci.org.uk/cd/public/docs/controlled_drugs_third_edition.pdf.</p>	<p>Please see the responses to Sections 1 and 3 and above which apply to the whole of this section.</p>
<p>5.2 Minor stock errors within the cabinet (e.g. broken capsules dropped ampoules) should be handled internally without the need for a PCT report form etc. Anything above the norm will be easily picked by inspectors for further investigation. The current specials dispensing and reporting regulations are a total and utter red tape lover’s dream, this should be reviewed as a matter of urgency.</p>	<p>Please see the response to Section 5.1 above.</p> <p>CD “specials”, which are drugs manufactured to meet specific clinical needs or purposes, are subject to the usual CD requirements regarding dispensing and reporting. In addition, as a “special”, for NHS reimbursement, additional information may need to be sent to the Primary Care Trust and /or a copy of the invoice to the NHS Business Authority for processing. These requirements were introduced in November 2011.</p>	

<p>5.3 There is a major safety issue in having to keep patient returns in the same cabinet as stock that can be dispensed/supplied. There is also a problem with the pharmacist having to keep the key to the CD cabinet on his/her person throughout the day and that is the risk of that pharmacist taking the key home. It is all right if that pharmacist is only away from the pharmacy whilst it is closed but not if the pharmacist is not working in the pharmacy the following day, particularly true for locums. It would be better to keep it in a 'safe' place within the pharmacy with restricted access.</p>	<p>Please see the response to Section 5.1 above.</p>	
<p>5.4 Storage requirements for CDs need to be reviewed to allow for new emerging technologies such as robotic dispensing and automated methadone dispensing machines to be utilised to their full potential.</p>	<p>Please see the response to Section 5.1 above.</p>	
<p>5.5 It does not necessarily make the safe custody of controlled drugs any more secure by locking them in a CD cabinet. If the premises are broken into the thieves manage to get all the controlled drugs. When I worked in a pharmacy in California it was specifically disallowed to put the controlled drugs together in any one place and they had to be put on the shelves in a non-alphabetical manner. This was thought to be a better way than the use of a CD cabinet as thieves had to spend more time finding them with increased risk of being caught. With the introduction of robots into the</p>	<p>Please see the response to Section 5.1 above.</p> <p>The principles of safe and secure storage of CDs apply to robotic storage and dispensing systems.</p>	

<p>pharmacy dispensing process if this system is operated controlled drugs can be stored randomly by the robot behind the locked interior of the robot storing system.</p>		
<p>5.6 Storage requirements need to be reviewed to allow for new emerging technologies such as robotic dispensing and automated methadone machines to be used to their full potential. Secondly the requirements for the destruction of out-of-dates and patient returns should be reviewed to be clearer and to widen the number of professionals who can participate in this activity. This process should be clear and transparent and not be limited by the availability of an RPSGB representative that at present, result in stock handling issues and increase potential of dispensing errors.</p>	<p>Please see the response to Sections 3.1, 5.1 and 5.5 above.</p>	

6. Comments on stock checks and running balances of controlled drugs

Comment	DH Response	Home Office comments
<p>6.1 I feel CD checks are important but feel they are more useful, especially in less busy pharmacies, if the stock check is done and signed off in the register by the duty pharmacist each time a CD is dispensed or received. This enables easier identification of when stock errors have occurred and avoids weekly checks being done on items, which are rarely used.</p>	<p>We consider that pharmacists and other healthcare professionals who supply CDs should maintain a running balance of stock in their CD register as a matter of good practice. This is made more important once electronic CD registers are in more common use.</p>	<p>Please see the responses to Sections 1.1 and 3.1 above which apply to the whole of this Section.</p> <p>The Home Office's Misuse of Drugs (Safe Custody) Regulations 1973 do not require periodic checks of CD stock – this is governed by local SOPs and professional guidance.</p>
<p>6.2 The requirement to balance the CD register weekly is a burden, taking at least an hour and wastes resource in terms of paper. I would suggest only balancing if we dispense a script or when there is a change in pharmacist</p>	<p>Please see the response to Section 6.1 above.</p>	
<p>6.3 Checking out CD balances is again another example of gratuitous over regulation that seeks only blame and retribution</p>	<p>Please see the response to Section 6.1 above</p>	
<p>6.4 As far as CD's are concerned the overage in liquids e.g. methadone make a mockery of running totals. We are also not in a learning supportive culture and CD errors now include miscounts leading to blame and a high level of stress for pharmacists when the cause may be another pharmacist's or dispenser's doing. In short scrap RP regulations and simplify CD</p>	<p>Please see the response to Section 6.1 above. The point about keeping a running total of liquid drug quantities is noted.</p>	

record keeping		
<p>6.5 The CD weekly check is a joke. With the current climate within companies of reducing staff levels, it has often come to a decision of getting peoples prescriptions done before close of day, or doing a longwinded CD balance I believe my ethical responsibility is to supply the prescription medications safely, rather than tie up the one dispenser with a bookkeeping exercise. Thus, I have often been guilty of writing in the RP book- “insufficient staff to do CD check this week”. Is my head on the line???</p>	<p>Please see the response to Section 6.1 above.</p>	
<p>6.6 Since working at a very busy pharmacy, dispensing a lot of CDs and therefore writing a lot in, there needs to be a simpler way. Also weekly checks, even though I understand the logic behind it, need to be made simpler or maybe electronic, like a methameasure system. This could scan in invoices which would know what’s being delivered and have a function to enter them out at time of dispensing or later, if for deliveries</p>	<p>Please see the response to Section 6.1 above</p>	
<p>6.7 I have personally been blamed for a CD error when I know that when I came in to the pharmacy as a locum, the running balance of the particular drug was not correctly established. I highlighted the fact when dispensing this product and two months later, the manager rang me to say that I must have made the error, I was forced to submit an error</p>	<p>Please see the response to Section 6.1 above.</p>	

<p>report in my name. Nobody second-checked the item as per the SOP and it was so busy on that day I could not chase a dispenser to check the starting balance and script item dispensed. I was not responsible for the 'error' – it was probably a mis-count done earlier that week-but as RP I had to 'cop for it'.</p>		
<p>6.8 How does counting my stock once every week prevent another Shipman? He obtained drugs legally through issuing of scripts. My local GPs prescribe 60 days' worth of CDs, flying in the face of Home Office guidance but all perfectly legal. All they would have to do is change a drug or dose and tell the family that they will return any unused stock from the previous script to the pharmacy on their behalf. Who would question the GP? Who would know they had removed the stock?</p>	<p>We agree that it is questionable whether governance systems, such as the current regulatory model, would ever entirely eliminate the risk of a determined individual diverting CDs for serious criminal use, as was the case with Harold Shipman. However, the evidence to date indicates that the current arrangements offer a greater degree of protection for patients and have reduced the scope for CD diversion than existed before.</p> <p>The Working Group referred to in Section 1.1 above found that the interpretation of the 2006 Regulations by some CDAOs had focused too heavily on securing the safety and security of CDs rather than optimising their safe clinical use. This imbalance is addressed in the final Regulations.</p>	
<p>6.9 Why do I need to count the same Schedule 2 Controlled Drugs and make a register entry that I have week in week out? It take over two hours each week. Over 104 hours per year not facing patients.</p>	<p>Please see the response to Section 6.1 above.</p>	
<p>6.10 The new regulations put an increased burden of work onto community pharmacy, not</p>	<p>Please see the response to Section 6.1 above.</p>	

all of which I am sure is necessary.

One "recommendation" is that all running balances are checked weekly. If you have a CD cabinet containing 50 lines, this can take a considerable time. I have known the running balance check take several hours, which is time not generally available. It has been suggested to me that you get the technician to do the check. Given that the pharmacist is responsible for any discrepancy, is this course of action wise? Keeping a running balance is probably a good idea. If balances are checked every time an item is dispensed, discrepancies are soon detected. Slow moving lines can be checked monthly, say.

7. Comments on prescribing of Controlled Drugs (CDs)

Comment	DH Response	Home Office comments
<p>7.1 The single biggest problem with controlled drugs are the handwriting/prescription regulations. This is the commonest source of friction between healthcare professionals and patients. Patients rarely understand the reasons behind these regulations and it is the pharmacist who gets the wrath of patients not prescribers who initiate the problem. An easier system needs to be put in place whilst still retaining anti-fraud processes. Once again, hospital pharmacies dispensing discharge medication need exemption or simpler processes.</p>	<p>We sympathise with the views expressed here. To help address matters concerning handwritten CD prescriptions, the Department of Health wishes to enable the electronic prescribing of all CDs, not just those in Schedules 4 and 5 of the Misuse of Drugs Regulations 2001. We will undertake the necessary regulatory changes in conjunction with other Government departments as and when resources permit.</p>	<p>The Misuse of Drugs Regulations 2001 - Regulation 15 - govern the prescription requirements for Schedules 2 and 3 controlled drugs.</p> <p>Since November 2005, the requirement for prescriptions for Schedules 2 and 3 CDs (except Temazepam) to be written in the prescriber's own handwriting (other than their signature) has been removed. This allows prescriptions for Schedules 2 and 3 CDs to be computer-generated and then signed by the prescriber in their usual signature. The Home Office circular introducing the changes is available at: http://www.homeoffice.gov.uk/about-us/corporate-publications-strategy/home-office-circulars/circulars-2005/048-2005</p> <p>There is currently no handwriting requirement (except for the prescriber's signature) for Schedules 2 and 3 CDs. All the other information on a prescription for Schedules 2 and 3 CDs, including the date, can be computer-generated.</p>
<p>7.2 With regards to CDs a lot of problems come from the framework required for a CD script to be legal, it should be sufficient that a pharmacist can contact the prescriber and</p>	<p>See the response to Section 7.1 above.</p> <p>Pharmacists are already able to supply Schedule 2 and 3 CDs, with some exceptions, against some prescriptions that have minor technical errors but</p>	

<p>clarify what is intended, and annotate the script accordingly. This is in the best interests of patients and two professional healthcare personnel should be able to sort it out without the need for a new prescription.</p>	<p>where the prescriber's intention is clear.</p>	
<p>7.3 The current regulations place a burden on the pharmacy team but none on a prescriber as they can even issue scripts with “technical errors” and not worry.</p>	<p>Please see the response to Sections 7.1 and 7.2 above.</p>	
<p>7.4 The requirement for definable dose prevents timely dispensing. Pharmacists should be able to amend this if the prescriber is contacted.</p>	<p>Please see the response to Section 7.1 and 7.2 above.</p>	
<p>7.5 I work in secondary care and our pharmacy service is provided by another NHS trust. Why are ward CD stock orders handled differently because we are a different organization within the NHS than wards with the host Trust. You can have the ludicrous situation where our wards are adjacent to the hosts wards, yet the CD order has to be signed by a doctor who has no real understanding of what he is signing for. When it comes to VAT the NHS is treated as one organization, why not for CDs?</p>	<p>Please see the Home Office comments here</p>	<p>The 2001 MDR provide authority for other healthcare professionals, such as senior registered nurses in charge of wards, to sign for stocks of controlled drugs to be used on wards. It is important to have a responsible healthcare professional signing for CD orders in order to maintain an effective audit trail for the movement of CDs within healthcare settings to minimise the risk of diversion and misuse.</p>
<p>7.6 It is frustrating that, as a professional practitioner, the Misuse of Drugs legislation does not permit our discretion to be exercised when a dosage is missed or the prescriber fails to sign the prescription. Under the current rules we have no alternative but to return the</p>	<p>Please see the response to Sections 7.1 and 7.2 above.</p>	<p>The Home Office recognises the need to ensure patient care is not compromised by the legislative framework. In conjunction with the Department of Health and the professional regulatory bodies, we have agreed wording to be used, when prescribing in instalments, to ensure that treatment can</p>

<p>patient or carer to the surgery to obtain an amended prescription. If this occurs at a weekend or out of hours this can present great difficulty for all. A sensible relaxation of the law to allow pharmacists to verbally confirm the prescription, with a requirement to furnish a correct prescription, would be to the benefit of all.</p>		<p>continue where a dose is missed by a patient.</p> <p>The nature and potency of the drugs involved, the associated high risk of diversion, and the harm posed by these drugs when misused mean that it is important to establish or confirm that the pharmacist is acting in accordance with the express directions of a practitioner or recognised healthcare professional. Removing the requirement for a signature will open the system to abuse and increase the risk of diversion and misuse.</p>
<p>7.7 Obtaining a signature on the back of CD forms provides an audit trail which we have found useful at times so we're quite happy with this requirement. Making CD entries is very time consuming but we can't envisage a better way of doing this. I think this is an important requirement. However, if the range of recordable CD-s could be reduced this would be an enormous help. For example, is methylphenidate abused to such an extent that it requires recording?</p>	<p>Please see the Home Office comments here</p>	<p>The requirement to make entries in the controlled drugs register for specific drugs is an important part of the monitoring arrangements for drugs that are potent and can be harmful or dangerous when misused. The Home Office will consider proposals to remove requirements applicable to specific drugs informed by advice from the statutory Advisory Council on the Misuse of Drugs.</p>
<p>7.8 Making the person collecting a CD sign for it – what is the point? Yes, it says it was collected but so what? If that person then flushes it down the toilet, where do you go from there? It is bureaucratic intrusion of little or no benefit. Also, patient returns – there is no requirement to log the return but if you do, we are now advised by our PCT to have a double</p>	<p>Whilst we appreciate these views, the primary purpose of these regulations is to strengthen and improve the governance arrangements for CDs, in order to reduce the risks to patient safety and of their inappropriate use.</p>	<p>There are no requirements under the MDR 2001 for the person collecting a CD on behalf of a patient to sign for the CD. However, a pharmacist when asked to supply a Schedule 2 CD by a patient's representative may, under regulation 16(6), request evidence of the representative's identity and refuse to supply the drug if not satisfied as to the identity of the person.</p>

signature in case of discrepancy.		
<p>7.9 A review of the prescribing and supply arrangements is urgently required to better support patient care. Too often patients who are prescribed a product without words and figures or without the complete dose are turned away from pharmacies. This is particularly true out of hours for palliative care patients where often there is a requirement to dispense these drugs without a legally valid prescription but in order to act in the best interest of the patient. Pharmacists should not be forced to act outside the law in these circumstances, but by not doing so patients can be left without adequate relief in their final hours.</p>		
<p>7.10 A lot of prescriptions for CDs are illegal when presented. A common fault is that the date is missing. On New Years Day I was presented with a prescription for Zomorph Capsules. Supply six tablets. Brought in by the on-call social worker. Prescriptions like this should be allowed to be dispensed without amendment, as it is obvious what was intended (Zomorph is only available as capsules). If the prescribers intention is clear, than the prescription should be valid and dispensable without amendment from the prescriber. This includes adding the date when it can be clearly established when the prescription was written.</p>	<p>Please see the response to Section 7.2 above.</p>	

8. Miscellaneous comments received on Controlled Drugs (CDs)

Comment	DH Response	Home Office comments
<p>8.1 The current process for transfer of stock between pharmacies is burdensome with forms being completed, photocopied and submitted to the PPD for evaluation. This is unnecessary and should be scrapped as it is preventing patients receiving items they need when neighbouring pharmacies hold the stock. It causes delays to treatment and in some cases pain and distress.</p>	<p>The use of a requisition form when transferring stocks of CDs between pharmacies is highly recommended as good practice. This ensures an adequate audit trail exists for the movement of stocks between branches, etc. Pharmacies should maintain appropriate stock control measures to ensure that stocks are replenished as soon as possible and not at the point when a patient needs a CD to ensure patient care is not impacted.</p>	<p>The Home Office will not support or encourage the movement of stocks of very harmful drugs, when misused, between pharmacies without an adequate audit trail.</p>
<p>8.2 Although not directly a part of this RTC, there are often difficulties with CDs as their use is regulated both by the Medicines Act and the Misuse of Drugs Act. For instance, we had a situation where the Medicines Act had enabled pharmacist independent prescribers to prescribe CDs but the Misuse of Drugs Regulations had not been altered to enable this. Therefore, for several years pharmacist independent prescribers were unable to prescribe CDs in practice, although this matter has now been resolved.</p>		<p>Amendments have been made to the Misuse of Drugs Regulations 2001 effective from April 2012 which permit Nurse Independent Prescribers and Pharmacist Independent Prescribers to prescribe the full range of CDs.</p> <p>The Home Office and the Department of Health will continue to work closely together on further proposals to improve the working of the relevant legislation.</p>
<p>8.3 CD Regulations need to be simplified. Only time the proof of collection is required is when a Healthcare professional is collecting. Their regulatory bodies should police and deal with any failures. Also they should keep a record of</p>	<p>The primary purpose of the CD regulations is to strengthen and improve the governance arrangements for CDs, in order to reduce the risks to patient safety and of their inappropriate use. In addition, please also refer to the responses given</p>	

all CDs received and who they gave it to.
The current system does not stop any diversion of CD.

in Sections 1.1 and 2.2 above.

