

The safer management of controlled drugs: Annual update 2022

Download the data we used in this report

Introduction

As the regulator for health and adult social care services, we are responsible for making sure that service providers, and other regulators, maintain a safe environment for the management and use of controlled drugs in England. We do this under the <u>Controlled Drugs (Supervision of Management and Use) Regulations 2013</u>.

As part of our responsibilities under these regulations, we report annually on what we find through our oversight. We use this information and our regulatory activities under the Health and Social Care Act to make recommendations to help ensure the continuing effectiveness of the arrangements for managing controlled drugs safely in England.

This report is important for:

 all controlled drugs accountable officers (CDAOs) in England and their support teams

- organisations that manage controlled drugs
- health and care professionals with an interest or remit in controlled drugs
- commissioners of health and care services
- professional healthcare and regulatory bodies.

The data in this annual update relates to the calendar year 2022, but we also include relevant information for the first part of 2023.

Our oversight activity in 2022

Register of controlled drugs accountable officers

We maintain and publish an <u>online register of controlled drugs accountable officers</u> (CDAOs) across England. This covers those organisations that are registered with us and are required under the 2013 Regulations as amended to have one. The regulations define these organisations as designated bodies and require them to notify CQC of their CDAO appointment.

We update this register monthly. At the end of 2022, there were over 1,000 CDAOs listed. We approved 6 requests to be exempt from the need for a CDAO during the year.

Updating details for controlled drug accountable officers

Over the last year, more organisations needed to appoint temporary CDAOs to cover circumstances such as extended leave and recruitment gaps. If your organisation needs to have a CDAO, it is important to ensure you tell us when the details about the person change. This is a legal requirement.

Where a temporary CDAO is in post for longer than 6 weeks, it is important that you notify us about this so we can include these current details on our CDAO register.

We provide resources and helpful information for CDAOs.

NHS England regional teams and controlled drug local intelligence networks

NHS England controlled drugs accountable officers (CDAOs) worked effectively and collaboratively during 2022. They held regular meetings that resulted in more consistent messaging to members of local intelligence networks (LINs) – both nationally and regionally.

There were 83 local intelligence network meetings across England in 2022. Each network met online at least twice, and several regions held a dedicated controlled drug learning event, as well as 2 nationally-organised learning events. We attended 75 network meetings along with other designated bodies and responsible bodies.

Local intelligence network meetings are an effective way to raise concerns and share intelligence and learning, as well as providing valuable networking opportunities for members.

Key concerns discussed at local intelligence network meetings

- Ineffective governance arrangements in services. Workload pressures sometimes mean that staff are unable to carry out audits regularly or in as much detail as needed.
- The diversion of controlled drugs in lower schedules. This can be a particular challenge to identify for organisations that use them in larger volumes.

- Failure to report losses of controlled drugs, either through diversion or accidental losses.
- Diversion of controlled drugs by health and care professionals.
- No communication about changes to people's medicines. For example, when a GP
 or hospital changes the directions for a person's medicines, and this is not passed
 on to those who are caring for them.
- Ongoing fraud with private prescriptions, often for controlled drugs in lower schedules.
- Care homes not using the <u>reporting tool</u> to report incidents to NHS England CDAOs.
- Arrangements for using oral liquids safely including balance checking, and how to better educate patients on the dangers of inaccurate dosing.
- Controlled drug patches, such as those containing fentanyl and buprenorphine.
 This includes inappropriate prescribing, where people don't need constant pain relief, as well as problems with administration.
- Loss of prescriptions in either postal or courier services. This is a particular issue for services who treat people for substance misuse.

Most NHS England regional CDAO teams published newsletters as an effective way of sharing information and maintaining contact with members between the network meetings.

We have had positive feedback from network members across all regions in relation to national learning events. During the year we had conversations with CDAOs in NHS trusts, some of whom provided feedback on their experience of local intelligence networks. We will share this feedback with NHS England CDAOs to consider for future meetings.

Controlled drug reporting tool

NHS England updated this tool in December 2022. The new design has improved how users report concerns and incidents and has streamlined other controlled drug functions.

The update has also helped to further standardise processes across regions. You can read full information on all of the upgrades to the tool, including contacts for technical assistance, on NHS England's website. The tool also now includes helpful training modules.

Controlled Drugs National Group

CQC leads the Controlled Drugs National Group, which met in March, June and November 2022. Membership comprises government departments, key regulators and agencies with a controlled drug remit in England, Scotland, Wales, Northern Ireland, Ireland and the Channel Islands.

Key discussion topics and issues of shared interest between our cross-border members included:

- controlled drug governance
- non-medical prescribing
- cannabis-based products for medicinal use (CBPMs).
- controlled drugs and medication safety
- Home Office licences.

A separate summary of activity from the past year shows how member organisations contributed to the overall safer management of controlled drugs. If you would like a copy of this summary, email medicines.enquiries@cqc.org.uk.

Operational Sub-group

The operational sub-group to the National Group also met regularly in 2022. Membership comprised:

- NHS England lead CDAOs
- specialist pharmacists and medication safety officers
- NHS Business Services Authority
- chief pharmacists
- Integrated care system (ICS) prescribing leads
- other government bodies.

Where appropriate, we also invited other healthcare professionals with relevant expertise to contribute.

Key issues in 2022

Prescribing controlled drugs without the right patient information

During our inspections in 2022, we found evidence of clinicians prescribing controlled drugs to patients without the relevant medical and medication history. We have seen examples where private prescribing services have not requested these details from the person's NHS GP or secondary care provider before issuing prescriptions, as well as examples of GP services that don't supply these details in an appropriate way when asked.

In 2021, the General Medical Council updated its <u>prescribing guidance</u>. This clarified that, unless in exceptional circumstances, doctors must have access to relevant information from the patient's medical records. If they do not, they cannot prescribe:

- controlled drugs or medicines that are liable to abuse, overuse or misuse
- when there is a risk of addiction and monitoring is important.

Substance misuse services

Instalment prescribing

Prescribing controlled drugs in instalments is currently only available on paper prescriptions. There is a significant need to progress this to electronic format through the Electronic Prescription Service (EPS). This would help to prevent avoidable harm and provide more seamless care for patients by avoiding delays or missed doses of medicines if prescriptions have been lost, delayed in transit or as a result of miscommunication between different care providers.

Good practice

During 2022, we have seen some examples of good practice in substance misuse services. These include how services involve people's families and carers for safer use of controlled drugs in the home environment. The following example highlights risk assessments and targeted interventions to reduce fatal opioid overdoses:

The provider of this service was leading a study to identify risk factors associated with opiate overdose. The study aimed to enable staff to:

- improve risk assessment and planning by helping them to screen clients for risk factors
- offer more targeted interventions to reduce the risk of a fatal opioid overdose.

Staff were still involved in piloting this work, and when we inspected, all clients in the service had a specific risk assessment around overdose. Staff had additional tools to help them deliver more targeted interventions with clients to reduce risk.

Calderdale Recovery

We also saw examples of services working collaboratively with community pharmacies to promote better patient outcomes, as in this example:

Staff had built and maintained good relationships with the local pharmacy. When a client did not collect their prescriptions the pharmacy would contact the service, which would trigger a follow-up. In situations where the client could not be reached, escalation processes would be implemented such as contacting their next-of-kin or the police, where necessary. This also enabled recovery workers to consider the person's treatment plan and review prescribing at the next visit, especially in light of any relapse or other potential risks.

York Drug and Alcohol Service

Paramedic requisitions for controlled drugs

NHS England CDAOs monitor controlled drugs that have been requisitioned in their area across all professions. When ordering controlled drugs, paramedics should use a unique PIN number on the mandatory requisition form (FP10CDF). However, we have recently heard about paramedics requisitioning controlled drugs without using a PIN – either because they were not aware they had to, or because they did not know where to obtain a PIN.

We encourage paramedics who need a PIN to contact their local NHS England CDAOs. See our list of CDAOs for their contact details.

DBS checks for staff working with controlled drugs who have no contact with patients

Employers use <u>Disclosure and Barring Service (DBS) checks</u> to find out whether potential or current employees have a criminal record. These are required when employees will have direct contact with patients and people in more vulnerable circumstances.

We have been alerted to an issue that could cause risks in relation to controlled drugs. In some regulated services, the medicines preparation units are located on sites where patients are not permitted. This means that staff working exclusively on these sites will not be able to access an enhanced DBS check. Whilst DBS checks are not the only way of undertaking employment checks, this can make it more difficult for employers to ensure that staff who have contact with medicines that include controlled drugs are suitable to be employed in that position.

Clinical staff collecting controlled drugs from pharmacies

The risk of diversion increases when there are poor governance processes to monitor medicines that are delivered directly to patients rather than as part of a 'regular' delivery round.

We have heard examples where clinical staff have prescribed lower schedule-controlled drugs on paper forms, taken the prescription to a pharmacy for dispensing but have then delivered a lower quantity of medicine to the patient. There is additional risk with paper prescriptions, as there are no electronic records on EPS.

Non-registered staff and diversion of controlled drugs

In our 2020 annual update we raised awareness of the cross-sector issue of non-registered staff (those who are not on a professional register) diverting controlled drugs. We still hear examples of cases where staff have been dismissed from employment and incidents have not been reported to the police or NHS England CDAOs.

This can result in several consequences:

- Diversion is concealed from a future employer as it will not show up on a Disclosure and Barring Service check.
- The person could therefore gain employment at another organisation in a role that requires them to handle controlled drugs.
- People who misuse these medicines personally, or who access them through an illegal chain may be harmed.

This highlights the importance of sharing information in an appropriate and timely way. Your local NHSE CDAO can provide advice on the best way forward if you have concerns in relation to this issue.

We also provide guidance on employment checks as a useful reference.

Home office licences

Applying for a licence

We often receive queries from services that need a controlled drugs licence. We are not responsible for issuing of licenses – this responsibility sits with the <u>Home Office</u>.

Organisations must ensure that they plan ahead if they anticipate the need for a Home Office licence. This includes services that are either newly-registered with CQC or those that gain registration as a result of a sale. It is also crucial to consider Home Office licences when making planned changes to current services. In practice, this means allocating sufficient time to complete the full application process, which can include responding to queries and the need to supply additional information.

Services also need to factor in time for a compliance site visit from the licensing team, as well as undertaking the correct DBS checks. These need to be enhanced DBS checks completed by the Home Office's preferred provider. At the time of writing this report, it takes 16 weeks from the point when an application is accepted as being validly made (without omissions or errors) to booking a compliance visit. In practical terms compliance visits have a lead-time, and when a service declines the date offered for a visit this could lead to additional delays in the application process. These considerations are crucial – a possible consequence is that services are left without a licence and are unable to provide services or treatment for people.

'Self-sourcing' of controlled drugs

A growing number of organisations are asking their employees to supply their own controlled drugs when on clinical duties to avoid the need for a Home Office controlled drugs licence. This is happening more often for out-of-hours services, community first responders and independent ambulance services. Given the risks of diversion and storing controlled drugs in employees' own homes, this service model should be the exception, rather than the rule.

Where services ask employees to supply their own controlled drugs, it is crucial to have appropriate governance processes so that there is assurance that medicines:

- have been obtained legally
- are stored appropriately
- are of an acceptable nature and quality.

Controlled drugs legislation and current practice

Applications for a Home Office licence are determined on a case-by-case basis. However, there are instances where the need to have a licence to comply with this legislation can appear disproportionate to the size of the service and the very small quantities of the controlled drugs required. It would be helpful for a review of the circumstances in which controlled drugs legislation enables possession of controlled drugs without a licence in certain health and social care environments. This could prove beneficial if it helped to clarify and reflect current practice and potentially reduce burden on providers.

Complex commissioning

As health and care systems work towards better integration of services, we are seeing examples of increasingly complex commissioning where controlled drugs are involved. In practice, this can sometimes mean several different services providing various aspects of care for people in a particular location. Where this happens, it is important that the roles and responsibilities in relation to controlled drugs are clearly set out, understood and agreed by all parties involved so that people receive safe care.

This is particularly the case where different providers prescribe and administer controlled drugs. It is also important to agree who is responsible for consistently reporting controlled drugs incidents to the NHS England lead CDAO. Services also need to consider how they will share learning with each other in relation to any incidents or near-misses.

Private prescribing of controlled drugs

Schedules 4 and 5

In our last annual update, we reported on the lack of national oversight of prescribing Schedule 4 and 5 controlled drugs by providers in the independent sector. Private prescriptions for controlled drugs in these schedules do not use standardised forms and cannot be monitored. This also means that it is much easier to forge prescriptions for dispensing. This can result in personal misuse, onward diversion, or both. We also see that prescriptions are being taken out of the area to be dispensed to avoid raising suspicion with the supplying pharmacy.

This lack of oversight means that we don't know the true scale of the issue – we rely on anecdotal evidence from those who report these incidents and from Coroners through Prevention of Future Death letters. A review of the impact of the way the current system operates would be helpful to determine the changes needed to make it safer and more effective for prescribers, patients, supplying pharmacists and organisations who need to have oversight.

Schedules 2 and 3

Private prescribers only need to declare the main organisation in which they undertake their prescribing when applying for private prescription forms (FP10PCDs).

This means that a prescriber can work across multiple different clinics, using the same prescribing pad, but the resulting data collected will show all prescriptions with the same organisation address. This is inaccurate and is a missed opportunity for better oversight of controlled drug prescribing practices in the independent sector.

Controlled drugs in adult social care services

Medicines errors

Each year, we ask registered adult social care providers to provide information about whether they administer controlled drugs, and if so, how many controlled drug-related medicines errors occurred in the service in the previous 12 months.

We analysed the information from those that responded and found that:

- 67% (13,501) of services (20,184) administered controlled drugs
- of the services that administer controlled drugs, 17% (2,248) reported controlled drugs incidents in the previous 12 months
- 39% (7,846) of services (20,122) reported no medicines errors at all.

Reporting incidents and near misses in services and having a good process to review these is where a 'just culture' is important. This enables support for staff to be open about errors and to learn from them. This is crucial to reduce the risk of a similar event happening again.

Our <u>guidance on medicines errors in care homes</u> offers information for providers to help with best practice in this area. Incidents related to controlled drugs (including loss or theft) should be reported to the local NHSE Controlled Drugs Accountable Officer (CDAO). Their contact details are on <u>our CDAO register</u>.

Application of transdermal (skin) patches

We continue to see varied processes and procedures in relation to applying patches containing controlled drugs and have heard about harm because of inadequate risk assessments and monitoring. We provide guidance on this, and a new guide from the Specialist Pharmacy Service was also published last year, which may also be helpful when designing and monitoring processes around patch administration.

STOMP guidance

During some of our inspections of adult social care this year, we have found examples of good awareness of the principles and application of <u>STOMP guidance</u> (stopping overmedication of people with a learning disability, autism or both). Some medicines that STOMP guidance refers to are controlled drugs, such as benzodiazepines or Z-drugs.

One of the key aspects of this guidance is ensuring that prescribing and administration of these medicines is appropriate and, where possible, that non-drug options are available so that people's behaviour is not controlled by using these medicines. The following example shows this.

Staff in the care home were exceptionally skilled in enabling people to express their views and wishes. For example, one person was unsettled and required medicines to help them remain calm. Staff spoke with the person's family and discovered they had a passion for art. So, they obtained an easel, canvas and oil paints to enable the person to paint and staff arranged for them to display their art at an in-house exhibition. The person settled in the service and spoke about the meaning behind their artwork, and no longer required their calming medicines.

Greensleeves Care Home

Controlled drugs in secondary care

During 2022, our Medicines Optimisation team reviewed medication safety in over 90% of England's NHS trusts. We held discussions with CDAOs and senior pharmacy leaders in NHS acute, community, mental health, and ambulance services. This was to help us understand how NHS services in secondary care were managing controlled drugs safely in the context of pressures on the system.

The key themes that we found through our conversations were:

- Role of the CDAO: Some CDAOs had access to training for the role, while others did not. There were also significant differences between the time and support for some CDAOs to undertake their role, with some stating they were concerned they did not have enough time to complete the required work effectively. The CDAO role was often performed alongside other roles, such as Medication Safety Officer, which also increased time and workload pressures.
- Governance: Most trusts reported that their board was accessible and any
 concerns raised with them were taken seriously. How trusts chose to manage
 their governance varied in response to their needs as a provider, and we saw
 some inventive methods of collecting data to help provide assurances that
 controlled drugs were being managed safely.

For example, one told us it had changed the audit template to an electronic survey, which automatically generates a report that can be sent to the ward manager. This trust also has a dashboard that enables staff to focus on any areas of concern and helps to analyse data.

However, we did find examples where incidents that should have been raised at board level were only discussed there as part of an annual report on controlled drugs, which meant that action to address issues was delayed. We also heard about instances where learning was not shared within trusts.

- Diversion: This was a concern, especially in surgical and busy areas. Lower schedule controlled drugs were a particular concern and diversion sometimes involved staff.
- Reporting incidents: We found that reporting cultures varied at different sites, even within the same trust. CDAOs and their supporting teams sometimes found it difficult to manage the volume of reported incidents. Where staff reported all incidents diligently, this contributed to large overall volumes, and although this increased the workload for CDAOs, they did not want to discourage a good reporting culture.

- Pain relief for end-of-life care: We heard good examples of multi-agency
 working to support good medicines optimisation for patients at the end of their
 lives. Some trusts raised the issue of accountability for controlled drugs in
 patients' own homes when several different providers of care are involved.
- Wet signatures: The need to have 'wet' or written signatures for controlled drugs
 often led to delays in the supply of medicines for patients and prevented
 healthcare settings from being able to make best use of their digital systems.
- Prescribing: We heard some good examples of monitoring prescribing of controlled drugs, including some de-prescribing programmes for opioids, z-drugs and benzodiazepines. Some of this work was shared with the local integrated care system (ICS), as in the following example:

"As part of our efforts to make sure that patients are not inappropriately prescribed long-term opioids, hypnotics and other medicines we've got a specialist pharmacist who works with our chronic pain team leading work on de-prescribing opioids across the city. We've shared that work with the ICS. We've also got a consultant pharmacist for older people working in our city, who is leading a wider piece of work around de-prescribing. De-prescribing is embedded into our clinical practice in relation to how we review patients' medicines at discharge. This ensures that medicines intended for short-term use while in hospital are reviewed at discharge and discontinued if appropriate."

- Improvement projects: We heard about a wide range of projects aimed at improving patient care. Staff had worked hard to develop them and were proud of the outcomes. The following are some examples of initiatives that staff told us about:
 - Where appropriate, switching prescribing from a liquid oral opioid to an oro-dispersible tablet (which dissolves in the mouth) to reduce risks around unintentional overdosing.
 - Following a review of discharge prescriptions, prescribers in the surgery and anaesthetics departments improving the clarity of instructions for GPs.
 - Working with police to carry out risk assessments of controlled drugs and electronic drug cabinets to look for further benefits of using automated processes to manage controlled drugs.
 - Developing an information leaflet for patients on 'managing your controlled drugs in your home'.
 - Using innovative ways to share messages across teams, such as a <u>video</u> on how to second check controlled drugs safely. This enables busy staff to engage and support the policy through short learning sessions.

Shared care

In last year's annual update, one of our recommendations was that "Health and care staff need to make sure they provide shared care in line with best practice guidance".

However, we still have concerns in this area, particularly where care is shared between NHS providers and those in the independent sector. Monitoring patients is a key concern, especially when they need tests at certain intervals.

Private prescribing of medicines licensed for attention deficit hyperactivity disorder (ADHD) is one area of concern where shared care can be ineffective. Prescribing of these medicines by private health providers again increased between 2021 and 2022, driven by increased awareness of these medical conditions and poorer access to NHS mental health services. Detailed prescribing data is available in the next section of our report. Figures 1 and 2, also show the increased prescribing of these medicines over the last 5 years. Although prescribing has increased in both the NHS and independent sector, the increase in private prescribing during the pandemic is steeper.

Where private health providers wish to share care with an NHS GP, it is crucial that they investigate whether this will be a possibility – both practically and in line with guidance from the Department of Health and Social Care. Patients must be assessed for this at the outset of treatment: if NHS treatments cannot be provided as part of the shared care, any tests such as blood tests are likely to incur additional costs.

Figure 1: Private prescribing of methylphenidate, lisdexamfetamine and dexamfetamine (2017-2022)

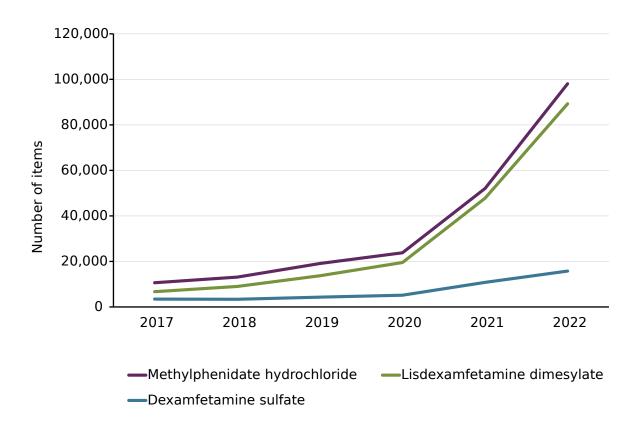
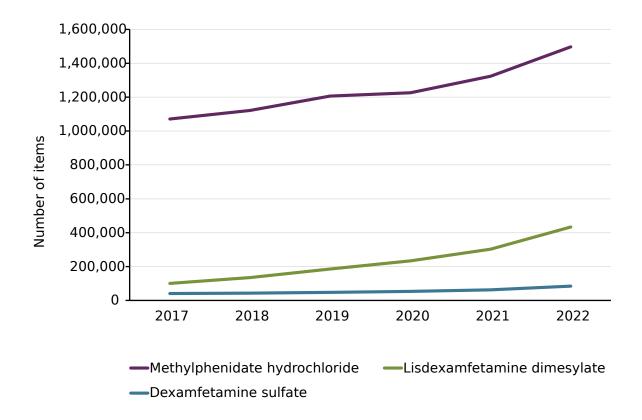


Figure 2: NHS prescribing of methylphenidate, lisdexamfetamine and dexamfetamine (2017-2022)



Note: This includes both primary care prescribing (FP10 prescription forms) and hospital prescribing (FP10HP prescription forms).

Workload pressures in community pharmacy

There continues to be significant workload pressure for staff in the community pharmacy sector. Community pharmacies are a crucial part of our health and care system, providing services and support to a range of health and care providers. We have seen the knock-on effect of these pressures in services registered with CQC.

Examples include where substance misuse services have taken on supervised consumption of opioid substitution treatment because the local community pharmacy cannot provide the service. Services that issue instalment prescriptions should communicate closely with their local community pharmacies to ensure that supervised consumption services are available and advise patients accordingly.

We have also seen that people who have been issued a paper prescription, often out of normal hours, are not always able to get a supply of their medicine at their nearest pharmacy because of closures.

Cannabis-based products for medicinal use

During 2022, we continued to register clinics in the independent sector that provide treatment with cannabis-based products for medicinal use (CBPMs). At the time of publishing, 18 providers that prescribe unlicensed CBPMs were registered, with more currently being assessed for registration.

During 2022 we continued to monitor and inspect providers in line with our current regulatory approach. Although we found some providers had made improvements in various aspects of their service, a stronger focus on good governance was sometimes needed to ensure safe, high-quality care.

CBPMs are Schedule 2 controlled drugs under the Misuse of Drugs Regulations 2001. They can be prescribed by, or under the direction of, a doctor who is on the specialist register of the General Medical Council to treat patients with a specific unmet clinical need.

As in previous years, almost all prescribing continues to be for unlicensed CBPMs in the independent sector. The most current available prescribing data for independent health services has shown an increase of 216% over the past year:

- from 1 January to 30 September 2021, 25,212 items were dispensed.
- from 1 January to 30 September 2022, 79,579 items were dispensed.

This data relates specifically to prescriptions that are dispensed in a community setting.

We are not able to publish the data for NHS prescribing of unlicensed CBPMs. This is because the number of items prescribed in the NHS is so small that this could potentially affect patient confidentiality.

Access to medicines for care at the end of life

The pandemic brought into sharp focus the challenges associated with managing pain and symptom relief during end-of-life care. We hear from care home providers about the cost and lengthy process associated with obtaining a Home Office licence to hold a very small quantity of controlled drugs as anticipatory medicines. In practice, this means that many care homes don't hold any stock, so they need to use other routes to prescribe and supply controlled drugs to ensure that patients can access these medicines.

We know there is a great deal of excellent work in relation to anticipatory prescribing to ensure that people get the medicines they need at the right time. However, it is sometimes difficult to predict when a patient might be nearing the end of their life, which can mean the right medicines are unavailable both within the care home setting and when people choose to die at home.

In some cases, delays to treatment and additional work can be caused by issues such as:

- incorrectly written prescriptions or authorisations to administer
- unavailability of stock
- access to medicines out of normal hours.

This is especially relevant given the ongoing pressures on health and care staff after the pandemic.

Good symptom management is such a crucial part of end-of-life care, so it would be helpful to understand more about the scale of this issue. We also need to understand the possible risks and benefits around the ability for nursing home providers to hold a very small stock of controlled drugs as anticipatory medicines to treat patients at the end of life only.

Over-prescribing medicines that cause dependence and withdrawal

In both our 2019 and 2020 reports, we raised awareness of Public Health England's evidence review, 'Dependence and Withdrawal associated with some prescribed medicines'. This addressed opioid medicines for pain, the gabapentinoids, benzodiazepines and z drugs (medicines that act in a similar way to benzodiazepines), and antidepressants.

Since the 2019 report, we have seen improved awareness and more initiatives to address this type of prescribing to improve patient outcomes in NHS GP services, as the following examples show.

The National Institute of Health and Care Excellence (NICE) has also recently produced a <u>patient resource</u> to support this work.

Following an audit to look at opioid prescribing, the practice found that 71 patients were on the maximum daily dose of these medicines. In response, the practice designed a pilot service in conjunction with the clinical commissioning group, the local hospital and Resolutions, a local drug and alcohol recovery service. A repeat audit at the end of the pilot showed that 31 patients had reduced the dose of these medicines.

Lea Vale Medical Practice

This practice had adopted the use of a medication risk stratification tool. This was designed to help identify any patients who are likely to be put at risk of harm from their medicines. The practice also used a pharmacist-led information technology intervention tool to help to reduce medication errors, and thereby improve medication safety.

Belvidere Medical Practice

In March 2023, NHS England released a <u>Framework for action for integrated care boards</u> (ICBs) and primary care to help support this ongoing priority. Actions at integrated care system level have the potential to provide leadership and improve local collaboration to benefit patients. Over the last year, we have heard about examples of this good work, including:

- A <u>range of opioid reduction projects</u> in the North East that include a campaign aimed at helping GP practices to review opioid prescribing in primary care. This includes videos of patients' lived experiences.
- The <u>'Living well with pain' programme</u> in Gloucestershire, which uses a system-wide approach to help bring services together for effective patient care. This is an evidence-based programme, focused on exercise and improved access to mental health services, to help people with chronic pain live as well as possible.

Transitioning to electronic systems

During 2022, we have seen more examples of the benefits of digital systems, such as this example of collaborative working between a hospice and an NHS trust:

The service worked with the acute hospital trust to implement an electronic system to prescribe medicines and record their administration. This system was used across all NHS hospital services and adult hospice services in Cornwall.

This meant that information about people's medicines was more readily available when they transferred between services. These electronic records were complete and up-to-date, with clear recording of allergies and reasons if medicines were not given.

Mount Edgcumbe Hospice

As services progress towards greater use of electronic systems and recognise the benefits, they still need to consider possible risks that are different to paper records. Examples of issues that we have heard about this year include:

- people still being able to divert controlled drugs from electronic storage
- loss of vital data with no appropriate back-up procedures, for example in electronic controlled drug registers
- staff not being up-to-date with system updates, leading to medicines errors
- lack of staff training and understanding in relation to the wider functionality of the system, including how electronic audits work.

There are also growing concerns from those who work with patients around the delay in changes to legislation to permit the full use of electronic systems. Services are now transitioning their digital functionality at pace, and are concerned that the new systems are not reflected in legislation.

Our guidance for adult social care services explains about <u>electronic medicines</u> <u>administration records (eMARs)</u> and how keeping good <u>digital record systems</u> can help to achieve good outcomes for people using services.

Governance of controlled drugs

Good governance is central to the safe and effective management of controlled drugs. We have previously made recommendations in relation to this in our annual updates. When we see problems with controlled drugs on our inspections, it is often because governance is poor and not functioning effectively.

We publish self-assessment tools for <u>primary</u> and <u>secondary</u> care organisations. These tools help you to establish whether you have the right governance processes in place, or if you need to make further considerations. The tools are available to download without having to provide any contact details.

Partnership working: NHS England controlled drug accountable officers and police controlled drug liaison officers

Multi-agency partnership working is an essential part of helping to ensure that controlled drugs are managed safely across health and social care. Both NHS England CDAO teams and police controlled drug liaison officers (CDLOs) are highly knowledgeable and experienced in providing advice and support about a range of controlled drug issues and concerns – from medicines errors to suspected thefts and unaccounted losses.

We encourage services to make contact where they need support following an incident or concern. You do not have to be a designated body to contact CDAOs or CDLOs. The Association of Police Controlled Drug Liaison Officers website enables you to check the up-to-date contact details for your <u>local CDLO</u> and your local NHSE CDAO's details are on our <u>CDAO register</u>.

Local authorities as Responsible Bodies

Under the Controlled Drugs (Supervision of Management and Use) Regulations 2013 local authorities have a 'Responsible Body' status. This means that they can be a part of local intelligence networks (LIN). Even though local authorities are crucial system partners in relation to the safer management of controlled drugs, we rarely see them represented within LINs. Where not already linked into a LIN, we encourage the local authority medicines lead to make contact with their local NHS England CDAO to discuss the possibility of joining the LIN.

National trends in the prescribing of controlled drugs

Notes on data: Data on prescribing is collected by <u>ePACT2</u> – an online application that provides authorised users with access to prescription data held by NHS Business Services Authority. For prescribing in the NHS, including hospitals and dental services, we have extracted data from this application for the years 2020, 2021 and 2022 to provide overall figures and trend analysis. For non-medical prescribing, the NHS Community Pharmacist Consultation Service, and requisitions and prescribing in independent primary care, the data for 2022 was supplied directly by NHS Business Services Authority.

We have not updated the data for 2021 that we published in our 2022 annual report. This is because there may be changes to overall figures as ePACT2 may be updated over time.

This year, we include <u>our raw analysis in open format files</u>. This will enable teams with a remit in controlled drugs to make more use of this data.

Prescribing trends in primary care

In this section, we highlight trends of the most prescribed controlled drugs.

Overall prescribing of controlled drugs in Schedules 2 to 5 in 2022

Total controlled drug items prescribed by NHS primary care services:

73,880,442 items in 2022 73,807,554 items in 2021

(a small increase of less than 0.5%)

The cost of this was £547,248,678 in 2022 compared with £575,120,712 in 2021 (a decrease in cost of 5%).

The most notable prescribing trends in NHS primary care in 2022 include:

- Marked increases in prescribing volumes of medicines that are licensed to treat attention deficit hyperactivity disorder (ADHD), such as dexamfetamine, lisdexamfetamine and methylphenidate. This is also echoed in the private prescribing trends.
- An increase in testosterone prescribing, which could be linked to increased awareness of its use for women experiencing menopause.
- A reduction in prescribing of pethidine, co-proxamol, temazepam and fentanyl.
- A reduction in prescribing of diamorphine. We did not see any corresponding increase of prescribing of morphine.
- An increase in non-medical prescribing overall, with pharmacists now undertaking just over half of this.
- Reductions in prescribing by NHS dentists, possibly linked to dental access issues.
- Higher prescribing of opioids in the North of England, which echoes trends we have seen in previous years.

Figure 3 shows overall prescribing levels in 2022 compared with the previous year.

Figure 3: Prescribing of controlled drugs by schedule in 2022

Schedule 2	9,226,618 total items in 2022
up by 1%	9,109,102 total items in 2021
Schedule 3	26,008,549 total items in 2022
up by 1%	25,836,714 total items in 2021
Schedule 4	13,062,052 total items in 2022
down by 2%	13,342,781 total items in 2021
Schedule 5 up by less than 0.5%	25,583,223 total items in 2022 25,518,957 total items in 2021

Of all prescribing of controlled drugs in primary care:

- **Schedule 2** accounted for 12%
- **Schedule 3** accounted for 35%
- **Schedule 4** accounted for 18%
- **Schedule 5** accounted for 35%

Patterns of prescribing in NHS primary care

In 2022, of the most prescribed controlled drugs, there was a **reduction in prescribing** for a number of controlled drugs compared with 2021 (figure 4).

Figure 4: Reductions in prescribing of controlled drugs in 2022

Diamorphine (Schedule 2) down by 65%	8,979 total items in 2022 25,402 total items in 2021
Temazepam (Schedule 3) down by 23%	555,427 total items in 2022 720,110 total items in 2021
Co-proxamol (Schedule 5) down by 14%	6,728 total items in 2022 7,833 total items in 2021
Oxazepam (Schedule 4) down by 12%	52,267 total items in 2022 59,346 total items in 2021
Pethidine (Schedule 2) down by 12%	7,157 total items in 2021 8,123 total items in 2022
Fentanyl (Schedule 2) down by 8%	812,439 total items in 2022 879,786 total items in 2021
Nitrazepam (Schedule 4) down by 7%	313,265 total items in 2022 335,309 total items in 2021
Co-dydramol (Schedule 5) down by 6%	1,426,820 total items in 2022 1,522,217 total items in 2021
Phenobarbital (Schedule 3) down by 5%	161,063 total items in 2022 169,776 total items in 2021
Zopiclone (Schedule 4) down by 4%	4,681,170 total items in 2022 4,872,068 total items in 2021

Methadone (Schedule 2) down by 3%	1,785,152 total items in 2022 1,836,787 total items in 2021
Dihydrocodeine (Schedule 5) down by 2%	1,432,483 total items in 2022 1,460,884 total items in 2021
Diazepam (Schedule 4) down by 2%	4,339,653 total items in 2022 4,448,994 total items in 2021

At the same time, of the most prescribed controlled drugs, there was an **increase in prescribing** in 2022, compared with 2021 (figure 5).

Figure 5: Increases in prescribing of controlled drugs in 2022

Lisdexamfetamine (Schedule 2) up by 45%	387,490 total items in 2022 266,918 total items in 2021
Dexamfetamine (Schedule 2) up by 35%	78,824 total items in 2022 58,494 total items in 2021
Testosterone (Schedule 4) up by 15%	334,161 total items in 2022 291,309 total items in 2021
Methylphenidate (Schedule 2) up by 12%	1,334,860 total items in 2022 1,188,128 total items in 2021
Pregabalin (Schedule 3) up by 5%	8,636,909 total items in 2022 8,243,352 total items in 2021

Midazolam (Schedule 3)	354,614 total items in 2022
up by 5%	338,178 total items in 2021

NHS non-medical prescribing

Overall prescribing of controlled drugs by non-medical prescribers (healthcare professionals other than a doctor or dentist) increased during 2022:

4,799,328 items prescribed in 2021 5,152,958 items prescribed in 2022(an increase of 7%)

Figure 6: Non-medical prescribing of controlled drugs in 2022

Pharmacist prescribing up by 12%	2,645,819 total items in 2022 2,361,921 total items in 2021
Nurse prescribing up by 3%	2,499,873 total items in 2022 2,427,897 total items in 2021
Paramedic prescribing down by 30%	5,897 total items in 2022 8,415 total items in 2021
Physiotherapist prescribing up by 19%	1,171 total items in 2022 984 total items in 2021
Radiographer prescribing up by 181%	101 total items in 2022 36 total items in 2021

Podiatrist prescribing

up by 33%

97 total items in 2022 73 total items in 2021

Prescribing by pharmacists accounted for 51% of all non-medical prescribing in 2022 (2,645,819 items). This is an increase of 12% since 2021. It is the first time that pharmacists have undertaken more than half of all non-medical prescribing as a professional group. Pharmacist prescribers are increasingly working in GP practices and primary care networks and this trend is likely to continue, particularly as all newly-qualified pharmacists will be independent prescribers by 2026.

Paramedic prescribing has decreased by 30% in contrast to an increase last year of 153%. Independent paramedic prescribers are not yet able to legally prescribe controlled drugs. Although recommendations were made to change the law, this has not yet progressed. The decrease in prescribing could be because of better awareness of this issue, certainly in part because NHS England CDAO teams have also been working to follow this up through their monitoring activities during the year.

Although we report increases in prescribing by podiatrists, physiotherapists and radiographers, the figures have increased from a relatively low base in both 2021 and 2020.

Going forward, although non-medical prescribing is increasing, it raises the question of how services ensure this is done safely and effectively. Services that employ non-medical prescribers should have systems to make sure they are working within the limits of their competency. They must also provide staff with appropriate supervision, which includes allocating an appropriate senior member of the relevant clinical team to provide day-to-day supervision. We have seen some good examples of this in our inspections of GP surgeries during 2022, as in the following example.

This practice had started periodic in-house prescribing assessments, which were completed by a GP trainer. This was to ensure that nurse prescribers continued to be competent. The practice encouraged advanced nurse prescribers (ANPs) to write reflections following their annual prescribing audit to identify any learning needs and support their personal revalidation process. The practice also supported continuing professional development for non-medical prescribers.

Peer support among the advanced clinical practitioners enabled them to discuss clinical cases and to use the discussions as learning opportunities. Any specific topics that were identified as learning needs were raised with the primary care network manager, who would then organise a specialist to present at one of the Friday lunchtime training sessions. These training sessions were often recorded so if staff were unable to attend they could access the training at a more convenient time.

Charing Medical Practice

We provide <u>guidance on non-medical prescribing</u> to support GP practices with this, and some of the principles are transferable to other settings.

NHS dental prescriptions for controlled drugs

Total controlled drug items prescribed by NHS dentists:

30,790 items in 2022 37,931 items in 2021(a decrease of 19%)

Dentists working in the NHS can prescribe 3 controlled drugs on NHS dental prescription forms to patients:

Dihydrocodeine: as in previous years, this was the most prescribed medicine, accounting for 84% of total dental prescribing in 2022.

25,826 items prescribed in 2022 32,516 items prescribed in 2021 (a decrease of 21%)

Diazepam and **temazepam:** these accounted for 16% of all dental prescribing in 2022. Between 2021 and 2022, prescribing of both medicines decreased (by 6% and 16% respectively).

These patterns in decreased prescribing could be a result of issues related to reduced access to NHS dental treatment.

ePACT2 Opioid comparators dashboard

Last year, we highlighted the newly-released ePACT2 Opioid prescribing comparators dashboard. We showed examples of some of the reports in the dashboard to demonstrate how useful this can be in understanding more about local prescribing issues.

We also looked at prescribing of opioids in a specific geographical area. When we looked at this data again we found the number of patients receiving opioid pain medicines per 1,000 patients in early 2023 remained similar compared with the same period in 2022. Prescribing is still highest in the north of England. This aligns with what we have found in previous years (figure 7).

Figure 7: Number of patients receiving opioid pain medicines per 1,000 patients by region in 2022 (15 April to 12 May 2022) and in 2023 (12 April to 9 May 2023)

Region	Number of patients receiving opioid pain medicines (2023)	Number of patients receiving opioid pain medicines per 1,000 patients (2023)	Number of patients receiving opioid pain medicines (2022)	Number of patients receiving opioid pain medicines per 1,000 patients (2022)
London	83,122	8	83,091	8
South East	133,490	14	133,503	14
East of England	102,000	14	102,356	14
South West	109,434	18	109,391	18
Midlands	219,778	19	213,790	19
North West	173,375	22	175,924	23
North East and Yorkshire	242,692	27	247,650	27

Full details about the dashboard specifications are on the <u>NHS Business Services</u> <u>Authority website</u>.

More prescribing data from this dashboard is available in our published analytics tables.

Fentanyl patch prescribing

We have also looked at how fentanyl patches are prescribed for older adults.

Figure 8: Fentanyl patch prescribing by age band

Age:	Age:	Age:	Age:	Total number of items prescribed
0-59	60-69	70-79	80+	
313,611	176,841	169,966	192,155	852,573

Although we have seen an overall reduction in the prescribing of fentanyl (all pharmaceutical forms, down 8% in 2022), prescribing for people over 70 years old forms a high proportion of all fentanyl patch prescribing. Although prescribing of fentanyl patches can be clinically appropriate in older people, these figures are a reminder of the need for a regular review of prescribing to ensure this is the case, and to reduce the risk of adverse effects.

Prescribing in NHS hospitals for community pharmacy dispensing

In 2022, hospital prescribing (on FP10HP prescription forms that can be dispensed in a community pharmacy) was also broadly in line with 2021.

Total controlled drug items across Schedules 2 to 5 prescribed in hospital using an FP10(HNC) or FP10SS form:

956,529 items in 2022 971,971 items in 2021(a decrease of 2%)

The cost of this was £ 15,876,710 in 2022 compared with £15,735, 985 in 2021 (an increase of less than 1%).

Of all prescribing of controlled drugs in hospitals for dispensing in a community pharmacy:

- **Schedule 2** accounted for 53%
- **Schedule 3** accounted for 17%
- **Schedule 4** accounted for 20%
- **Schedule 5** accounted for 10%

Figure 9: Decreases in hospital prescribing of controlled drugs for community pharmacy dispensing in 2022

Temazepam (Schedule 3) down by 24%	2,152 total items in 2022 2,841 total items in 2021
Methadone (Schedule 2) down by 15%	282,184 total items in 2022 330,620 total items in 2021
Midazolam (Schedule 3) down by 14%	2,106 total items in 2022 2,444 total items in 2021
Buprenorphine (Schedule 3) down by 14%	123,600 total items in 2022 143,238 total items in 2021
Chlordiazepoxide (Schedule 4) down by 15%	1,511 total items in 2022 1,775 total items in 2021

Figure 10: Increases in hospital prescribing of controlled drugs for community pharmacy dispensing in 2022

Lisdexamfetamine (Schedule 2) up by 30%	46,309 total items in 2022 35,747 total items in 2021	
Dexamfetamine (Schedule 2) up by 29%	5,627 total items in 2022 4,359 total items in 2021	
Methylphenidate (Schedule 2) up by 19%	161,943 total items in 2022 135,693 total items in 2021	

NHS Community Pharmacist Consultation Service

The national NHS Community Pharmacist Consultation Service (CPCS) was launched in October 2019. It aims to reduce pressure on primary and urgent care services, including emergency departments and out-of-hours GP services. The service refers people to community pharmacies for advice, treatment, and urgent repeat prescriptions, and may supply certain controlled drugs in specific circumstances for a limited period.

The controlled drugs most commonly supplied by the service in 2022 were:

- co-codamol (in a range of forms, including tablets and capsules) 30/500mg, 15/500mg and 8/500mg
- **codeine** 15mg and 30mg tablets
- **dihydrocodeine** 30mg tablets
- morphine sulphate oral solution 10mg/5ml
- **clonazepam** 500mcg tablets
- **clobazam** 10 mg tablets

- **co-dydramol** 10/500mg tablets
- **diazepam** 2mg and 5mg tablets

Private controlled drug prescribing in independent primary care

Total controlled drug items prescribed privately across independent primary care services:

225,482 items in 2022 131,999 items in 2021

This is an increase of 71% – the main contribution towards this trend comes from the increased prescribing of schedule 2 controlled drugs licenced to treat ADHD.

Of all private prescribing of controlled drugs in independent primary care:

- **Schedule 2** accounted for 94%
- **Schedule 3** accounted for 6%

Private prescribing of Schedule 2 controlled drugs

Prescribing of Schedule 2 controlled drugs alone increased by 80%:

211,130 total items in 2022 117,431 total items in 2021

This figure does not include unlicensed cannabis-based products for medicinal use and has largely been driven by the increase in prescribing for medicines licensed for ADHD.

Figure 11: Schedule 2 controlled drugs prescribed in independent primary care

Methylphenidate accounted for 47% (up by 88%)	98,115 total items in 2022 52,080 total items in 2021
Lisdexamfetamine accounted for 42% (up by 87%)	89,297 total items in 2022 47,831 total items in 2021
Dexamfetamine accounted for 8% (up by 46%)	15,830 total items in 2022 10,831 total items in 2021

Last year, we highlighted concerns about increased prescribing volumes of Schedule 2 controlled drugs combined with shared care arrangements, which meant that this was an area of risk. We raise this risk again in this report and will continue to monitor this.

We did not see any significant reductions in private prescribing for other Schedule 2 controlled drugs during 2022.

Private prescribing of Schedule 3 controlled drugs

13,383 total items prescribed in 2022 14,022 total items prescribed in 2021(a decrease of 5%)

Pregabalin: although the volume prescribed was lower, it was still the most prescribed drug in Schedule 3, accounting for 55% of all Schedule 3 prescribed items:

7,395 total items in 2022 7,798 total items in 2021(a decrease of 5%)

Midazolam: we saw an increase in private primary care prescribing:

977 total items in 2022

622 total items in 2021

(an increase of 57%)

Prescribing of some other Schedule 3 controlled drugs has reduced in 2022 compared with 2021 (figure 12):

Figure 12: Reductions in prescribing of Schedule 3 controlled drugs in 2022

Temazepam	595 total items in 2022	
down by 30%	848 total items in 2021	
Gabapentin	964 total items in 2022	
down by 11%	1,083 total items in 2021	
Buprenorphine down by 7%	2,150 total items in 2022 2,311 total items in 2021	

Requisitions

Requisitions are documents that allow the appropriate people to order medicines for use in their professional practice, such as ordering a stock of controlled drugs that are later administered to patients.

The volume of requisitions has decreased in the last year:

12,444 total items requisitioned in 2022 14,384 total items requisitioned in 2021

(a decrease of 13%)

Looking at where these requisitions came from in 2022:

- 62% of all requisitions were from NHS providers (compared with 59% in 2021)
- 38% were from independent organisations (compared with 41% in 2021)

The top 10 controlled drugs on requisition remained the same in 2022 as for 2021, apart from methadone, which was replaced by lisdexamfetamine. Figure 13 shows the most commonly requisitioned controlled drugs in 2022.

Figure 13: Requisitions of Schedule 2 and 3 controlled drugs in 2022

Pregabalin	16% of all requisitions (1,826 total items)
Methylphenidate	12% of all requisitions (1,522 total items)
Gabapentin	8% of all requisitions (1,026 total items)
Morphine sulfate	8% of all requisitions (1,008 total items)
Midazolam	8% of all requisitions (1,030 total items)
Oxycodone	7% of all requisitions (826 total items)
Buprenorphine	5% of all requisitions (666 total items)
Fentanyl	5% of all requisitions (662 total items)
Lisdexamfetamine	4% of all requisitions (549 total items)
Tramadol	4% of all requisitions (438 total items)

Recommendations

From our analysis of prescribing data, feedback from controlled drug local intelligence networks, and our wider inspection and regulatory work, we make the following recommendations to drive improvement in the safer management of controlled drugs:

• Make sure your governance processes are up-to-date and fit for purpose. In the last 2 years we have made recommendations around the importance of governance in the context of controlled drugs. We continue to monitor the progress, but still find areas that need to improve across health and social care. This is particularly the case where there are complex commissioning arrangements for services.

For example, where several providers are involved in delivering a person's care, it's important to have clear roles and responsibilities in relation to controlled drugs, such as reporting incidents. All parties involved must understand and agree these so that people receive safe care.

Local intelligence networks can provide examples of good governance processes, which providers can adopt and tailor to their own services. You can also use our self-assessment tools for <u>primary</u> and <u>secondary</u> care organisations.

• Make sure prescribing at transfer of care is completed safely. Clinicians must have the relevant medical and medication history before prescribing controlled drugs to patients. Private prescribing services should request these details from a person's NHS GP before issuing prescriptions, and NHS GP services should supply these details in an appropriate way when asked. See <u>prescribing guidance</u> from the General Medical Council. • Know the identity of your local controlled drugs accountable officer (CDAO) and police controlled drug liaison officer CLDO. Any organisation with a responsibility around controlled drugs must have these details and know how to report controlled drugs incidents. CDAOs and CDLOs are important partners and can provide help, support and advice on a wide range of controlled drugs issues, as well as for reporting incidents.

The Association of Police Controlled Drug Liaison Officers website enables you to check the up-to-date contact details for your <u>local CDLO</u> and details of your local NHSE CDAO are on our <u>CDAO register</u>.

- Work collaboratively to improve the prescribing, managing and monitoring
 of controlled drugs. We have already seen examples of how better collaboration
 and partnership working as part of a local system can result in improved safety
 and better outcomes for people.
- Make sure you have a valid Home Office controlled drugs licence if you are required to have one. This involves forward planning to check when licences are due to expire, or when a new licence is needed. You must allocate enough time to complete this process, otherwise it will affect your ability to provide care. The Home Office provides further advice.

We will continue to monitor progress against these recommendations.

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