General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Dispensary Green, Unit 3, Sherwood Network Centre, Newton Hill, New Ollerton, Nottinghamshire, NG22 9FD

Pharmacy reference: 9011755

Type of pharmacy: Internet

Date of inspection: 17/10/2022

Pharmacy context

This is an internet pharmacy with physical access to the premises closed to the public. It provides both NHS and private services. The pharmacy specialises in dispensing private prescriptions for specific controlled drugs received directly from Care Quality Commission (CQC) registered clinics. And people can nominate the pharmacy to receive and dispense their NHS prescriptions. Through its NHS service the pharmacy dispenses some medicines in multi-compartment compliance packs, designed to help people to take their medicines. And it supplies medicines to people living in care homes. It supplies the medicines it dispenses through a delivery service.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

Follow this link to find out what the inspections possible outcomes mean

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy does not identify and manage all the risks associated with its supplies of specific higher-risk medicines. It does not have risk assessments for individual treatments and conditions. And it does not have relevant information, such as prescribing policies to help the team manage the risks when supplying medicines in this specialised area.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy doesn't identify and manage all the risks associated with its services. It doesn't complete risk assessments for all its services and the higher-risk medicines it supplies. And it doesn't engage in ongoing audit processes to help manage these risks safely. The pharmacy clearly advertises how people can provide feedback and it acts on this feedback to help inform improvement. It keeps the records it needs to by law up to date and it protects people's private information appropriately. Pharmacy team members are aware of how to recognise and raise concerns to help safeguard vulnerable people. They openly and honestly discuss mistakes they make during the dispensing process. And they act to reduce risk following these discussions.

Inspector's evidence

The pharmacy was part of a wider group providing specialist services associated with the prescribing and supply of specific controlled drugs (CDs), many of which were unlicensed medicines, also known as ‘specials’. It operated as a separate legal entity to the prescribing service. And it offered its secure digital platform to the group’s own clinic and to other CQC registered clinics prescribing these specific CDs. A large proportion of its workload was generated from the group’s own CQC registered clinic, based in London. The pharmacy’s digital platform allowed clinics to securely upload scans of private prescriptions for the specific CDs ahead of providing the pharmacy with a hard copy of the prescription. Each clinic was registered separately on the platform, as was each prescriber. All prescriptions dispensed through the private service were on NHS CD private prescription forms, known as a FP10PCD. The pharmacy employed a dedicated team of patient coordinators, known as the customer service team. These team members worked remotely from the pharmacy. This team had direct contact with members of the public accessing the private service. And it worked in a customer service facing role, managing payments, and answering non-clinical queries. Patient coordinators could contact a member of the in-house pharmacy administration or dispensing team live when speaking to members of the public to support them in answering queries.

The pharmacy minimised some risks by clearly separating tasks associated with the two sides of its business model by having two dispensaries: one for the private service and the other for the NHS side of the business. Most tasks undertaken by the pharmacy’s administration team supported the private service. Each dispensary had a set of standard operating procedures (SOPs). These SOPs were reviewed two yearly and there was a SOP review and change request form available for team members to complete, if they found any inconsistencies between the documented SOP and what happened in practice. The SOPs for the pharmacy’s private service had recently been reviewed and included responsible pharmacist (RP) requirements, CD management and stock management. There was a range of helpful appendices to the SOPs to support pharmacy team members in their role. NHS service SOPs were comprehensive, these were due for review. Pharmacy team members had completed training competencies in relation to the SOPs and had signed to accept they would work in accordance with them. They were confident in demonstrating how they completed their tasks, and showed a clear understanding of both their own job roles, and of the job roles of other team members. Pharmacy team members were knowledgeable about the types of products being dispensed and understood processes required by law when dispensing the specific CDs for the private service. For example, the process for sending a CD and unlicensed medicine to the Channel Islands. Workload was managed well with planned time in each dispensary for the pharmacist to complete clinical checks of prescriptions and

accuracy checks of medicines. Due to some feedback received, the pharmacy had recently completed an audit monitoring the time taken from prescribing to delivery of medicines through the private service. This was to monitor the efficiency of its workflow and communication with the clinics.

The pharmacy had a risk assessment that focussed on areas such as health and safety, business contingency, training, confidentiality and the supply and delivery of medicines. There was evidence of version control and regular update in relation to this risk assessment. But the pharmacy had not completed a specific risk assessment relating to the individual services it provided, or of the specific CDs it supplied. In its risk assessments it had not taken into consideration that the specific CDs were higher-risk medicines and many of them unlicensed. The pharmacy had not requested information such as copies of prescribing policies or risk assessments from the clinics it dispensed prescriptions from. This meant it didn't have some relevant information available to help ensure the pharmacy always supplied the specific CDs appropriately. The pharmacy had not completed any clinical audits related to the supply of medicines through its private service. And without specific information about the prescribing from the clinics, it would find it difficult to assess the findings of any audit. The pharmacy sent the FP10PCDs to the NHS Business Services Authority every month so there was external visibility of prescribing. But any prescribing data generated through following this process would be provided to the clinics, and was not shared with the pharmacy. The pharmacy had commissioned an independent audit focussed on the way it delivered its services. And it had implemented some recommendations which had been taken onboard and implemented. For example, a change to the holding arrangements for specific CDs whilst awaiting collection from the courier. But the audit had not considered the specific nature of some of the services provided, and the need for ongoing risk assessment and audit processes.

The pharmacy had tools to support its team members in recording mistakes found and corrected during the dispensing process, known as near misses. There was evidence of consistent near miss recording across both dispensaries. The NHS team had used an electronic system to record its near misses for some time, this supported the team as it produced trend analysis data of the types of mistakes being made. And the team provided an example of how they continuously shared learning from near misses. For example, by separating medicines in similar looking packaging. The private service team was in the early stages of transferring to the electronic near miss reporting system. The pharmacy had worked with the system provider to set up bespoke near miss and incident reporting templates as there had not been an option to record the specific CDs dispensed on the system. The private service team demonstrated actions they had taken to reduce risk by separating specific CDs with similar names within its secure cabinets. Pharmacy team members understood how to respond to and report mistakes identified following a person receiving their medicine, known as dispensing incidents. And the pharmacy kept dispensing incidents reports with details of the outcome of the investigation and the actions taken to reduce the risk of a similar incident occurring. Pharmacy team members engaged in regular team meetings to share learning from patient safety events. And they demonstrated how these meetings helped to support them in reducing risk. For example, two team members completed full balance checks of physical CD stock daily. These checks took place independently of each other and were then checked against the CD register.

The pharmacy had a procedure for managing feedback and complaints. And it provided clear information on its website about how people could contact the pharmacy or raise a concern. The pharmacy had experienced a sharp rise in concerns in 2021. These concerns largely related to communication between the clinics and the pharmacy and delays in people receiving their medicines. The complaints had informed the content of a webinar, chaired by a patient representative, in which the superintendent pharmacist (SI) and operational pharmacist (OP) held a question and answer session with people. A representative from a one of the manufacturers that the pharmacy worked closely with was also on the panel and answered questions. They answered queries relating to the supply chain and

good manufacturing practice (GMP) guidelines. This forum had allowed people to provide feedback and receive an apology from the pharmacy for some of the issues experienced. And learning from the issues had been used to inform the implementation of the pharmacy's digital platform. The remote patient coordinator team handled the majority of feedback from people. And queries were managed through ticket numbers to help monitor progress and resolution times. All calls were recorded and the SI had oversight of the feedback the pharmacy received.

The pharmacy provided evidence of its up-to-date indemnity insurance arrangements. A sample of records required by law were examined. The RP notice was displayed prominently and contained the correct details of the RP on duty. The RP record was held electronically and completed as required. The pharmacy held information relating to the supply of each unlicensed medicine with its complete certificate of conformity, in accordance with the requirements of the Medicine and Healthcare products Regulatory Agency (MHRA). The pharmacy only held these for several months following the supply being made. They were then secured in box files and sent to a centralised secure storage facility. Team members confirmed that these could be retrieved if needed. The pharmacy kept an up-to-date electronic CD register with daily balance checks of physical stock against the register. Entries within the register were seen to be comply with legal requirements. The pharmacy had specific procedures relating to information governance and data security. These set out clearly how it protected people's confidentiality. Its website contained details of its privacy policy and its staff handbook reinforced how its team members should process people's confidential information. The pharmacy held confidential waste securely and this was collected periodically by a secure shredding company.

The pharmacy's SOPs included specific SOPs relating to safeguarding vulnerable people. And contact information for safeguarding teams was accessible. Pharmacy team members, including patient coordinators had completed learning on the subject and knew how to raise a concern about a vulnerable person. A team member highlighted how a recent concern from the local delivery driver about a person potentially not taking their medicine as intended had been shared with the person's own GP.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy employs a suitable team of people to manage its workload. And it has appropriate contingency arrangements in place in case of staff absence. The pharmacy actively engages with its team members to help inform improvements to service delivery. And it encourages its team members to speak up and share learning through regular team meetings. Pharmacy team members generally engage in some ongoing learning relevant to their role. But there are sometimes delays in recognising the need to enrol team members on qualification training.

Inspector's evidence

A regular pharmacist worked at the pharmacy four days a week. The remaining day each week was covered by PIPs working for the group's clinic, as was cover for leave. The pharmacy did not routinely use locum pharmacists due to the specialist nature of the business. The pharmacy manager was a qualified dispenser, they were supported by another qualified dispenser in a deputy manager role. There was a pharmacy technician, a further six qualified dispensers, three administration team members, a delivery driver, and a trainee dispenser. Three of the dispensers and the trainee dispenser held dual roles as they also worked within the administration team. This allowed for flexibility to cover leave and supported the pharmacy's business continuity arrangements. The pharmacy also employed the SI and a pharmacy operations manager. These management roles included regular communication with the group's clinic. And the operations manager was involved in daily meetings with the pharmacy's offsite customer service team manager, who managed the patient coordinators employed by the pharmacy.

The delivery driver completed tasks associated with the NHS service only. They had commenced their role after October 2020, when GPhC guidance relating to the minimum training requirements for pharmacy support staff had changed. The driver had read the pharmacy's SOPs and had received internal training, including learning associated with safeguarding vulnerable people. But they had not completed an accredited training course as required. Swift action was taken during the inspection to enrol the driver on a suitable training course to support their learning needs and evidence of this was presented. A member of the administration team had recently changed their role to include some packing tasks associated with the supply of medicines. A discussion took place about the need to enrol this team member on an accredited learning programme if they were to continue in this role.

The RP had attended a one-day training course to support them in their role. But this training did not include activities or assessments to ascertain their level of understanding about the specific CDs supplied and to ensure they had sufficient knowledge to carry out appropriate clinical checks. The RP demonstrated evidence of reading they had completed to support them in their role. And they provided some examples of where they would question the appropriateness of a prescription. But this was restricted to formulation or dosages rather than the suitability of the medicine for the person's condition. And there was no evidence of interventions being recorded. Following the inspection, the GPhC received evidence of the RP completing assessment-based e-learning relevant to their role through NHS Health Education England.

The pharmacy maintained a training portfolio with evidence of qualifications and regular e-learning completed by its team members. And pharmacy team members received protected training time and

regular appraisals within work to support their learning needs. In addition to personal learning there was evidence of regular team meetings taking place. The pharmacy kept notes of the topics and outcomes discussed within these meetings. And it displayed the most recent meeting's notes for its team members to read. The team meetings were well structured with topics including health and safety, processes, patient safety and learning discussed. Recent notes identified that a team member had shared some specific learning about the different types of medicines the pharmacy supplied through its private service.

The pharmacy did not set its team members specific targets to meet. The pharmacy had a whistle blowing policy. And its team members had a good understanding of how to raise concerns or share their feedback at work. They were confident in sharing their ideas at work. And these ideas were taken onboard by the pharmacy to support it in delivering its services safely. For example, a team member had suggested using formal 'information notes' attached to prescription forms. These notes were used to communicate messages between the administration team and dispensary team about a prescription.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are suitable for the provision of healthcare services. They are clean, secure, and well maintained. The pharmacy's website provides clear information to people about the pharmacy's registered status.

Inspector's evidence

The pharmacy was secure and in a good state of repair. Visitors to the pharmacy were required to ring a bell for access and they signed into a visitor book. The pharmacy was clean throughout with floor spaces kept free from trip and fall hazards. There was appropriate hand washing facilities available to its team members. Lighting was bright throughout the premises and portable air conditioning units helped keep room temperature at a suitable level during summer months. Windows could also be opened during the working day to increase ventilation. The premises consisted of a good size office used by the administration team, off this area there was access to staff kitchen and toilet facilities and to both dispensaries. The dispensaries were an adequate size for the level of activity taking place.

The pharmacy's website included the name, address, and contact information for the pharmacy. The pharmacy used the GPhC's voluntary internet pharmacy logo, this linked directly to the GPhC's register. It also provided details of the SI. But it did not prominently advertise how to check the SI's registration status. The website also provided a clear set of terms and conditions, and its zero tolerance policy on harassment and abuse.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy ensures its services are accessible to people, and it informs people and prescribers of potential delays in the service caused by circumstances outside of its control. The pharmacy makes some checks to ensure it obtains its medicines from reputable suppliers. And it generally stores its medicines safely and securely with regular checks to make sure medicines are in good condition and suitable to supply. But it doesn't always obtain supportive information to help its team ensure the supplies of its higher-risk medicines are appropriate.

Inspector's evidence

The pharmacy's website provided details of how people could access both its NHS and private services. And it provided information about the nature of the medicines it supplied. This included a frequently asked questions section, and details of the question and answer session from its 2021 webinar. Further information on the website informed people how they could transfer their NHS prescription to the pharmacy and advertised the pharmacy's care home services. There were also pages providing health and lifestyle advice, including managing anxiety, fear, and panic. The pharmacy's website had information to warn people about the potential delays to its private service due to the current postal worker strikes. The website did not advertise medicines and people could not access clinic appointments directly through the website. People could register with the pharmacy for website login. This provided access to their own personal platform page to track their prescription once the pharmacy had received a scanned image from the clinic. The pharmacy team understood the vulnerabilities in the supply chain of the specialist medicines it dispensed. It obtained regular stock status updates from its suppliers and shared this information with the clinics who sent prescriptions to the pharmacy. This attempted to avoid delays in people receiving their medicines.

The registration process for the digital platform required people to provide two forms of identification. This part of the process and other customer service tasks such as payment were managed by the offsite customer service team. The onsite pharmacy team received notification of a prescription through the digital platform.. This involved the clinic sending a scanned image of the prescription. The administration team then completed a series of checks including checking the prescription was legally valid and checks relating to the prescriber. For example, checking they were on the GMC's specialist register. They moved forward with processing the prescription by checking stock availability. Once the hard copy of the prescription was received by registered post the administration team completed the pre-dispensing checks and confirmed the availability of the medicine, a patient coordinator from the customer service team then sent a secure payment link to the person to pay for the prescription. The pharmacy kept a clear audit trail of each step of the prescription journey. This included recording details of who had processed the prescription at each stage. Prescriptions only progressed to the 'ready for dispensing' stage on the digital platform after all checks had been completed and payment had been made. The pharmacy completed manual monitoring checks related to the frequency of supply of the specific CDs against the digital platform and the patient medication record (PMR). But they could not check this was in accordance with the clinic's own prescribing policies, as these were not available. The pharmacy received some post-dated prescriptions. And it had appropriate processes to prevent the preparation and supply of medicines on these prescriptions before their due date.

The dispensing team completed labelling and assembly tasks prior to prescriptions being clinically

checked, and medicines being accuracy checked by the pharmacist. Dispensing labels attached to the medicines did not include information about the risks associated with driving under the influence of the medicine. This warning was available on the product label but in some circumstances, it was covered by the dispensing label and as such was not visible. This had not been picked up as part of the pharmacist's checks. A discussion highlighted the importance of safe and appropriate label placement when dispensing medicines. The team packaged the medicines securely with a clear address label and tracking ID and held the packages securely until collected by the courier. The pharmacy team was able to contact the patient coordinators if required at each stage in the dispensing process. For example, if a person was prescribed two items but only wanted one of them dispensed. A team member explained that this situation prompted referral by the patient coordinator back to the prescriber to ensure this was clinically appropriate, and to allow the prescriber to update the person's care plan. But the pharmacy did not keep the record of these types of interventions and it did not have access to people's care plans to support it in ensuring the process was followed correctly.

The pharmacy was aware that the prescribing clinics conducted both face-to-face consultations and remote consultations as part of the prescribing process. It checked the registration of medical doctors to ensure they were on the General Medical Council's (GMC's) specialist register as required. PIPs working for the group's own clinic worked closely under the supervision of a medical director using a shared care protocol. The shared care protocol included details of which specialist medicine could be prescribed and under what circumstances. And they had completed some specialist training to support their role. The SI reported that the pharmacy completed some onboarding checks before partnering with a clinic including a formal interview and a request for some professional documents such as identification, Disclosure and Barring service checks of prescribers, indemnity insurance checks, proof of registry on the GMC specialist register and checks of the clinical scope of practice. But it didn't record details of these initial checks or any routine ongoing checks it made. And the onboarding checks did not include receipt of the clinic's own risk assessments or their prescribing policies. The pharmacy didn't request any information relating to the condition the medicine was prescribed for, or have access to the clinical record. This meant the pharmacy had no way of verifying if the clinics were prescribing for the listed conditions as per NICE guidelines. The pharmacy didn't request any information from the clinics regarding how they communicated with people's own GPs.

The pharmacy had procedures to support the supply of medicines through its local delivery service and contracted courier services. And it had clear audit trails related to both delivery processes. The pharmacy supplied some specific CDs to people living in the Channel Islands. Its team members demonstrated clear processes for ensuring the necessary licenses were in place before exporting the medicine. This included a license to import the medicines issued to the person receiving it and a Home Office CD export license issued to the pharmacy. The medicine was supplied with a covering letter issued by the SI and details of how customs could check the registration status of the pharmacy supplying the medicine, along with contact information for the pharmacy. But the registration number of the pharmacy quoted within this covering letter belonged to the pharmacy's previous premises. This could potentially cause delays in a person receiving their medicine.

For the NHS service, members of the public nominated the pharmacy to receive their prescriptions. The pharmacy maintained an audit trail of the prescriptions it received and of the medicines it delivered. It ordered some prescriptions on behalf of care homes following notification from the home of what medicines its residents required. But most care home teams ordered prescriptions themselves for the people living in the home and these were transferred to the pharmacy through the NHS Electronic Prescription Service. The pharmacy was provided with a copy of a re-ordering Medicine Administration Record (MAR) sheet on each occasion. And this was checked against prescriptions received to help identify any missing items or queries.

The pharmacy supplied some medicines to care homes in multi-compartment compliance packs. It maintained records associated with the way it supplied these medicines. And it supplied MARs for each person's medicine, this included the supply of electronic MARs to one home. This supported the team in responding to any queries it received. But the pharmacy didn't always supply patient information leaflets (PILs) to the care homes unless the medicine was new. Team members took ownership of their work by signing the 'dispensed by' and 'checked by' boxes on medicine labels when dispensing medicines. The pharmacy assembled some medicines in multi-compartment compliance packs for people residing in their own homes. It used individual records to support it in managing this service and in monitoring and recording changes to people's medicine regimens. A sample of assembled compliance packs contained full dispensing audit trails and clear information about the medicines assembled inside them. But the pharmacy didn't routinely supply people with PILs when supplying medicines in this way. It did supply PILs when supplying medicines in original containers. Team members working in the private service dispensary supplied specific information leaflets to support people in using the specific CDs safely. The pharmacy team had a basic understanding of the requirements of the valproate Pregnancy Prevention Programme (PPP). And it had the tools to support the checks required if it received a prescription for a person within the at-risk group. But the pharmacy supplied valproate to some people living in care and it had not sought information to assure itself that these people received an annual specialist review.

The pharmacy sourced medicines from licensed wholesalers and from licensed specials suppliers. The SI provided assurances of initial checks that were completed when setting up an arrangement with a specials supplier. This included ensuring the supplier had the necessary specials and home office licenses as required. But the pharmacy did not document these checks, and there was no evidence to support how often it repeated these checks. Medicine storage was generally orderly but dedicated space for the storage of medicines in the NHS dispensary was nearing its capacity. And there were several examples of risk being increased by storing different strengths of the same medicine on top of each other. The pharmacy held stock of CDs securely and storage within the secure cabinets was orderly. Due to the specific CDs being natural products they were vulnerable to environmental factors. The pharmacy engaged in temperature mapping audits to help ensure the storage environment inside the cabinets was appropriate. This involved fitting recording thermometers in each CD cabinet and sending them away for analysis. The pharmacy supplied the specific CDs within their original packaging. This reduced the risk of them being subject to any environmental factors within the pharmacy and during the transit process. The pharmacy stored medicines subject to cold chain requirements safely in a refrigerator. It kept a fridge temperature record to ensure it stored these medicines at the correct temperature.

The team completed regular date checking tasks, and short- dated medicines were clearly identifiable. Team members recorded opening dates on liquid medicines to help ensure they remained fit to supply. Pharmacy team members working in the private services dispensary were aware of the short shelf-lives of many of the products they dispensed and actively checked expiry dates to ensure the medicine would remain in date for the duration of treatment. The pharmacy had appropriate medicine waste bins and CD denaturing kits to support in the safe disposal of pharmacy waste. A folder in each dispensary held details of drug alerts and recalls issued by the MHRA. And the pharmacy had appropriately engaged in an investigation following a concern relating to the safety of a specific CD.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment and facilities it needs to provide its services. It maintains its equipment appropriately. And its team members use the equipment in a way which protects people's confidentiality.

Inspector's evidence

Pharmacy team members had access to up-to-date electronic reference resources. For example, the British National Formulary (BNF). And they could access the internet to help resolve queries and to obtain up-to-date information. The pharmacy's computer systems were password protected and information was regularly backed up. The pharmacy had a range of clean equipment available to support the delivery of pharmacy services. For example, calibrated measuring cylinders for measuring liquid medicines. Equipment associated with the supply of medicines in compliance packs was single use. Electrical equipment was in good working order and there was evidence of monitoring checks to ensure it was safe to use.

What do the summary findings for each principle mean?

Finding	Meaning
✔ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✔ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✔ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.