General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Medication Delivery Services Ltd, Unit C6, Meridian Industrial Estate, Hoyle Road, PEACEHAVEN, East Sussex, BN10 8LW

Pharmacy reference: 1103465

Type of pharmacy: Internet / distance selling

Date of inspection: 04/01/2023

Pharmacy context

This pharmacy provides its services 'behind closed doors' from a warehouse unit on an industrial estate on the outskirts of Peacehaven near Brighton. It is not open for people to visit the pharmacy in person as it mainly dispenses prescriptions for people in care homes. It supplies some of its medicines in multi-compartment compliance packs to help people and their carers manage their medicines. It also delivers some medicines to people who live in their own homes. This was a targeted inspection so not all standards were inspected.

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 has insufficient evidence to show that it has adequately considered the risks associated with providing its services. The pharmacy has made a number of errors recently which might have been avoided if it had more thoroughly assessed those risks.
		1.2	Standard not met	Patient safety incidents are inadequately recorded with no evidence of reflection upon the possible causes, or of any clear learnings from those incidents. There is little evidence of any action being taken to help prevent similar mistakes being repeated.
		1.6	Standard not met	The pharmacy does not keep adequate records of its controlled drugs (CDs), they are untidy, disorganised and in some cases inaccurate. Some entries have been altered without the pharmacy making it sufficiently clear who made the alteration, why they did so or when. The pharmacy destroys some CDs without having authorisation. It also does not ensure that CD records are always available for inspection upon request. The pharmacy repeatedly fails to maintain a contemporaneous, accurate and complete record of the responsible pharmacist on duty.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Not assessed	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not do enough to make sure that people in an at-risk group are adequately warned about the risks involved in taking high-risk medicines such as those containing valproates.
5. Equipment and facilities	Not assessed	N/A	N/A	N/A

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

Summary findings

The pharmacy is not thorough enough when assessing the key risks involved in providing its services. It does not do enough to learn from its mistakes and prevent them from happening again. It does not keep adequate records of those mistakes and any changes it may have made. The pharmacy does not satisfactorily maintain all of the records that the law requires it to keep. And it doesn't keep those records in an easily accessible place so that they can be readily checked. It is also does not keep a satisfactory record of which pharmacist(s) were responsible for the operation of the pharmacy on a day-to-day basis, as required by law. But it does have suitable written instructions available to help its team members complete their tasks correctly and safely. And it keeps those instructions up to date.

Inspector's evidence

There were up-to-date Standard Operating Procedures (SOPs) in place to support all professional standards which had last been updated in February 2021. The superintendent pharmacist (SI) and managing director (MD) both confirmed that these were shortly due to be updated as they did this every year. Each SOP had a signature sheet signed by team members to show that they had read and understood it. The pharmacy had also created some separate SOPs to reflect the changes they had made to various procedures during the COVID-19 pandemic.

No written risk assessments were available but the SI and MD were able to describe some of the processes they had put in place to manage risks that had beeen identified. For example, different colour baskets were used for assembling different care homes' prescriptions to reduce the risk of mixing them up. And stock for individual prescriptions was placed in individual baskets to reduce the risk of error. But there was no evidence of any changes being made to the final accuracy checking procedure following a number of recent errors.

Errors and near misses were recorded on separate sheets, one for each care home. Those sheets examined did not contain enough detail to clearly identify the nature of the incident(s) recorded. There was no clear evidence of reflection upon the possible causes, or of any action having been taken to prevent the same mistakes being repeated. There was little evidence that the records had been reviewed, although the RP did discuss them with the team and had some notes of those meetings. But the notes did not clearly indicate what, if any, changes had been made. Those team members questioned did confirm that the RP did discuss their errors with them to help them avoid making the same mistakes again. The MD also confirmed that dispensing errors, which had not been identified until after the medicine(s) had left the premises, were reported to the NHS Learning from Patient safety Events (LFPSE) service via the PSNC website.

Staff were able to describe what action they would take in the absence of the responsible pharmacist (RP), and they explained what they could and could not do. They outlined their roles within the pharmacy and where responsibility lay for different activities. All dispensing labels were signed by two people to indicate who had dispensed the item and who had checked it. The RP notice was correct and clearly displayed for people to see, but the electronic RP record was found to be incomplete. The electronic RP record could not be accessed on the previous inspection as the RP's NHS Smartcard had expired at that time. So, the pharmacy had reverted to a paper record, and the SI had been reminded of her obligation to maintain the record. On this occasion the electronic RP record was found to have

significant gaps from mid-May 2022 onwards, and there were only two entries for all of December 2022. Furthermore, there was no GPhC registration number against any of the entries for the SI. The only entries, of those examined, that appeared to be correct were for a locum pharmacist. The MD explained that only those with administrative permissions could create the initial entry for a pharmacist before they could then enter themselves on the record. There was no satisfactory explanation for the missing registration number. The SI again agreed to revert to a paper record. But when the inspector returned the following day, it was only when the paper record was requested that the necessary entry for that day was made.

The Controlled Drug (CD) registers were not available for inspection upon request. The SI explained that they had been taken home for her to make the necessary entries as they didn't have sufficient time during the working day over the Christmas and New year period. The inspector returned the following day to examine the registers and identified a number of failings with the records.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. Pharmacy team members are appropriately trained, and the pharmacy keeps suitable records of their progress. They have a satisfactory understanding of their role, and they work well together.

Inspector's evidence

There were two trainee dispensing assistants, a foundation trainee pharmacist, the managing director and the superintendent pharmacist (who was also the RP) on duty at the time of the inspection. This appeared to be sufficient for the workload at the time. The foundation trainee had completed her training elsewhere and was working at the pharmacy until the next opportunity for her to sit the registration assessment. The two trainee dispensing assistants were about to complete their initial three months of employment at the pharmacy. The SI provided assurances that they would both be enrolled on an accredited training programme as soon as the three-month period had finished.

There was a sheet for each team member setting out the tasks they were responsible for, with space for them to indicate whether they were competent or still needing further training. This was used to track their progress and was based upon the tasks in the relevant SOPs. Upon questioning, team members confirmed that the SI showed them how to complete their tasks and they had on-the-job training. All three of them seemed happy with their work and were observed to be helping each other.

Principle 3 - Premises ✔ Not assessed

Summary findings

This principle was not assessed during the inspection

Inspector's evidence

This principle was not assessed during the inspection

Principle 4 - Services **Standards not all met**

Summary findings

The pharmacy provides a service which it tailors to meet the needs of those it serves. But it is making numerous errors which indicate that it is not always operating its dispensing service effectively. And there was little evidence of it making improvements in response to those errors. Its team members identify people supplied with high-risk medicines but they don't leave the warnings visible enough to help people take their medicines safely. And they don’t remind them of the warnings often enough. The pharmacy sources, stores and generally manages its medicines safely. And it makes sure that the medicines it supplies are fit for purpose.

Inspector's evidence

The pharmacy specialised in dispensing prescriptions for people living in care homes, or who needed their medicines in multi-compartment compliance aids. Controls were seen to be in place to reduce the risk of errors, such as using baskets to keep individual prescriptions separate. All the prescriptions for an individual care home were kept separate from those for other care homes as described under Principle One.

The pharmacy had a number of computer systems in place to help it carry out the various tasks involved in meeting the different needs of all its care homes. The main patient medication record system (PMR) was used to download all the NHS electronic prescription service (EPS) prescription tokens. The pharmacist on duty then undertook a clinical check of each prescription token before it was scanned into another system used for producing an electronic medicines administration record (eMAR) chart for the care home.

Care homes using these eMAR charts had a hand-held terminal linked to the system in the pharmacy so that they could see the scanned prescription token as well as the eMAR chart relating to it. This helped to minimise any queries the care home might have relating to the prescription. The system also allowed the pharmacy to see when the care home had signed the medicine in upon delivery from the pharmacy, as well as when it was administered by the care home staff. The MD highlighted some recent problems they had been experiencing with this system. The system was frequently crashing resulting in delays with completing tasks. One such system crash occurred during the inspection. The MD also stated that when a care home started to use another pharmacy with this system, the whole record transferred to the new pharmacy. This meant that if they had any queries, they couldn’t access the historic data to investigate. He did confirm that the historic dispensing data was held on the main pharmacy PMR system. However, it was the detail including dosage times etc that was no longer available to them. If a care home moved to another pharmacy that didn’t use this system, then they still had access to the archived data.

The pharmacy used a third system for labelling the assembled compliance packs. The labels had the facility to include a photograph of each tablet or capsule. This wasn’t used in all cases as the shape or colour often varied from one delivery to the next owing to current fluctuations in the supply chain. Product descriptions were added by hand if they weren’t already on the label. As none of the three systems were directly linked, the SI ensured that every prescription token was carefully cross-checked against the current entries on each of the other two systems before anyone produced any dispensing labels. Any discrepancies between the prescription token and the previously recorded entry on the

labelling system were noted on a form which was then checked with either the care home or GP, whichever was appropriate. The compliance packs were then assembled according to the specific needs of the care home. The inspector queried the safety of having so many manual interventions between the various systems used by the pharmacy. The MD had previously demonstrated how the system was used and emphasised the checks made to ensure accurate transcription of the data from one system to the next. Some recent incidents had prompted the MD and SI to consider a more integrated system which required less manual intervention.

A final accuracy check was carried out by the RP to recheck that everything was as prescribed by the GP, and as expected by the care home. The SI was confident that the final accuracy check was robust. But she accepted that there had recently been a significant number of errors, which indicated that the service was not always operating effectively. And she was not able to give examples of any significant changes being made to the dispensing operation in order to reduce the error rate. All items that could not be supplied in full were noted on a collated owings form provided to the care home with the delivery. There was a forward planner on the wall detailing a re-ordering schedule and the delivery schedule for each of the care homes, and for the individual deliveries to those people receiving compliance packs at home. Patient Information Leaflets (PILs) were provided with the compliance packs.

The delivery service was previously tailored to the individual needs of each care home. But during the pandemic, the pharmacy had standardised its delivery service and implemented a new policy of only delivering to one care home at a time and not entering their premises. Delivery records were electronic and enabled the team to track each bag of medicines. Each bag was barcoded so that when the care home checked it in on their system a complete audit trail was visible to the pharmacy.

Staff were aware of the risks involved in dispensing valproates to women who could become pregnant. The SI confirmed that they did supply valproates to a small number of people in the at-risk group, but they hadn't recently checked whether they, or their carers, were aware of the importance of using long-term contraception. A prescription for sodium valproate awaiting its final check was examined. It was found to have the dispensing label placed over the warnings printed by the manufacturer.

Medicines were obtained from recognised licensed wholesalers including unlicensed specials. The pharmacy was currently experiencing significant difficulties with one of its wholesalers in particular. This resulted in incomplete deliveries, delivery failures and deliveries arriving at unpredictable times. All of this made it harder for the pharmacy to meet the needs of the care homes and people it served. Fridge temperatures were recorded daily and those examined were seen to be within the correct temperature range.

Controlled Drugs (CDs) were stored securely in two approved cabinets bolted to the wall in accordance with the regulations. One cabinet was used for storing stock for dispensing, and the other was for unwanted items that had been returned to the pharmacy or were out of date. The records of returned CDs appeared to be in order. The keys to the cabinets were kept on the pharmacist's person.

Principle 5 - Equipment and facilities ✔ Not assessed

Summary findings

This principle was not assessed during the inspection.

Inspector's evidence

This principle was not assessed during the inspection.

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.