General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Inspire Pharmacy, Unit 18, Croft Road, Newcastle Under Lyme, Newcastle, Staffordshire, ST5 0TW

Pharmacy reference: 9011381

Type of pharmacy: Internet / distance selling

Date of inspection: 06/05/2021

Pharmacy context

The pharmacy is situated in an industrial unit on a business park. The pharmacy relocated to the current premises around a year ago. Members of the public do not usually visit the pharmacy in person. The pharmacy delivers medicines using their own drivers and couriers. The pharmacy mainly dispenses NHS prescriptions to people in the community and in care homes. It supplies a large number of medicines in multi-compartment compliance aid packs to help people take their medicines at the right time. The pharmacy has a website (www.Inspirepharmacy.co.uk) which provides information about the pharmacy and people can also purchase a range of over-the-counter medicines. The inspection was undertaken during the Covid 19 pandemic.

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 have adequate systems in place to identify and manage risks such as suitable standard operating procedures, risk assessments prior to initiating new services and procedures in place to learn from dispensing incidents.
		1.6	Standard not met	The pharmacy's responsible pharmacist (RP) record and CD registers are not accurate.
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 not all met	4.2	Standard not met	The pharmacy team carries out activities requiring pharmacist supervision without a responsible pharmacist. The pharmacy is not able to demonstrate that the medicines it sells via the internet are clinically appropriate.
		4.3	Standard not met	The pharmacy does not manage and store medicines in a secure and organised manner. It does not properly restrict unauthorised access to some medicines. The pharmacy cannot provide assurance that the temperature of all the medical fridges are appropriately monitored. Some medicines in the pharmacy are not stored in their original packaging and have not been appropriately labelled.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy does not identify and manage all of the risks involved with its services. The pharmacy's records are not always accurate, which could make it harder to understand what has happened if problems occur. Members of the pharmacy team do not always follow the pharmacy's written procedures. So they may not always work effectively or fully understand their roles and responsibilities, and who is accountable for what. The team members do not make full records or review their errors, so they may miss learning opportunities.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) for the services provided, with signatures showing that members of the pharmacy team had read and accepted them. However, some SOPs had not been tailored to the distance selling pharmacy environment and others were not being followed. For example, the sales of over-the-counter medicines and the responsible pharmacist (RP) SOPs. Pharmacy team members knew when they should refer queries to the pharmacist, but the team did not have a clear understanding of the RP requirements. They routinely carried out activities which required an RP, when there was no RP signed in. For example, labelling and assembly of prescription medicines. Team members were wearing uniforms and name badges showing their role.

There was an electronic error recording system which could be used to record and review both near miss incidents and dispensing errors. An example of a previously recorded dispensing error was seen. This involved the supply of out-of-date glycopyrronium ampoules. But no learning outcomes were recorded, such as reviewing the date checking procedure or re-checking the expiry dates of dispensary stock. The pharmacy superintendent (SI) said errors were discussed with members of the pharmacy team. He provided an example where the stock for Tramadol and Trazadone had been segregated following a previous error. But there was no evidence of near miss errors being recorded or reviewed, so the team may be missing out on some learning opportunities.

The pharmacy supplied a small number of pharmacy (P) medicines via its website. The pharmacy's operation manager said a risk assessment for the online sales had been completed, but she could not locate it. She said it did not include a risk assessment of the individual medicines, to determine whether they were appropriate to supply online. She confirmed that the risk of people abusing medicines had been considered and a maximum quantity cap had been introduced for two medicines which were known to be abused; Solpadeine and Phenergan Elixir. When the pharmacy received a request for a P medicine the operation manager manually checked the person's name and address and what they had previously ordered, before sending the request to the pharmacist for review. There were no documented audits in relation to the online sales such as records of decisions to make or refuse sales. Subsequent to the inspection the SI advised the inspector that he had decided to stop selling Phenergan Elixir from the pharmacy.

The operation manager dealt with complaints and submitted an annual complaints report to the NHS. The pharmacy's complaint procedure and a 'contact us' form were available on the pharmacy's website. A customer satisfaction survey was carried out annually. An area identified which required improvement in a previous survey was providing advice on healthy living. The operation manager

normally visited the care homes every three to six months to carry out audits. She confirmed she acted on any feedback received at these visits. For example, one care home reported issues with the electronic medicine administration records (MARs) so she arranged some formal training to be provided for the care home staff. Visits to the care homes had not been possible during the pandemic but they were in regular contact by telephone.

The SI and operation manager believed that adequate insurance arrangements were in place, which included the online sales of P medicines, but they couldn't provide evidence of this. Following the inspection, the operation manager contacted the pharmacy's insurance provider and upgraded their insurance to an appropriate policy covering all of the services, and she forwarded the details to the inspector.

An RP notice was displayed and there was an electronic RP log. The RP for the previous day was the SI, but he had not recorded a time at which he finished. This was added by the SI when the omission was pointed out to him. The RP log showed the SI generally worked from 5pm until 11pm on Tuesdays and Thursdays. The SI said this was because of the pharmacy's NHS contractual requirements to operate from 5pm to 11pm on those days. The SI explained that most of the pharmacy team worked from 9am on those days and a regular locum pharmacist usually worked from 9am to 6pm on Thursdays. However, on sixteen Tuesdays and four Thursdays since 1 January 2021, the RP log showed that there was no RP until 5pm on those days. So, the pharmacy was effectively operating without an RP on these days. The SI did not fully understand the RP record keeping requirements. This meant the pharmacy could not reliably demonstrate when a pharmacist was present, as required in the RP regulations.

Controlled drug (CD) registers were maintained electronically and running balances were recorded. The SI said the CD balances should be checked each month, but these checks had not been completed since January 2021. Four random balances were checked, and three were found to be incorrect. Following the inspection, the SI investigated the discrepancies and found that supplies made on the day of the inspection and the previous day had not been recorded. He provided copies of the prescriptions and confirmed that he had made the entries and the records were now accurate. Patient returned CDs were recorded in a separate register. Records for private prescriptions and emergency supplies appeared to be in order.

Members of the pharmacy team had read and signed the information governance (IG) policies and procedures which included information about confidentiality. Confidential waste was collected in a designated bin and then collected by a waste disposal company. A member of the team correctly described the difference between confidential and general waste. A leaflet entitled 'How we look after and safeguard information about you' and a privacy statement were available on the pharmacy's website, although the privacy statement had not been updated with the new pharmacy address following the relocation from unit 10 to unit 18, which might be confusing for people. The operation manager and SI did not know if the website was secure and compliant with information security management guidelines and the law on data protection. They could not provide assurance that there were secure facilities for collecting, using and storing people's details and a secure link for card payments. They said they assumed this to be the case as the website had been developed by a company who had set up other pharmacy websites and the payment was using PayPal secure checkout. The operation manager agreed to confirm this with the website developer. Subsequent to the inspection she confirmed that a meeting had taken place and they were reassured that data was encrypted and held securely using firewalls. They had also decided to enhance the security of the website by also applying for a SSL certificate.

The SI and locum pharmacist had completed the Centre for Pharmacy Postgraduate Education (CPPE)

level 2 training on safeguarding. Other members of the team had a basic understanding about safeguarding and knew to report any concerns regarding children and vulnerable adults to the pharmacist. There was a notice on display which contained the contact numbers of who to report safeguarding concerns to in the local area.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. Team members have the right training for the jobs they do and receive informal feedback about their performance. They are given opportunities to discuss issues but these communications are not always recorded, so the pharmacy might not always act on any issues raised.

Inspector's evidence

The RP was a regular locum pharmacist who usually worked one day each week in the pharmacy. The operation manager was a trainee dispenser and there were two other trainee dispensers and a delivery driver on duty at the time of the inspection. There was also a new member of the pharmacy team who had been working at the pharmacy for around two weeks. He hadn't read the pharmacy' SOPs. The SI stated that references had been obtained and a Disclosure and Barring Service (DBS) check carried out before they started work. The pharmacy provided induction training for new members of staff before enrolling them onto accredited training courses. The staffing level was adequate for the volume of work during the inspection. Staff worked set hours and planned absences were organised on an electronic calendar, so that not more than one person was away at a time. The SI was not due in to work until later that day but came into the pharmacy when he was made aware that an inspection was taking place. He was present for most of the inspection.

The operation manager explained that online training resources were available for the team, but not much training had been carried out since relocating to the new premises, due to the extra workload caused by the pandemic. One of the dispensers said she had been given some training time to work on her dispensing assistant course and she was close to finishing it.

Day to day issues were discussed between the team as they arose, but these were not recorded so there was a risk they issues raised might not be properly addressed. The pharmacy team discussed their performance and development informally with management. A member of the team said they would feel comfortable talking to the operation manager or the SI about any concerns they might have. There was a whistleblowing policy.

The RP was empowered to exercise her professional judgement and could comply with her own professional and legal obligations. For example, refusing to sell a pharmacy medicine because she felt it was inappropriate. The operation manager said no targets were set as the SI wanted everyone to be patient-focused.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises provide a suitable environment for people to receive healthcare services from.

Inspector's evidence

The premises were clean, spacious and in a reasonable state of repair. The temperature and lighting were adequately controlled. The pharmacy was fitted out to a good standard, and the fixtures and fittings were in good order. Staff facilities included a kitchen area and WCs. There was a separate dispensary sink for medicines preparation with hot and cold running water. The size of the dispensary was sufficient for the workload. Team members were wearing face masks and were generally working at benches which were at least two metres apart. The pharmacy's website contained accurate details about the pharmacy, but it still contained the MHRA EU internet logo, which had not been operational since the UK left the EU, so this might be confusing to people.

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

Summary findings

The pharmacy does not always operate safely. The pharmacy team sometimes carries our activities which require supervision when the pharmacist is absent. And it sells some higher-risk medicines without making sufficient checks to make sure these supplies are appropriate. The pharmacy does not always store medicines in an organised and secure manner, and it cannot show that it stores medicines requiring refrigeration at the correct temperature.

Inspector's evidence

This is a closed pharmacy which provided its services to people at a distance. Information about the pharmacy's services and operating hours were available on its website along with a wide variety of health information. People could contact the pharmacy by telephone or email. The operation manager described an occasion when she had signposted a person for support outside of the pharmacy, and the person later contacted her to thank her and let her know that she was regularly receiving help from this organisation. The pharmacy had a mobile app for people to order their medicines from their doctors' surgery.

Customers wishing to purchase medicines via the internet were required to complete a questionnaire which was reviewed by the pharmacist before the supply was allowed. If the sale was declined then payment would be refunded. However, the questions were the same for all the P medicines and they were not always relevant to the medicine requested. For example, the emergency hormone contraceptive (EHC) Levonelle. The identity of the person requesting the medicine was not verified, which may be a safeguarding risk for some medicines. The RP said she would usually telephone the person requesting Levonelle or a medicine liable to abuse such as Phenergan Elixir to check that the sale was appropriate. However, she did not record these calls, so there was no evidence of this. The RP explained that she had refunded a sale of Levonelle because following questioning she realised that the person was purchasing it to take on holiday as a precaution, in case it was needed, which was not a licensed use . Records of sales were recorded for each customer, so patterns could be monitored. Many sales had been refunded because the operation manager or pharmacist considered them to be inappropriate. However, examples were found which would indicate that people might be misusing medicines. One person had made several requests for Phenergan Elixir using different addresses. Another person had requested around nine bottles of Phenergan Elixir between 4 March 2021 and 27 April 2021. The pharmacy had refunded five bottles but supplied four bottles within this time frame. One person had purchased 24 packets of Solpadeine in one year. This was not in line with the current guidance or the pharmacy's written procedures which specifies that medication containing codeine is for short-term use only and for a maximum of 3 days.

The team carried out activities requiring an RP, when no RP was signed in or present. The SI confirmed that on Tuesdays, he was the only pharmacist who worked at the pharmacy and he usually worked as RP from 5-11pm. He said the pharmacy team assembled prescription during the day and then he would check them during the evening. This lack of supervision was a risk to patient safety. When the SI was asked what happened when wholesale drivers arrived at the pharmacy with CDs, which required a pharmacist to be present on the premises, he said he popped in from time to time during the day. However, there was no record of this on the RP log. A member of the pharmacy team confirmed that they would dispense medicines and put away stock before 5pm on Tuesdays when the pharmacist was

not present. But they said they would not send or supply medicines from the pharmacy when a pharmacist was not present. They said any CDs which were received would be given to the pharmacist for safe storage, however they could not explain what happened if the CDs were delivered when the pharmacist was not present.

The pharmacy had a delivery service. The service had been adapted to minimise contact with recipients, in light of COVID-19. The delivery driver would leave the patient's bag of medicines at the door, knock, and stand back to allow social distancing whilst the patient picked up the bag. The driver would wait and if there was no answer, the medicines were returned to the pharmacy. Deliveries were recorded electronically on electronic delivery software. The pharmacy dispensed instalment prescriptions for some patients on methadone solution, and a driver delivered the medication to patient's homes following a risk assessment and agreement by the drug and alcohol service.

Some prescriptions were delivered nationally using a courier. Medicines were packed and sent using the courier's tracking software. Usually a signature would be required, but the courier had adapted their process in response to current COVID-19 guidance. The SI said that only medicines which did not require refrigeration or CD safe storage would be sent using a courier. P medicines sold via the website were also sent by courier.

The pharmacy team initialled dispensed by and checked by boxes on dispensing labels to provide an audit trail. They used dispensing baskets to separate individual patients' prescriptions to avoid items being mixed up. The baskets were colour coded to help prioritise dispensing. Prescriptions were checked for validity during the final accuracy check.

The SI said he contacted patients who were taking a high-risk medicine such as warfarin, lithium and methotrexate. Appropriate information was available to supply to patients if necessary. But details of counselling were not recorded, so team members could not refer to this information when reviewing a person's PMR or providing further advice. The pharmacy team were aware of the risks associated with the use of valproate during pregnancy and educational material was available to supply with the medicine. The SI said he was not aware of any current patients who were in the at-risk group.

Round 80 people received their medicines in multi-compartment compliance aids. A team member said people would be started on a compliance aid at the request of a GP surgery or domiciliary care provider. Otherwise a verbal assessment about their suitability was completed by telephone, but this was not recorded by the pharmacy. Information about current medication was stored on the patient medication record (PMR). Any medication changes were confirmed with the GP surgery before the PMR was updated. A dispensing audit trail was completed, and medicine descriptions were usually included to enable identification of the individual medicines. Packaging leaflets were not usually included, despite this being a requirement. This means people might not have easy access to all of the information they need. Disposable equipment was used to provide the service.

The pharmacy supplied residents of around 24 care homes using the electronic "CAPA" system. The care home used an electronic tablet to update MARs and to re-order monthly prescriptions. The pharmacy was able to view the re-order information. When prescriptions were received the pharmacy would upload them onto the CAPA system to enable the care home to view the prescriptions. Any queries could be highlighted on the CAPA system and the care home was informed. Medicines were supplied in their original packaging for this system and so these included packaging leaflets.

Medicines were obtained from licensed wholesalers. The pharmacy ordered stock manually. There were no stock control systems such as stock counts or audits. Any unlicensed medicines were sourced

from a special's manufacturer, but the SI said they had not had a request to supply an unlicensed medicine for some time. The SI said stock was date-checked on a three-month basis and short-dated stock was highlighted with a sticker. The pharmacy had a diary to record short-dated stock. But there was no recent record indicating when stock had last been checked, or when was due to be checked again. A spot-check of medicines did not find any out-of-date stock. But there was a lot of medicines which were due to expire within a month and were not highlighted with a sticker. There were also a large number of loose foils containing tablets which were stored outside of labelling regulations with no indication of their expiry date or batch number.

CD stock was stored in the CD cabinet. There was some segregation between current stock, patient returns and out of date stock. Due to COVID-19, patient returned medication was quarantined for a few days. After this time staff would sort and dispose of the returned medication in designated bins located away from the dispensary. A number of patient-returned CDs were found in an office including morphine sulphate ampoules and Oxynorm ampoules and liquid. The SI said they, and the other medicines, were being quarantined in line with COVID-19 guidance. He said they had only been returned that morning and he would sort the CDs out later that day.

There were a number of medicines fridges, each with a thermometer. The minimum and maximum temperatures were being recorded daily for two of the fridges, and records showed they had been within the required range for the last three months. But there was no record of temperature monitoring for a third fridge in the compliance aid room. So, there was a risk that the medicines stored in this fridge might not be at the appropriate temperature. The fridge temperature remained within the required temperature range of between two and eight Celsius during the inspection. Drug alerts were received electronically on the patient safety software. Details of alerts which had been actioned and by whom was electronically recorded, providing an audit trail.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

Members of the pharmacy team have the equipment and facilities they need for the services they provide. They maintain the equipment so that it is safe to use.

Inspector's evidence

The staff had access to the internet for general information. This included access to the British National Formulary (BNF), BNF for children and Drug Tariff resources. There was a selection of glass liquid measures with British Standard and Crown marks. Separate measures were designated and used for methadone. The pharmacy also had triangles for counting loose tablets including a designated tablet triangle for cytotoxic medication. Equipment was kept clean. All electrical equipment appeared to be in working order. Computers were password protected and it was not possible to see into the pharmacy from the outside. A cordless phone was available in the pharmacy which allowed the staff to move to a private area if the phone call warranted privacy.

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.