General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: The Pharmacy, The Abbey Health Centre, Finchale Avenue, BILLINGHAM, Cleveland, TS23 2DG

Pharmacy reference: 1108932

Type of pharmacy: Community

Date of inspection: 13/02/2020

Pharmacy context

The pharmacy changed ownership at the end of 2019. This pharmacy is within a health centre on a housing estate on the edge of the town centre. It opens for 100 hours over seven days. The pharmacy has a drive through facility at the side of the pharmacy. This service is available first thing in the morning and at night. The pharmacy dispenses NHS and private prescriptions. And provides supervised methadone consumption. It supplies some people with medicines in multi-compartment compliance packs, designed to help these people to take their medicines. It provides a limited 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 doesn't identify and manage all the risks associated with providing pharmacy services. It has not implemented suitable procedures to manage its services since the change of ownership. Pharmacy team members have not read the standard operating procedures. And the pharmacy has poor workflow and management, mainly due to issues with the computer system and inadequate planning. There is evidence that things have gone wrong due to the pharmacy not suitably managing its systems and taking limited effective action to resolve these.
		1.2	Standard not met	The pharmacy does not adequately assess the safety and quality of the services. It has poor arrangements in place to learn from mistakes. This increases the risk of them happening again.
		1.3	Standard not met	The pharmacy team members generally did not understand their roles and responsibilities and the risks in selecting and supplying medicines for people's prescriptions.
		1.4	Standard not met	The pharmacy doesn't have a clear mechanism within the pharmacy for people to raise concerns regarding the service. And the team members are not reporting all complaints they receive. So, the pharmacy cannot action these appropriately to improve and resolve issues.
		1.5	Standard not met	The pharmacy has insufficient evidence of appropriate professional indemnity insurance
		1.7	Standard not met	The pharmacy does not obtain appropriate consent from people to have their medicines supplied from a different pharmacy. And it doesn't have consent from these people to share their personal information as part of this process. The team has limited training and knowledge about protecting people's confidentiality.

Principle	Principle finding	Exception standard reference	Notable practice	Why
2. Staff	Standards not all met	2.1	Standard not met	There are not enough suitably qualified pharmacy team members to operate the pharmacy safely and effectively. The unqualified team members are receiving limited training. And due to the current working environment there is little time to support these team members. They cannot always find stock or items waiting collection due to their limited knowledge and insufficient experience.
		2.5	Standard not met	There is evidence the company has taken insufficient action when the pharmacy team has raised concerns regarding staffing at the pharmacy and lack of working computer terminals. The company does not discuss with team members upcoming major events such as a refit to understand additional pressures in the current overstretched working conditions.
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 does not manage all its services in a safe and effective way. This includes the failure to supply medicines to people in a timely manner, having limited records and audit trails. It fails to deliver people's medicines as they expect. And it makes limited or no arrangements to inform them of this. It has poor processes to manage the supply of medicines in multi-compartment compliance packs.
		4.3	Standard not met	The pharmacy does not appropriately manage all of its stock. This includes not having sufficient stock to fulfil people's prescriptions and not having basic stock items for people to buy such as paracetamol.
5. Equipment and facilities	Standards not all met	5.1	Standard not met	The pharmacy has only one working computer terminal. And there is evidence of this compromising safety as people are not getting their medicines in time. And no access to the previous computer system is causing difficulties checking previous records.

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

Summary findings

The pharmacy doesn't identify and manage all the risks associated with providing pharmacy services. It doesn't make sufficient plans when making key changes to the ways of working in the pharmacy. This includes introducing a new computer system for dispensing. Pharmacy team members have not read the procedures they are required to since the change in pharmacy's ownership. And several team members have virtually no experience in working in a pharmacy setting. So, this is contributing to risks and the poor running of the pharmacy. The pharmacy team members do not fully understand their roles and responsibilities. They do not know what they should do if things go wrong. They are not supported to report and resolve incidents and complaints and learn from these. The pharmacy generally keeps people's information secure but it has not appropriately gained consent to share people's private information for its services off site. The pharmacy generally keeps all the records as required, by law in compliance with standards and procedures.

Inspector's evidence

The pharmacy changed ownership at the end of December 2019. Since this time there had been significant changes in staffing and issues with the computer system. These had led to issues with managing the service. For example, there was evidence that people using the pharmacy had not received medicines in a timely manner. The pharmacy had not been able to fulfil prescriptions due to running out of stock of some medicines. And people reported having to wait in excess of an hour when they returned to collect owed medicines. This was due to the team not being able to locate prescriptions and items.

The pharmacy previously had five working computer terminals. On the date of the inspection it only had one working computer terminal. The new computer system had been installed at the beginning of February. The old system had been taken away. The patient medication records (PMR)s had not transferred properly. Some entries showed duplicates for people but generally one of the entries was blank. And the other did not have a full record of previous details. The pharmacist used summary care records (SCR) to check information when required but this was time consuming. Previously the three computer terminals had been in the main part of the dispensary with one in the back dispensary. And one in the consultation room. Now only the one in the back dispensary was connected to the system. The one in the consultation room could access the internet only. The team did not know when this would be sorted, and the pharmacy was really struggling with only one working computer for all tasks.

The team members explained that when the company took over, it provided them with an employee handbook. The company told them that the standard operating procedures (SOPs) were on the company website. But they could not access these due to passwords not working. In addition, the majority of the team members left which caused considerable time pressure on those remaining and new starters. So, there was no time to read any SOPs. One member of the team from another pharmacy was a Pre-Registration Trainee (Pre-Reg) who had completed his pre-registration year and was waiting to sit the pharmacist registration exam. He advised he had undertaken his training in one of the owner's other pharmacies. The team could not locate the previous SOPs so could not use these for reference. So, new members of the pharmacy team employed since the change of ownership had only received verbal instructions. And had received limited training and were dispensing items in a busy dispensary

with little support and supervision. They described how they looked at a name of the drug on the prescription and picked it from the shelf. They could not find all items due to their lack of knowledge. And had very limited knowledge of branded and generic medicines. And if items would be in the fridge or not.

The pharmacy had plenty of room, both shelf and bench space. But this was not being well managed due to the current changes. The team had some baskets with items waiting to be dispensed on the floor. And the team members were filling these from a recent delivery of stock which they had placed on a bench. The Pre-Reg explained that since he had come to the pharmacy about two weeks ago, he had rearranged all the dispensary stock with the help of other team members from another of the owner's pharmacies. They had removed documents and papers from the previous owner. The pharmacy team members used white baskets to indicate people were waiting in the pharmacy. And if the team members could not find prescriptions for people, they would put their name and address on to a piece of paper and place in a basket for the Pre-Reg to look on the system to establish where it could be in the process. And then the team member would try to locate it.

The team described that the pharmacy had previously undertaken the dispensing and supply of the multi-compartment compliance packs. But the dispenser who had undertaken this service had left. The team seemed unclear of the system now adopted. It advised the pharmacy had sent several prescriptions for compliance packs to two other pharmacies under a different ownership but linked to this company. It had sent about 20 prescriptions to a local pharmacy in Redcar and sent many more to another pharmacy based in the Brierley Hill in the West Midlands. The team did not know of the system but showed some packs bagged up from the other pharmacies which were in the usual retrieval system. The packs had backing sheets, with the name and addresses of the other two pharmacy premises and no name and address of this pharmacy. The backing sheets observed were loose and not attached to the compliance packs. The packs contained four weeks of compliance packs and had no patient information leaflets (PILs) for people. It was unclear where the prescriptions were. The team explained that the pharmacy had failed to collect some prescriptions from the surgery for several people who received their medication in compliance packs which meant it had not done these for people as expected. Someone from the pharmacy had now collected these. The team explained that the pharmacy had requested replacement prescriptions for some of these people as it had not known where the prescriptions were. A dispenser advised she made up some packs as best she could for people who came in for their packs so that they were not left without medication. The audit trails and records were poor for the compliance packs dispensed locally. So, there was a risk that people would now receive duplicated supplies of their medicines.

The pharmacy delivered several packs to people's homes. But the pharmacy's drivers had left several weeks ago. Agency drivers had been used for a short while. But they did not always turn up. The pharmacy had not advised people that it would not deliver their medicines and waited for people to phone to say they had not got their delivery as expected. The team then told people to come to collect their medication. And if they could not, they advised the pharmacy could deliver either Monday or Thursday. The Pre-Reg advised he delivered some medication to people. The pharmacy team explained that they did not have access to telephone numbers for people as the previous computer system had not transferred these over to the new computer system. And the company had disconnected the previous system. The team were unaware of any process for the pharmacy to obtain consent from people who received medication in the compliance packs, now dispensed offsite. This was particularly important as this dispensing pharmacy was a different legal entity. The team had not read, and they were unaware of any specific SOPs for this service and consent.

The pharmacy was not following any process for learning from mistakes. The computer system had only three near miss errors recorded since 13 January 2020. All recorded on 11 February. But none before or

since. It was reported by the team members that the company had told the team to stop recording any near miss errors in the book that was still available and to record them electronically. As the pharmacy only had the one computer terminal it was difficult to record any near miss errors. The Pre-Reg was the only person who could record these. The Pre-Reg advised that he recorded these on the PMR system under counselling notes. And the live system was linked to the head office so they could produce reports in the future. The pharmacist advised he generally told the individuals of mistakes. And changed items but did not record any. This meant that the team could not share errors. And the newer starters could not learn from their mistakes which could contribute to the same mistakes being repeated. The pharmacist indicated that some forms of mistakes he just rectified due to times constraints.

During the inspection there were numerous complaints by people about the service. Several members of the public were vocally expressing their concerns about how long the pharmacy was taking to find things or not find them. And that the pharmacy did not have medicines in stock. As the pharmacy could not completely supply all the items on several prescriptions, people were taking their prescriptions to pharmacies elsewhere. They were complaining about the lack of staff and that they had received the wrong medication. Around every third prescription could not be completely supplied. And about every second or third person complained to the team at the counter about the service, waiting and staffing.

The pharmacy displayed a notice asking people to be understanding during the change of ownership. It stated, 'I am available to discuss any issues between 9am and 4.30pm in the pharmacy Monday to Friday'. But this gave no indication of who the person was. And there was no contact number. The pharmacist did not really get involved with any of the issues directly with people raising their concerns about the service. The pharmacy team members dealt with people at the counter. And they were mostly told to come back, go to the surgery or take their prescriptions elsewhere. The Pre-Reg explained how the company recorded any incidents on to the computer system. He had recorded two on to people's PMR. And advised that the company could search using the part he filled in, so it was aware of the complaints. One had been the delivery driver delivering an item to the wrong person. And the other had been a dispensing error with the wrong medication. There was no evidence of sharing and learning from these safety incidents.

The inspection was completed in combination with dealing with concerns raised to the General Pharmaceutical Council (GPhC). The pharmacy was not aware of the specific concerns. But aware of verbal complaints about the pharmacy over the last few weeks.

The pharmacy team could not advise on the current pharmacy indemnity insurance arrangements. The inspector spoke to the SI later who advised that cover was in place. But the SI did not provide sufficient evidence of the details for the insurance.

The pharmacy displayed the correct responsible pharmacist (RP) notice. The pharmacist advised the company had ceased recording in the paper responsible pharmacist book. And now recorded records electronically. The Pre-Reg recorded the entries on the computer for the pharmacists. The entries are required to be made by the pharmacists themselves. The controlled drugs (CD) registers looked at mostly met legal requirements. The headings were incomplete for several pages. And some new registers only indicated a total stock on the front cover and there was no entry in the first page of the register. One of the books had loose pages and the pharmacist advised he had asked for new registers. There were some of the new company's registers in place. Physical stock of an item selected at random agreed with the recorded balance. The pharmacy kept a record of CDs which people had returned for disposal. These were in order and the pharmacy had destroyed these recently. So, it did not allow a build-up in the CD cabinet. The pharmacy kept special records for unlicensed products with the certificates of conformity completed. It maintained private prescriptions electronically. But these could not be shown. As no one knew how to access the register correctly. They team could not explain where

it recorded the emergency supplies.

The pharmacy had some generic leaflets which explained people's rights under the Data Protection Act. And how the pharmacy dealt with information it recorded. The new starter explained that she must not say anything outside the pharmacy about patients. And she explained about disposing of confidential waste. One person told the inspector that a team member shouted over from the dispensary asking what the medicines were for. She had not replied as she had not wanted everyone to know. The Pre-Reg advised that the company had a safeguarding SOP online. This was not confirmed during the inspection.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy doesn't have enough suitably qualified staff for the services it provides. And there are periods of time when there are not enough trained staff to operate safely and effectively. The majority of the team members are dispensing with little training which is a significant risk. They get some support and ask questions. But their lack of experience is contributing to risks in the dispensing process and risks that errors may occur. Some training material is not relevant to their current roles as they are not completing basic training. The pharmacy does not have an adequate process to raise concerns. And pharmacy team members feel the concerns they raise are not addressed.

Inspector's evidence

The pharmacy had lost eleven pharmacy team members since the change of ownership. Only two qualified dispensers had remained and one member of the team who worked as a medicines counter assistant (MCA). The MCA worked part time and had started in July 2019. She had commenced the course around November 2019 but reported that the new company had told her to stop the course. The pharmacy had two pharmacists who were new to the company. They both worked as locums. The Pre-Reg advised he had worked at this branch since the end of January. The second pharmacist had been employed for the afternoon through to the evening but left for lunch and returned around 6.30pm. So, there was only one pharmacist present.

One the day of the inspection the two dispensers left during the afternoon. And the MCA left in the early evening. There were three unqualified team members working in the dispensary. One described that she was on an apprenticeship scheme and this was her fourth day. The other two advised they were dispensers in training but did not know what course they were going to do. Neither had any experience working in a pharmacy previously. They had worked for three to four weeks in the pharmacy. One of them showed a training booklet the owner had asked her to complete. This was the Royal Society of Public Health Level 2 booklet entitled ‘Understanding Heath Improvement’. In addition, there were three further members of the team. They had all commenced work between two to five weeks ago. None of them had any pharmacy training qualification. The team thought one of them had undertaken some voluntary work in a pharmacy before. The Pre-Reg and the pharmacist explained they tried to assist and show the new starters how do tasks. But this was difficult with the staffing levels and work waiting to be done. The team advised the SI had provided some training to the new starters.

The Pre-Reg advised the company communicated with him. And he thought that the pharmacy was starting a refit the next day. But he was not sure and until shop fitters arrived, he would not know. The rest of the team did not know about the start of the pending refit. Some of the team advised they had communicated with human resources department. And they had left messages but didn’t get replies. The team had concerns about the staffing, lack of computer terminals and the effect on the workload. They were not appraised of the latest situation, which was affecting the workload and atmosphere in the pharmacy. This affected both people using the pharmacy and the team.

The superintendent (SI) had had worked at the pharmacy the previous month. But had not attended since the issue with the computer system. The pharmacist had a contact telephone number and could speak to him if required.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are of a suitable size for the services it provides. And people can have private conversations with the team in a consultation room.

Inspector's evidence

The pharmacy was clean. And fitted out to an acceptable standard with suitable space for dispensing, storing stock and medicines and devices waiting for collection. But the dispensary was disorganised, at the current time, mainly due to the team rearranging shelves. The pharmacy team had some baskets which required items to complete the prescriptions, stored on the floor. The team had used most of the bench space available with baskets stacked waiting for the team to dispense.

The room temperature was comfortable, and the pharmacy was well lit. The sink in the dispensary for preparation of medicines was clean. Separate hand washing facilities were in place for the team. A cleaner came in from the health centre for 20 minutes morning and night to carry out cleaning. The pharmacy had two adequately sized, clearly signed, sound proofed consultation rooms which allowed confidential conversations to be undertaken. The team used one for the methadone supervision generally and the other was used for other services and quiet words when required. But people could not access the second consultation room at present due to bags of rubbish piled at the internal entrance.

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

Summary findings

The pharmacy does not manage all services safely and effectively. It supplies some people with medicines in multi-compartment compliance packs. But the pharmacy manages and organises this service poorly. This could contribute to errors such as people not receiving their medication in time or risk of receiving duplication of packs. The pharmacy doesn't adequately manage its dispensing service. It doesn't have sufficient basic stock for people's prescriptions. And for them to buy some medicines over-the-counter. It doesn't have reliable audit trails for some of its services. The pharmacy team members may not always identify people who take higher-risk medicines. And this means they may miss opportunities to give these people the advice and information about their medicines they may need to take them safely. The pharmacy obtains its medicines from reputable suppliers. And it mostly stores its medicines appropriately.

Inspector's evidence

The pharmacy had a main entrance from the car park. And an internal entrance from the health centre. There was some customer seating. The pharmacy displayed a notice advising of change of ownership to Jhoots Pharmacy. It displayed the hours of opening. There was a leaflet 'Your guide to this Pharmacy' which was generic. And did not specify the pharmacy and did not have the hours of opening completed. The pharmacy had a defined professional area. And items for sale were mostly healthcare related. But the stock levels were depleted. For example, it had no paracetamol for people to buy. The team advised they had not to order any more stock for the counter.

The pharmacy provided the Community Pharmacist Consultation Service (CPCS). People accessed the CPCS service through NHS 111 referrals. The CPCS linked people to a community pharmacy as their first port of call. This could be for either the urgent provision of medicines or the treatment or advice for a minor illness. It had received a few referrals, mostly in the evening and weekend.

The pharmacy stored medication waiting collection in labelled bags in boxes alphabetically on shelves in various location in the pharmacy. It appeared to have sections for completed prescriptions. And sections for part-filled prescriptions and owings. It generally kept these in dispensing baskets with the prescriptions. It also had baskets stacked on top of each other with downloaded prescriptions waiting for the team to dispense. And other baskets in another section waiting for stock to come in for the team to complete these. The team had difficulty in locating people's prescriptions throughout the afternoon. The boxes were full and difficult to look through. So, people's medication was not always located. The team asked the pharmacist or Pre-Reg. The Pre-Reg checked the computer system to establish where the prescription items were likely to be. And assisted in advising the team of the likely the location. They generally then found it or established there was some issue with the computer system. On several occasions the team could not find the actual prescription so wrote down the names and address of people and the items expected. The pharmacy had developed this process due to the numerous issues. The Pre-Reg showed that some of the issues were out with the control of the pharmacy by showing the NHS tracker which showed there was no prescription for some people.

There was an audit trail of the dispensing process. The new starters had been told to initial the dispensing boxes on labels. And were doing so on items dispensed that day. But on occasions the team members had not left the stock container with the items for checking. The compliance packs looked at generally did not have the 'dispense by' and 'checked by' boxes completed. Or had one signature across

both boxes. These included compliance packs supplied from the other pharmacies in Redcar and Brierley Hill.

The pharmacy had a range of alerts stickers at the dispensing and checking bench. The pharmacy could add these on bags which would raise awareness that people required to received additional counselling. Only the pharmacist was aware of the valproate Pregnancy Prevention Programme. He obtained additional booklets and cards which the pharmacy kept in the consultation room. And advised he would provide these to people in the at-risk group. No one could confirm if any audit had been undertaken. And there was a risk that the pharmacy had lost this information in the computer transfer. The new starters were unaware of any requirements. And the Pre-Reg was unclear. The stock location was not marked in any way to alert the team when selecting these products. The pharmacy had no alert stickers to advise the team members to select certain high-risk items with care. The Pre-Reg advised that the new computer system generated additional warning labels for the Look-Alike Sound-Alike (LASA) drugs. And these would highlight to the team. But this was no operational yet.

The pharmacy offered a substance misuse service. It had around 50 people who received methadone. The pharmacy was hand measuring methadone. The pharmacist present during the day had a box he kept completed prescriptions he had supplied for the day in. And he entered these in the CD register before leaving for the day.

The pharmacy delivery process had been severely affected over the last few weeks. The current driver had left. And after a period of using agency drivers, the pharmacy had a driver, but he only worked two afternoons a week. The Pre-Reg advised the pharmacy tried to deliver as many as they could. But there was an expectation that people would come to collect their medication if it was not delivered. There was no mechanism to let people know that the pharmacy was having difficulties with deliveries.

The pharmacy refrigerator was from a recognised supplier and observed to be within the required temperature range to store medicines. The pharmacy used fridge stickers on bags to prompt the person handing the medication over that the pharmacy needed to add some medication required to complete the supply. The medication which the pharmacy had dispensed and labelled was in a large basket in the bottom of the fridge in a disorganised manner. And the team members generally struggled to locate items for people.

The pharmacy sourced items from recognised wholesalers such as Norchem and AAH. The team members generally had no knowledge of the Falsified Medicines Directive (FMD). The pharmacist was aware but did not know what the company was doing regarding this. The pharmacist was aware of drug safety alerts and recalls. And actioned these. But was not aware of the company process for these. The pharmacy team advised they used to undertake regular date-checking using a template. But advised that since the change in ownership they had not undertaken any date checking. No out of date stock was observed on shelves. Some liquid medication was marked with the date of opening which allowed the team to check to ensure the liquid was still suitable for use. The team used appropriate medicinal waste bins for patient returned medication. The contents of the bins were securely disposed of via the waste management contractor. The pharmacy had appropriate denaturing kits for the destruction of CDs.

Principle 5 - Equipment and facilities **Standards not all met**

Summary findings

The pharmacy has insufficient equipment to deliver its services safely and effectively. It has only one working computer terminal which is severely compromising services to people. And it has inadequate arrangements in place to resolve this. The pharmacy mostly uses the equipment and facilities in ways to maintain people's privacy.

Inspector's evidence

The pharmacy team members had access to a range of up-to-date reference sources, including the British National Formulary (BNF). They used the internet as an additional resource. The pharmacy had measuring equipment available of a suitable standard including clean, crown-stamped measures. It had a measure for measuring methadone. But would benefit from a greater range of measures to ensure all volumes were suitably measured. The pharmacy had previously used Methameasure, but the new owner had taken this system out. It also had a range of equipment for counting loose tablets and capsules.

There was only one computer terminal working which was out of view of the public. It was password protected. Only the Pre-Reg was familiar with the computer system. The pharmacists present were learning it. And relied on the Pre-Reg doing all the labelling. The computer provider had been unable to reconnect the other three computer terminals. And the team used the one in the office for limited internet access. The team used the NHS smart card system to access to people's records. The pharmacy only had one working phone line.

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.