General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Southchurch Pharmacy, 535 Southchurch Road, Unit 6, SOUTHEND ON SEA, Essex, SS1 2AY

Pharmacy reference: 1104787

Type of pharmacy: Community

Date of inspection: 12/12/2023

Pharmacy context

The pharmacy is located on a busy main road in a largely residential area near Southend-on-Sea. The pharmacy provides NHS dispensing services and the New Medicine Service. And it provides medicines as part of the Community Pharmacist Consultation Service. The pharmacy supplies medicines in multi-compartment compliance packs to some people who live in their own homes and need this additional support. And it supplies medicines to a small number of care homes. It also provides substance misuse medications to a small number of people. The pharmacy receives most of its prescriptions electronically. The pharmacy had been issuing private prescriptions as part of a walk-in prescribing 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 adequately identify and manage the risks associated with its prescribing service. It does not carry out risk assessments for this service or have procedures for diagnostic pathways. And team members do not always follow the pharmacy's standard operating procedures.
		1.2	Standard not met	The pharmacy does not audit or monitor the safety and quality of its prescribing service. And it does not have regular review processes to ensure that it can identify areas for improvement.
		1.2	Standard not met	The pharmacy cannot adequately demonstrate that it always learns from its mistakes or makes changes to help minimise the chance of a similar incident.
		1.6	Standard not met	The pharmacy does not keep adequate records for its private prescribing service, including records about its consultations with people, and the prescriber's reasons for issuing a prescription. The pharmacy's prescriber does not use the required forms for private prescriptions for controlled drugs.
		1.7	Standard not met	The pharmacy does not always appropriately protect or dispose of people's personal information properly.
		1.8	Standard not met	The pharmacy has not fully considered and mitigated the risks of supplying medicines liable to misuse to vulnerable people.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy does not ensure that team members are enrolled on the right training for their role in a timely way. And it cannot demonstrate that its pharmacist prescriber only prescribes medicines within their area of competence.
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 cannot demonstrate that its prescribing service is safe. For example, the pharmacy's prescriber does not make the appropriate records to show that medicines

Principle	Principle finding	Exception standard reference	Notable practice	Why
				are only supplied when clinically appropriate. The pharmacy doesn't seek consent to share information with other healthcare providers or share details about what has been prescribed with people's regular prescribers when it has consent to do so. It does not monitor the safety and quality of its prescribing service. And it does not always issue legally valid prescriptions. Taken together, this means that people using the service could be put at risk.
		4.3	Standard not met	The pharmacy does not have robust date-checking processes to make sure people do not receive date-expired medicines. It does not always keep medicines in appropriately labelled containers. And it cannot show that it always stores medicines which require cold storage at the right temperatures.
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 or manage the risk associated with all its services. It does not routinely monitor the safety and quality of its prescribing service. And it does not keep records about consultations with people using this service. The pharmacy cannot sufficiently demonstrate that it always learns from its mistakes. It does not routinely record mistakes that happen during the dispensing process. And this could mean that team members are missing out on opportunities to improve the pharmacy's services. The pharmacy cannot demonstrate that it protects vulnerable people seeking medicines liable for misuse. The pharmacy does not manage its confidential waste properly, or always protect people's personal information. People can provide feedback about the pharmacy's services. And the pharmacy largely keeps its records up to date and accurate.

Inspector's evidence

The pharmacy provided a wide range of NHS and private services. NHS services included seasonal influenza and Covid vaccinations, and a substance misuse service. The superintendent pharmacist (SI) who was also a pharmacist independent prescriber (PIP) and the responsible pharmacist (RP) provided the private services. Private services included ear syringing, weight loss medicines and prescribing treatment for a range of acute presentation such as chest infections and pain relief. Some services such as weight loss medicines were provided using a patient group direction (PGD). The SI carried out the consultation for the PGD led services and if appropriate would supply the medicine. All the services were provided face-to-face at the pharmacy. The pharmacy did not have written risk assessments, written procedures, or prescribing policies for its private prescribing service. But the services provided under the PGDs did have the key questions to ask listed within the PGD.

The SI explained that he would undertake a consultation if a person presented with an acute complaint, and he would issue a private prescription if appropriate. There was no written framework to follow when a medicine was prescribed. The SI explained how he tailored the consultations depending on the individual he was treating. However, he did not record these actions or record what questions were being asked and what advice he was giving to the person to make sure there was appropriate safety netting. During the inspection, several records were reviewed. There was a record of the private prescription issued which had the name of the prescriber for each prescription dispensed but not the prescriber's details. The PIP did not document any discussions that had taken place between the person and the prescriber, and the PIP did not record a reason for their decision to prescribe. The pharmacy was not conducting any clinical audits or reviews to identify whether the PIPs prescribing decisions were aligned with national guidelines and to assess whether adequate clinical decisions and justification for prescribing were made, or suitable information was provided to the person throughout the consultation process.

The pharmacy had standard operating procedures (SOPs) and the superintendent pharmacist (SI) and one of the dispensers had signed to show that they had read, understood, and agreed to follow them. Team members were not always following the SOPs. For instance, the 'bagging up and handing out' SOPs indicted that the prescription should be attached to the bag, but this was not done. And this could make it harder for team members to refer to the original prescription if there was a query and it may also increase the chance of items being handed out when the prescription had expired. The SI said that he would ensure that the SOPs were followed in future.

The pharmacy had a way of recording near misses, where a dispensing mistake was identified before the medicine had reached a person. There was one near miss recorded in July 2023 and one in November 2023. Team members said that there had been other near misses, but these had not been recorded. A team member mentioned a recent dispensing error involving a higher-risk medicine, where the wrong medicine had been supplied to a person. The medicines were still stored next to each other on the same shelf. The SI initially said that he was not aware of the incident but after being prompted by another team member he recalled it. He had not completed an incident report form or root cause analysis but said he would do this following the inspection.

There was limited workspace in the dispensary. There were several stacks of baskets waiting to be checked that team members said had been dispensed the day before. There was an organised workflow which helped staff to prioritise tasks and manage the workload. And baskets were used to minimise the risk of medicines being transferred to a different prescription. The team members did not always sign the dispensing label when they dispensed each item to show who had completed this task. The SI was seen initialling dispensing labels when he had checked the medicines.

The dispenser said that the pharmacy would remain closed if the pharmacist had not turned up in the morning and she knew which tasks she should not undertake. The trainee medicines counter assistant (MCA) knew that she should not hand out dispensed medicines or sell pharmacy-only medicines if the pharmacist was not in the pharmacy.

The pharmacy had current professional indemnity insurance. The private prescription records were completed correctly. But there were several private prescriptions written by the PIP that did not have the required information on them when the supply was made. And there were several prescriptions for Schedule 2 and 3 CDs which were not written on the correct FP10PCD form. The SI said that he was not aware of this requirement, but the requirement was clearly stated in the pharmacy's SOPs which the SI had authorised for use, and he had signed to show that he had understood them. The nature of the emergency was not always recorded when a supply of a prescription-only medicine was supplied in an emergency without a prescription. This could make it harder for the pharmacy to show why the medicine was supplied if there was a query. The SI said that he would ensure that this information was recorded in future. The SI said that people were usually referred to their GP if they wanted an emergency supply during surgery opening hours. And it a person needed an emergency supply outside these hours, he would write a prescription for them. There were signed in-date patient group directions available for the relevant services offered. Controlled drug (CD) registers examined were filled in correctly, and the SI said that the CD running balances were checked at regular intervals. But this was not in line with the frequency stated in the SOPs. This was discussed with the SI during the inspection. During a spot check of some Schedule 2 CDs, it was found that the balance in the CD register did not match the physical stock available for two items. The recorded quantity of one CD item checked at random was not the same as the physical amount of stock available. The right RP notice was clearly displayed, and the RP record was largely completed correctly. The SI did not routinely complete the RP record at the end of the day, and he had not completed it when there was a different pharmacist working the following day. There were two days in July 2023 when the pharmacy had been open, and the RP record had not been completed. The SI said that he would ensure that the RP record was completed properly in future.

Confidential waste was routinely placed in with pharmaceutical waste for disposal. Team members said that they did not have time to shred it. A notice with a person's name and CD delivery days was displayed on a wall in dispensary and it was visible from the shop area. The SI said that this would be removed from the wall. People's personal information on bagged items waiting collection could

potentially be viewed by people in the shop area. Computers were password protected and the people using the pharmacy could not see information on the computer screens. Smartcards used to access the NHS spine were stored securely and team members used their own smartcards during the inspection.

The complaints procedure was available for team members to follow if needed. Team members said that there had not been any recent complaints.

The SI said that he had completed level 2 safeguarding training. However, as described under Principle 4, he was prescribing medicines liable to misuse which meant that there was a significant risk that these medicines were prescribed for people they were not safe or appropriate for. There was some evidence that the pharmacy had prescribed these medicines to people with a previous history of drug misuse. And the pharmacy did not inform people's regular prescriber about the medicines supplied by the pharmacy as part of the private prescribing service. Other team members said that they had completed training about protecting vulnerable people. The delivery driver could describe potential signs that might indicate a safeguarding concern and would contact the pharmacy promptly if they had any concerns about a person. The SI said that there had not been any safeguarding concerns at the pharmacy. The pharmacy had contact details available for agencies who dealt with safeguarding vulnerable people.

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

Summary findings

The pharmacy cannot adequately demonstrate that its pharmacist independent prescriber only prescribes medicines within their scope of competence. And it does not always enrol its staff on the appropriate training courses in a timely way. This could mean that they do not have all the skills and knowledge they need to undertake their tasks safely. However, the pharmacy generally has enough team members to provide its services safely. And trained team members do some ongoing training but this is not very structured. This could make it harder for them to keep their knowledge and skills up to date.

Inspector's evidence

The SI was working on the day of the inspection with one trained dispenser and one trainee MCA working during the inspection. The SI's wife was working in the dispensary at the start of the inspection. She said that she had been helping on and off for nearly two years and she had been undertaking some dispensing tasks during this time. The SI confirmed that his wife had not been enrolled on an accredited dispenser's course and he said that he was going to enrol her on one promptly. The pharmacy was largely up to date with its dispensing.

The SI provided his training certificates for the ear syringing service and a signed declaration of competence for weight loss services. However, he could not provide, when asked, evidence of relevant training completed to cover all other aspects of the clinical services that the pharmacy offered. This included evidence of training relating to prescribing medicines for pain and acute infections. And he was unable to provide any evidence of any peer reviews or testimonials during the inspection.
The trainee MCA appeared confident when speaking with people. She was aware of the restrictions on sales of medicines containing pseudoephedrine. And she would refer to the pharmacist if a person regularly requested to purchase medicines which could be abused or may require additional care. She asked people questions to establish whether the medicine was suitable for the person it was were intended for.

The dispenser said that she undertook some pharmacy-related training in her own time, but there was no regular ongoing training provided by the pharmacy. The pharmacy did not have regular team meetings. But some team members said that they had had their appraisals recently. Targets were not set for team members.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises generally provide a suitable environment for the pharmacy's services. And people can have a conversation with a team member in a private area. But the pharmacy could do more to reduce potential trip hazards in staff-only areas.

Inspector's evidence

The pharmacy was secured from unauthorised access. It was bright, clean, and largely tidy throughout. But there were several boxes on the floor in the dispensary and these presented tripping hazards. Team members explained that the boxes were usually kept there as there was limited room in the pharmacy to store these. Pharmacy-only medicines were kept behind the counter. There was a clear view of the medicines counter from the dispensary and the pharmacist could hear conversations at the counter and could intervene when needed. Air conditioning was available, and the room temperature was suitable for storing medicines.

There were a few chairs in the shop area for people to use while waiting. The consultation room was accessible to wheelchair users and was in the shop area. It was suitably equipped and well-screened. Conversations at a normal level of volume in the consultation room could not be heard from the shop area. Toilet facilities were clean and not used for storing pharmacy items. There were separate hand washing facilities available.

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

Summary findings

The pharmacy cannot provide adequate assurances that its prescribing service is safe. The pharmacy does not monitor or review its prescribing activity, particularly when prescribing pain medicines and antibiotics. It does not keep any records about the consultations its prescriber has with people. It doesn't seek consent from people to share information with other healthcare providers. And its prescriber does not record their reasons for prescribing when they don't have consent to share information with the people's regular prescribers. This increases the risk that the pharmacy supplies prescription medicines to people which are not clinically appropriate, and people's conditions might not be properly monitored. And this is particularly concerning in relation to the prescribing of medicines liable to abuse or misuse. The pharmacy does not ensure that people who get their medicines in multi-compartment compliance packs receive all the information they need to take their medicines safely. The pharmacy does not have robust processes to make sure expired medicines are not supplied to people. And it does not always keep medicines in appropriately labelled containers. This could increase the risk of people getting medicines which are not fit for purpose. However, the pharmacy gets its medicines from reputable suppliers. And people with a range of needs can access the pharmacy's services.

Inspector's evidence

There was step-free access to the pharmacy through a wide entrance with an automatic door. Team members had a clear view of the main entrance from the medicines counter and could help people into the premises where needed. Services and opening times were clearly advertised and a variety of health information leaflets was available.

The SI was prescribing mainly antibiotics for acute infections such as chest infection, and treatments for pain. He said that he used the NICE and local antibiotic guidelines when prescribing antibiotics. But the PIP did not document their consultation with the person or any assessments undertaken to justify the reasons for prescribing. There was no arrangements for follow up and monitoring. There was no mechanism in place to avoid unnecessary over-prescribing of antibiotics such as informing people's regular prescriber. Several prescriptions had been issued for medicines liable to misuse such as morphine, oxycodone, diazepam, zopiclone, zolpidem and co-codamol. The SI explained that these medicines were mainly prescribed because the person was in a lot of pain and could not get an appointment with their regular prescriber and he did not want the person to be without treatment. However, evidence was seen of people being prescribed drugs liable to misuse on repeated occasions. For example, one person received monthly supplies of a CD used to treat insomnia over a 12-month period. The SI explained that he had checked the person's Summary Care Record (SCR). But the SI had not documented his consultations or recorded that the SCR had been checked. When asked, the SI was unaware of the importance of sharing information about the treatment given to people with other healthcare providers involved in their care, such as their regular GP. He confirmed that the pharmacy did not ask people for their consent to inform their regular GP about the treatment they had received. And the prescriber had not made a record about their decision to prescribe in the absence of people's consent to share information. This meant the pharmacy did not have assurances that the treatment was being appropriately monitored.

The pharmacy also ran an ear syringing clinic where the SI undertook the assessment and carried out

the ear syringing. The SI had access to detailed information and guidance to provide the service safely. Additionally, the pharmacy had just started working with a third-party, CQC-registered specialist prescribing service. The SI explained that this was to dispense private prescriptions issued by the service. To date, just one prescription had been dispensed.

The pharmacy provided a weight loss service to a small number of people via a PGD. This was done via a face-to-face consultation and a supply was made if appropriate. There was a set of screening questions that the person answered before the pharmacist would undertake a weight check to work out the BMI. The consultation covered all the key information and records of BMI were documented.

The SI said that prescriptions dispensed for higher-risk medicines were highlighted. The dispenser said that the pharmacy supplied valproate medicines to a few people. But there were currently no people in the at-risk group who needed to be on the Pregnancy Prevention Programme (PPP). The SI said that he would refer people to their GP if they needed to be on the PPP and weren't on one. Team members were not aware that the warning card could be removed from the packaging to allow room to attach the dispensing label.
The pharmacy used licensed wholesalers to obtain medicines and medical devices. Stock was stored tidily in the dispensary. The SI said that the pharmacy had a record of when expiry date checks had been undertaken. But there were many date-expired medicines found with dispensing stock during a spot check. And several medicines were found which were not kept in their original packaging. And the packs they were in did not include all the required information on the container such as batch numbers or expiry dates. There were several boxes which contained mixed batches found with dispensing stock.

The pharmacist explained the action the pharmacy took in response to any alerts or recalls. And these were kept for future reference. But not keeping the medicines in appropriately labelled containers could make it harder for the pharmacy to date-check the stock properly or respond to safety alerts appropriately. CDs requiring safe storage were kept in an appropriate cabinet. Denaturing kits were available for the safe destruction of CDs.

Team members working on the day of the inspection said that they had not checked the temperatures recently, even though the records indicated that they had been checked. And the SI agreed that the entries made on the computer record had been entered without the thermometer being physically checked. When checked, the current temperature was within the appropriate range on the day of the inspection. But the maximum temperature showing on the thermometer was 18 degrees Celsius. The SI said that he would ensure that the fridge temperatures were checked daily in future, the thermometer reset, and the correct temperatures recorded on the computer. The fridge was suitable for storing medicines and was not overstocked.

Team members said that that 'owings' notes were provided when prescriptions could not be dispensed in full, and people were kept informed about supply issues. Prescriptions for alternate medicines were requested from prescribers where needed. However, prescriptions were not routinely kept at the pharmacy to refer to when dispensing 'owed' quantities. Team members said that these items were dispensed from labels. This could increase the chance of errors. The SI said that uncollected prescriptions were checked regularly and items remaining uncollected after around three months were returned to dispensing stock where possible. Prescriptions or dispensing tokens were not kept with the medicines which meant that these were not available when medicines were handed out. And this could increase the chance of medicines being handed out when the prescription was no longer valid.

The SI said that people had assessments to show that they needed their medicines in multi-compartment compliance packs to show that they needed them. The dispenser said that prescriptions

for people receiving their medicines in the packs were ordered in advance so that any issues could be addressed before people needed their medicines. And people would usually contact the pharmacy if they needed their 'when required' medicines when their packs were due. The pharmacy kept a record for each person which included any changes to their medication, and it also kept any hospital discharge letters for future reference. The dispenser said that she usually prepared the packs before going on planned leave, but other team members knew how to manage these in her absence if needed. Team members wore gloves when handling medicines that were placed in these packs. The backing sheets were not attached to the trays. This could increase the chance of them being misplaced. There was no audit trail to show who had dispensed and checked each tray. This could make it harder for the pharmacy to identify who had done these tasks and limit the opportunities to learn from any mistakes. Medication descriptions were put on the packs to help people and their carers identify the medicines, but patient information leaflets were not routinely supplied. This could make it harder for people to have up-to-date information about how to take their medicines safely. These points were discussed with the dispenser and the SI during the inspection, and they said that the issues would be addressed.

Deliveries were made by a delivery driver. The pharmacy did not currently obtain people's signatures to help minimise the spread of infection. When the person was not at home, the delivery was returned to the pharmacy before the end of the working day. A card was left at the address asking the person to contact the pharmacy to rearrange delivery.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. It uses its equipment to help protect people’s personal information.

Inspector's evidence

Suitable equipment for measuring liquids was available. Separate liquid measures were used to measure certain medicines only. Triangle tablet counters were available and clean. A separate counter was marked for cytotoxic use only. This helped avoid any cross-contamination. Tweezers were available so that team members did not have to touch the medicines when handling loose tablets or capsules.

Up-to-date reference sources were available in the pharmacy and online. The phone in the dispensary was portable so it could be taken to a more private area where needed. The SI said that the blood pressure monitor was tested yearly. The weighing scales appeared to be in good working order.

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.