

Registered pharmacy inspection report

Pharmacy Name: Burwash Pharmacy, 9 Burwash Road, HOVE, East Sussex, BN3 8GP

Pharmacy reference: 1107887

Type of pharmacy: Community

Date of inspection: 10/05/2022

Pharmacy context

This is a community pharmacy in a largely residential area. It dispenses NHS prescriptions. And it dispenses medications into multi-compartment compliance packs for some people who need help managing their medicines. The pharmacy provides a private prescribing service both for people coming into the pharmacy and, more commonly, online. It provides a travel clinic and the New Medicine Service. Enforcement action has been taken against this pharmacy, which remains in force at the time of this inspection, and there are restrictions on the provision of some services. The enforcement action taken allows the pharmacy to continue providing other services, which are not affected by the restrictions imposed. The inspection was undertaken over two days, on 10 and 13 May 2022.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; Statutory Enforcement

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 manage the risks associated with its services, particularly its online prescribing service. It has put in place procedures to help mitigate the risks, but it does not always follow them.
		1.6	Standard not met	The pharmacy does not always keep clear records of its prescribing decisions, particularly when a medicine is prescribed outside of its written procedures.
		1.7	Standard not met	The pharmacy does not always obtain appropriate consent from people before contacting their regular doctors about medicines the pharmacy prescribes. And it cannot demonstrate that it obtains appropriate consent before accessing people's Summary Care Records.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website allows people to start a consultation from a page which details a particular prescription-only medicine. This could increase the chance that people receive medication which is not appropriate for them.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not always provide its services safely, particularly its online prescribing service for weight-loss medicines. It does not always follow its own procedures and so it cannot adequately demonstrate that its systems are safe.
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 adequately manage the risks associated with its services, particularly its online prescribing service. It has put in place written procedures to help mitigate the risks, but it does not always follow them. The pharmacy does not always obtain appropriate consent from people before contacting their regular doctors about medicines the pharmacy prescribes. And it cannot demonstrate that it obtains appropriate consent before accessing people's Summary Care Records. It does not always keep clear records of its prescribing decisions, particularly when a medicine is prescribed outside of its written procedures. Otherwise however, the pharmacy generally keeps the records it needs to. Staff know how to safeguard the welfare of vulnerable people. And when a mistake happens, staff generally respond well.

Inspector's evidence

The pharmacy offered an NHS dispensing service. And it provided a private prescribing service which people could walk into the pharmacy for, or more commonly, access online through the pharmacy's websites. A pharmacist independent prescriber (PIP) issued prescriptions for the private prescribing service. Almost all the prescribing was done online, and primarily for Saxenda. There were other prescription-only medicines (POMs) available on the website, such as treatments for asthma, genital herpes, erectile dysfunction, and period delay. But the superintendent pharmacist (SI) who was also the PIP explained that only one prescription which was not for Saxenda had been issued via the website in the last year. And she thought that this may have been for erectile dysfunction. The vast majority of people accessed the pharmacy's prescribing service online, and the SI thought that only one or two prescriptions had been issued in person around six months ago.

The SI had undertaken a clinical audit in February 2022 and submitted the results prior to the inspection. The audit considered the prescribing of Saxenda and was based on professional guidance issued by the Royal Pharmaceutical Society (RPS). It highlighted areas for improvements and recommended actions, such as making people aware of the symptoms of pancreatitis. During the visit, the SI confirmed that she was intending to undertake a further audit in May 2022, and every six months following that.

Prior to the inspection, the SI had sent the inspector a risk assessment for the online prescribing service. The assessment considered the risks associated with the service, such as inappropriate supplies. The potential risk of the person not being the person they claimed to be was addressed by using a third-party system to check people's IDs. There were several potential risks listed in the assessment such as people not meeting the prescribing conditions or patients who had associated risk factors (for example an eating disorder) which were to be mitigated by using mandatory virtual interviews.

The pharmacy had a range of standard operating procedures (SOPs), and most staff had signed to indicate that they had read and understood them. The SI said that she would ensure the remaining staff went through and signed the SOPs relevant to their roles. The trainee dispenser was clear about what she could and could not do if the responsible pharmacist was absent from the pharmacy. There was a written SOP for the mandatory virtual interviews which said that if a high-risk medicine had been requested a virtual interview must be conducted with their initial order. Examples of high-risk medicines were given in the SOP as Ventolin and Saxenda. The SI explained that she had changed the

way the pharmacy did this, so that people could be contacted by phone if there was not a virtual interview. However, this change was not reflected in the existing written procedure in place at the pharmacy. On the second day of the inspection, the SI showed an updated SOP for mandatory virtual interviews which said that people should be contacted three times via phone and sent a text message after each call. If there was no response, then the person would be sent an email which included a patient information leaflet and a video demonstrating how the Saxenda pen worked. The person would be asked to confirm receipt of the email, after which the prescription would be processed. However, many supplies had already been made whilst the previous written SOP was in place.

On the first day of the inspection, the SI described three orders the pharmacy had received on 9 May. She said all three people had been unwilling to attend a virtual interview for various reasons. It was not fully clear if they were receiving their first supply of Saxenda or not, although the SI said that one of them had received the Saxenda from the pharmacy before. There were some records seen on the prescribing system with no notes attached, but the printed copy of the prescription included notes to indicate a virtual interview had not been done. Three further records were found where the Saxenda appeared to have been supplied, but there had been no virtual interview done. The SI said that there had been reasons for this, including that there had been a problem with the website, or that the person had not been contactable. For the person who had a problem with the website, the SI said that she had a phone consultation with the person but had not kept notes of this. The SI explained that notes on the prescribing system that indicated that the person's date of birth or address was checked meant that a virtual interview had not been done. And that the records for virtual interview would state that their ID (for example a passport or driving licence) had been checked.

On the second day of the inspection, ten prescribing records selected at random over a range of dates for Saxenda were examined where the record appeared to be for an initial supply. The private prescription record was examined to confirm whether they were initial supplies or not. The SI was unable to provide a better method to identify if they were initial supplies. Of these ten records, one of the records indicated that the person had picked up the medicine from the pharmacy directly and so did not need a virtual interview. And six of them either indicated a virtual interview had not been done, or there were no notes found in the pharmacy from an interview. The SI explained that there had been various reasons for this, including a people not being willing to attend a virtual interview and preferring to do it by phone, no response from the person after several phone calls, and a person entering the wrong phone number. For these records, the SI indicated that the supplies had still been made. The SI said that sometimes people did not want face-to-face contact and preferred to speak on the phone or communicate electronically. Where a virtual consultation had taken place and notes had been made, the notes appeared comprehensive. And there were notes kept for some of the people who had received phone calls. For other records, and the records examined where people had not received a virtual interview or phone call, no records of clinical decisions or justifications for prescribing were found on the system. Following the inspection, the SI confirmed that the prescribing decision would be documented on the computer system using the same document that the person filled in to request the medicine.

When people filled in the questionnaire on the website, they were required to enter the name of their GP. This field was checked against a database of all the GP surgeries in the country. Once someone had provided their GP details and a supply of Saxenda was provided, the pharmacy contacted the surgery to ask for their email address. An email was then sent to the surgery via an automated system, but the SI was not able to show any examples of what the emails looked like during the inspection. The questionnaire people filled in asked them if they gave consent for the pharmacy to contact their surgery, and they were able to proceed if they selected 'no'. Some examples were seen on the prescribing system where people had selected 'no', and the SI said that the pharmacy routinely contact

the person's GP in practice. She explained that she had told her IT provider that it should be mandatory for people to give consent for this and thought that it was a glitch when it appeared on the completed consultation forms. During the inspection, she contacted her IT provider, and they changed the online questionnaire so that it highlighted if someone selected 'no' to consent. And if this happened, the page displayed 'We need your consent to inform your GP about this medication'. The SI said that they had received no complaints from people whose GPs had been contacted but had received some emails from surgeries who had said that the patient was not registered at their surgery. And said that people's GPs were only contacted to obtain the surgery's email address. Following the inspection, the pharmacy provided ten emails from people's GPs. Nine of them indicated that the person did not belong to that surgery.

Staff described how they dealt with dispensing mistakes which were identified in the pharmacy (near misses), and mistakes where the medicine had been handed to someone (dispensing errors). If a mistake happened, it was discussed within the team.

Other records the pharmacy was required to keep beyond the prescribing system generally complied with requirements. Private prescription records and records of unlicensed medicines dispensed seen were complete. The controlled drug (CD) registers were kept electronically, and examples seen contained the required information. A random check of a CD showed that the physical quantity in stock matched the recorded balance in the register. The responsible pharmacist (RP) records seen had been completed correctly, but there were two RP notices on display. The second notice had been removed by the second day of the inspection.

People were able to give feedback in person at the pharmacy or by sending a message via the pharmacy's website. People could also leave feedback on the NHS website, and the pharmacy had received two positive reviews. The pharmacy was in the process of handing out patient questionnaires to obtain feedback from people visiting the pharmacy. The pharmacy's indemnity insurance certificate on display had expired. Following the inspection, the inspector contacted the pharmacy's indemnity insurer who confirmed that the pharmacy had current cover.

No confidential information could be seen from the public area, and confidential waste was appropriately disposed of in a shredder. Staff were seen using individual NHS smartcards to access NHS electronic systems. The pharmacy's electronic prescribing system had been updated since the previous inspection, and users now had their own individual logins. The apprentice technician demonstrated that she was unable to access the prescribing system, except to see what had been prescribed, and other activities she would need for dispensing.

The SI said that if people gave consent to contact their GP, then she would look at their summary care record (SCR) if she had any further queries or there was an issue. But the question on the website asking people for their consent to contact their GP did not indicate clearly that they were being asked for consent to look at their SCR. And in practice, the answer to this question on the questionnaire did not seem to be taken into account in the consultation as the SI had assumed it was mandatory to give consent anyway. The SI could only describe one example of a person's SCR she had recently accessed, but there was no note seen on the person's record that the SCR had been accessed, or what the details from the SCR had been.

The RP confirmed that he had completed level 2 safeguarding training. The apprentice technician had previously worked in a role in social care and was clear about how the pharmacy could help safeguard people. She said that if she had any concerns she would speak with a pharmacist. And staff were able to describe what they would do if they had any concerns about the welfare of a vulnerable person who

came into the pharmacy.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to provide its services, and they have done the right training for their roles. Team members are able to raise any concerns. And they get ongoing training to help them keep their knowledge and skills up to date.

Inspector's evidence

At the time of the inspection there was the SI (who was also the PIP), one trained dispenser, two trainee dispensers, an apprentice technician, and a trainee pharmacist. Staff were up to date with their workload. Designated members of staff usually dealt with the online side of the business. Staff were able to describe their own roles and responsibilities.

Staff described receiving ongoing training, including both informally from the SI or RP, and courses such as antibiotic stewardship. A record of the training courses completed was maintained in the pharmacy. Staff felt comfortable about raising any concerns or making suggestions. There were no targets set in place for staff.

Principle 3 - Premises Standards not all met

Summary findings

The pharmacy's website allows people to start a consultation from a page which details a particular prescription-only medicine. This could increase the chance that people receive medication which is not appropriate for them. Otherwise however, the pharmacy's premises are suitable for the services it provides, and they are kept secure from unauthorised access. People can have a conversation with a team member in a private area.

Inspector's evidence

The pharmacy's premises were generally clean and tidy, with adequate space for safe dispensing. The online business was done from a large room adjacent to the main dispensary. There was a consultation room which provided an adequate level of privacy if someone wanted to talk with a team member in private. The premises were secure from unauthorised access. The pharmacy had clear plastic screens protecting the counter, to help control the spread of infection.

The pharmacy had two websites, www.burwashpharmacy.com and burwashmedsdirect.co.uk. The former site directed people to pages on the latter when medicines for conditions such as weight loss were requested. And it was the latter website which was used for requests for prescription-only medicines. This website was arranged in a way which allowed people to start a consultation from a page which indicated a particular POM. For example, the pharmacy's website had a page for 'weight loss' which led through to a page called 'weight loss pen'. The page stated that the treatment the pharmacy provided was Saxenda, and people were able to start a consultation directly from this page. The page for 'asthma' listed a range of inhalers, but the conditions page stated 'asthma inhaler' rather than 'asthma'. This meant that people would start the consultation for an asthma inhaler rather than the medical condition of asthma. At the start of the inspection the pharmacy's website showed Saxenda on the home page, but the SI made changes during the inspection to remove this.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not always provide its services safely, particularly its online prescribing service for weight-loss medicines. It does not always follow its own procedures and so it cannot adequately demonstrate that its systems are safe. However, it obtains its medicines from reputable suppliers and largely stores them properly. It assembles some multi-compartment compliance packs in advance of the prescription arriving. And this could increase the chance of a dispensing mistake happening.

Inspector's evidence

The pharmacy had step-free access from the street. And there was just enough space for people with wheelchairs or pushchairs to manoeuvre. There was a small selection of leaflets in the public area, and there were some signs in the front window to inform people about the services the pharmacy provided. People could also access some services online through the pharmacy's websites.

The pharmacy used an ID-checking system from a third-party provider for use with online orders. The SI had previously demonstrated how she had tested the system to ensure it was robust. She said that an audit was undertaken on the system every few months and spot-checks to check it was working as intended.

The SI had not had any online orders where she had felt the need to decline on a clinical basis and had declined none for this reason so far. Some orders had been declined because there had been an issue with the payment. The SI explained that the online questionnaire was set up in a way whereby any order where the body mass index (BMI) was outside the stated range, the system would automatically decline it. And the computer was set up to only allow a maximum of five Saxenda pens a month. She said that the summary of product characteristics (SPC) for Saxenda did not currently have a maximum length of treatment. And that she had found some people got down to the right weight and then reduced their dose.

On the previous inspection, the dose on the labels for the Saxenda dispensed was generally 'as directed'. On this inspection it was seen from the private prescription record that the labels had directions of doses people should use. After each order where the pharmacy had had difficulty in contacting the person, the person was sent an email which contained a link to a video on how to use the Saxenda. The SI explained that people receiving Saxenda received a follow-up email after 28 days which included asking them how they were getting on with the medicine, and how it was working for them. This change had only recently happened when the IT system had been updated in April 2022. The SI explained that if a person responded to the email, then the tile on the system changed colour to indicate this, and she then looked at the response. She said that this had not yet happened in practice due to the IT system only recently changing. And if someone did not respond to the email then nothing happened. Following the inspection, the SI provided examples of follow-up questionnaires which people had completed. These varied in format and included asking people if they were experiencing any problems with using the medicine or had experienced any side effects. People were asked for their weight as part of this process, but it was not clear from the documentation that any progression in their weight loss was considered. As people were only asked to submit their current weight and there was no reference in the documentation seen as to their initial weight. This could make it harder for the pharmacy to know how a person was progressing with their weight loss, and if the medicine was still

appropriate for them.

The trainee dispenser went through how the Saxenda was packaged to help it remain at the right temperature during transit. This included using bubble wrap, ice packs, and then the medicines were picked up by a courier. The SI had previously confirmed that the packs could keep the contents cool for up to 72 hours, depending on the pack used.

Dispensed prescriptions for CDs awaiting collection were sometimes highlighted to alert the team member handing it out about the limited validity date of the prescription. But this did not always happen. One dispensed prescription for a CD was found which had already expired, and this was removed. Staff said that they would ensure the CD prescriptions were more consistently highlighted in the future. No dispensed prescriptions for higher-risk medicines such as warfarin or methotrexate were found in with the dispensed prescription. The inspector discussed with team members of the additional counselling which was needed for these types of medicines. Team members were aware of the additional guidance about pregnancy prevention to be given to people in the at-risk group who took valproate-containing medicines. The packs of valproate seen had the warning cards attached. Staff could not locate the associated information leaflets and said that they would order more in.

Dispensed multi-compartment compliance packs seen were labelled with a description of the medicines inside. And the packs had an audit trail to identify who had dispensed and checked the packs. Patient information leaflets were routinely supplied with the packs, so that people had up to date information about their medicines. Some packs were seen to be assembled (but not supplied) in advance of the prescription coming in. This may make it more likely that a dispensing error could occur and was discussed with the staff during the inspection. The apprentice technician explained that the packs were checked again when the prescription arrived in. People were assessed for their need for the packs by their GP.

The pharmacy delivered some medicines to people in their own homes locally. Due to the pandemic, the pharmacy was not usually obtaining signatures from recipients, and kept an audit trail of the deliveries that had been made. Signatures were obtained from recipients when CDs were delivered.

The pharmacy obtained its medicines from licensed suppliers, and generally stored them tidily. Medicines requiring cold storage were kept in fridges and the temperatures were monitored daily. Records of temperatures seen were within the appropriate range. Liquid medicines were marked with the date of opening to help staff know if they were still suitable to use. Some dispensed bottles of liquid CDs had been dispensed and although they were stored securely, they had not been labelled. This was discussed with the SI on the first day of the inspection and had been resolved by the second day of the inspection. Date-checking of stock was done regularly, and this activity was recorded. No date-expired medicines were found on the shelves checked at random.

Team members described how they actioned drug alerts and recalls that came in, but said that none received recently had applied to any of the pharmacy's stock. Medicines people had returned were separated from stock and placed into designated containers.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment it needs for its services. And it uses its equipment in a way which helps protect people's personal information.

Inspector's evidence

There was a range of calibrated glass measures for the measuring out of liquids. Tablet and capsule counting equipment was clean, and a separate counting triangle was used to count cytotoxic medicines to help avoid cross-contamination. Staff had access to up-to-date reference sources including the internet. The phones were cordless and could be moved somewhere more private to help protect people's personal information. There was sanitising hand gel available for the staff to use.

What do the summary findings for each principle mean?

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