General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Rutland Late Night Pharmacy, 45A,B,C,D High Street, Oakham, Rutland, LE15 6AJ

Pharmacy reference: 9011894

Type of pharmacy: Community

Date of inspection: 30/10/2023

Pharmacy context

This is a community pharmacy situated in the town centre. Most of its activity is dispensing NHS prescriptions and selling medicines over the counter. The pharmacy supplies medicines in multi-compartment compliance packs to people who live in their own home. The pharmacy is also providing the COVID-19 winter booster service and seasonal flu vaccinations. In addition, the pharmacy provides a wide range of private services including weight loss medicines, travel vaccinations, aesthetics, hay fever injections, ear syringing and treatment for a range of acute presentations which consist mainly of acute infections such as urinary tract infections and chest infections.

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 some of the risks associated with its prescribing services. The pharmacy does not have risk assessments and prescribing policies for all of the services it provides.
		1.2	Standard not met	There is insufficient evidence that pharmacist independent prescribers' (PIPs) prescribing is peer reviewed by another prescriber/pharmacist.
		1.6	Standard not met	The PIP does not record any of the discussions that take place between them and the person receiving care. And the PIP does not document their consultation with the person on the person's pharmacy medication record.
		1.8	Standard not met	The pharmacy can’t demonstrate that it adequately protects vulnerable people seeking medicines for weight loss through its online service.
2. Staff	Standards not all met	N/A	N/A	N/A
3. Premises	Standards not all met	3.2	Standard not met	The pharmacy's website does not provide all the required relevant information to people using its services. And the pharmacy is advertising off-licence use of medicines which is against MHRA guidance.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy cannot clearly show that its prescribing service is managed and delivered safely. When prescribing at a distance, the service doesn't always independently verify a person's medical history or weight for medicines for weight loss. The PIP does not always keep satisfactory records of their consultations. And does not record their reasons for prescribing when they don't have consent to share information with people's regular prescribers. The prescribing service doesn't always tell people when a medicine is being used off-licence.

Principle	Principle finding	Exception standard reference	Notable practice	Why
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 identify and manage some of the risks associated with its prescribing services. It does not have risk assessments and prescribing policies for all its services. There is insufficient evidence that the PIPs' prescribing is subject to clinical audits. Although records of supplies made against patient specific directions are made, discussions that take place between the person and the PIP are not always documented and the PIP does not document their consultation with the person for acute conditions on the person's pharmacy medication record. The pharmacy doesn't share information with the person's usual doctor when it supplies of higher-risk medicines such as Ozempic for weight loss. And the pharmacy can't demonstrate that it protects vulnerable people seeking medicines for weight loss adequately through its online service. This means that some people who may misuse or overuse weight loss medicines may not be identified by prescribers working for the pharmacy. The pharmacy has some procedures to learn from its mistakes. But because it does not routinely record all its mistakes it might miss opportunities to improve its ways of working. The pharmacy manages people's electronic personal information safely.

Inspector's evidence

In addition to dispensing prescriptions, the pharmacy provided a wide range of NHS and private services. NHS services included Covid 19 autumn boost vaccination and seasonal influenza vaccinations. Private services included weight loss medicines, travel vaccinations, aesthetics, hay fever injections, ear syringing and treatment of a range of acute presentations which consisted mainly of acute infections such as UTIs or chest infections. Most of the pharmacy's services were provided face-to-face at the pharmacy but the weight loss service could also be accessed online through the website www.rutlandpharmacy.co.uk. The pharmacy did not have written risk assessments or prescribing policies in place for all of the services provided. But the services provided under the patient specific directions (PSDs) did have the key questions to ask within the PSD. A pharmacist independent prescriber (PIP) provided the private services. Some services such as travel vaccinations, hay fever injections and weight loss medicines were provided through a patient specific direction (PSD) written by the PIP. The PIP or a second pharmacist carried out a consultation. The PSD included all the relevant questions to ask the person when undertaking a consultation. The responses from the person to the PSD were then reviewed by the PIP and, if appropriate, the PSD gave written authorisation for the pharmacist to carry out the administration aspect.

When people presented with an acute complaint the consultation was only undertaken by the PIP. And a private prescription was written, not a PSD. There was no written framework when the PIP prescribed a medicine. The PIP verbally explained how they would tailor the consultation depending on the individual they were treating. However, the PIP 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.

The pharmacy provided aesthetics treatments for Botox, derma fillers and platelet rich plasma treatments. All assessments were undertaken by the PIP. The PIP had detailed information and guidance in order to provide the service safely. The pharmacy also ran an ear syringing clinic where an audiologist undertook the assessment and carried out the ear syringing.

During the inspection, a number of records were reviewed. When the consultation was conducted under a PSD there were the necessary records in place including the questionnaire and the treatment plan. Where a consultation was conducted by the PIP there was a record of the private prescription issued which had the names and identity of the prescriber for each prescription dispensed. However, 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 or not prescribe.

The pharmacy was not conducting any clinical audits or reviews carried out by another prescriber to identify whether PIPs' prescribing decisions were aligned with national guidelines and to assess whether adequate clinical decisions and justifications for prescribing were made, or suitable information was provided to the person throughout the consultation process.

In relation to other pharmacy activities, the pharmacy had a set of standard operating procedures (SOPs) that needed to be reviewed, which could mean that they don't reflect current best practice. For example in relation to the recording and reviewing of near misses. The pharmacy manager explained that they were being reviewed. The pharmacy team members had signed the SOPs to show they had read and understood them. Staff were seen dispensing medicines safely. The team understood their roles. For example, the accuracy checking pharmacy technician was able to explain the process for accuracy checking including the need for a clinical check of the prescription by a pharmacist before she could complete the accuracy check. And there was clear accountability in relation to prescribing with records showing who prescribed the medicines and completed consultation notes in the PSD. The staff member asked understood how to sell medicines safely and knew when to seek the pharmacist's advice. Staff knew that prescriptions were valid for six months apart from some controlled drugs (CDs) which were valid for 28 days. Some but not all prescriptions containing CDs were highlighted to remind staff of their shorter validity. This might mean that some prescriptions were supplied beyond their 28-day validity.

The pharmacy had some processes for learning from dispensing mistakes that were identified before reaching a person (near misses) and dispensing mistakes where they had reached the person (errors). Near misses were discussed with the member of staff at the time. The aim was to record them in the near miss log but when the log was checked the last entry was in March 2023. The pharmacy manager said that she would make sure that staff started recording near misses.

The responsible pharmacist (RP) record was mainly accurate, but the pharmacist did not usually sign out when they stopped being the RP. The pharmacy stayed open into the evening, so the record might not clearly show the time that the RP changed. There was a notice on display saying who the RP was, but it was for the previous RP. When this was pointed out the pharmacist changed the notice. Most of the entries checked at random in the CD register during the inspection agreed with the physical stock held. The inspector was notified after the inspection that discrepancies found had been resolved. CD balance checks were completed, but these were not as regular as the SOP required. Patient-returned CDs were recorded in a designated register upon destruction. Patient-returned CDs and date-expired CDs were clearly marked and separated from stock CDs to prevent dispensing errors.

The pharmacy had a complaints procedure and an information governance policy. Access to the electronic patient medication record (PMR) was password protected. Confidential information was stored and destroyed securely. Professional indemnity insurance was in place. The pharmacy's team members understood safeguarding requirements and could explain the actions they would take to safeguard a vulnerable person.

The PIP had completed level 3 safeguarding training. They said that they carried out a video/telephone consultation with people accessing the online weight loss service. And they checked information,

including weight, on the person's Summary Care Record (SCR). But, they did not make records of the information they gathered or provide assurance by way of written processes that this approach was sufficiently robust. And the SCR may not always provide an up-to-date record of the person's weight. This meant there was a risk that these medications were prescribed for people for whom they were not safe or appropriate.

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

Summary findings

The pharmacy's team members work together to manage the day-to-day workload within the pharmacy. And the team have the skills to deliver services safely, and they know how to raise a concern if they have one. Some ongoing structured training could enhance the service provided.

Inspector's evidence

During the inspection, the pharmacy team managed the day-to-day workload of the pharmacy effectively. There were three pharmacists, one was a PIP, one was providing the vaccination service, and the third was the RP. There were also one accuracy checking technician, four trained dispensers and one trainee dispenser, one trained counter assistant and one trainee counter assistant. Members of the team worked well together. Team members were observed supporting each other and referring queries to the pharmacist when needed.

The PIP was very experienced and worked in other roles within the NHS where they prescribed regularly. The PIP explained how they shared any learning from their other NHS roles and looked to help improve their own service as a result. The PIP also delivered training in vaccination technique and travel health both externally and internally. They had trained a number of colleagues at the pharmacy.

The PIP was able to provide training certificates for their aesthetics service and also explained that they attended annual updates. At the point of the inspection they were unable to provide documented evidence of other relevant training completed to cover all other aspects of the clinical services that they offered. But the PIP was able to demonstrate their competence in the areas they were prescribing in. And after the inspection they provided their records. They did not have any evidence of any peer reviews or testimonials during the inspection and did not provide any supporting evidence after the visit. The PIP said that they were not given any incentives to prescribe.

When asked, members of the team said they would be comfortable discussing any issues they had at work with the pharmacist and knew how to raise a concern if they had to. They had an annual review where they were able to give and receive feedback. Staff were given informal training by the pharmacist and were given some opportunities for development, for example they had completed training to provide vaccinations. But did not have regular ongoing training to keep their skills and knowledge up to date.

Principle 3 - Premises **Standards not all met**

Summary findings

The pharmacy's website does not provide all the required relevant information to people using its services. Some of the information displayed is potentially misleading. And the pharmacy is advertising the off-licence use of medicines which is against MHRA guidance. People can receive services at the pharmacy in private when they need to. The pharmacy keeps its premises safe, secure, and appropriately maintained.

Inspector's evidence

Outside, the pharmacy had several bright modern facias. One facia was in a different colour and had Rutland Private Clinic written on the sign. The pharmacist explained that the pharmacy used 'Rutland Private Clinic' as an alternative trading name to advertise the pharmacy. All healthcare activities were provided by the registered pharmacy. The pharmacy had reasonable access for people with a disability or a pushchair to get into the pharmacy. Inside it was neat and tidy with good fixtures and fittings, and a clear route to the pharmacy counter. It had soft lighting and suitable seating. The dispensary was a reasonable size for the services provided. There was suitable heating and lighting, and hot and cold running water was available. Unauthorised access to the pharmacy was prevented during working hours and when closed.

The pharmacy had signage for people using the Covid-19 vaccination service. Specific seating was available and two of the consultation rooms were being used for the service. There was a third consultation room available for other people visiting the pharmacy to have a private conversation with pharmacy staff.

People could find out information about the services provided, book face-to-face appointments and also access remote treatments through the pharmacy's two websites. The first website, www.rutlandpharmacy.co.uk, provided information about the services provided by the pharmacy. It contained details about who owned the pharmacy, its location and contact details. It did not state who the PIPs were or their registration status. This website advertised a hay fever vaccination service which showed Kenalog as the active ingredient. This did not comply with MHRA guidance, and the pharmacist was sign posted to the guidance. The website also advertised the off-licence use of Ozempic for weight loss. MHRA guidance indicates that off-licence use of medicines should not be advertised. The website showed that there was a private doctor service although this service was not being offered at the time of the inspection. However, the website was laid out in such a way that people had to complete the consultation before indicating which prescription-only medicine (POM) they would prefer.

The second website was branded under www.rutlandclinic.co.uk . This website offered private health care services and aesthetics. It did not contain any information about who had clinical oversight of the pharmacy. It did not provide information to people about how they could raise a complaint or how the services advertised were regulated. The pharmacist explained that it was a simple website branded to reach people who would not usually use a pharmacy service. The lack of information on the website could cause confusion for people wanting to access these services.

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

Summary findings

The pharmacy cannot clearly show that its prescribing service is managed and delivered safely. When prescribing at a distance, the service doesn't always independently verify a person's medical history or weight for medicines for weight loss. The PIP does not always keep satisfactory records of their consultations. And does not record their reasons for prescribing when they don't have consent to share information with people's regular prescribers. The prescribing service doesn't always tell people when a medicine is being used off-licence. However, the pharmacy gets its medicines and medical devices from reputable sources. It stores them safely and it knows the right actions to take if medicines or devices are not safe to use to protect people's health and wellbeing.

Inspector's evidence

The pharmacy had reasonable access for people with a disability or a pushchair to get into the pharmacy. The pharmacy team understood the signposting process and used local knowledge to direct people to local health services. The RP was mainly upstairs in the dispensary where medicines were dispensed. Staff communicated with each other by going up and down the stairs or through a walkie talkie, as necessary. This separation made supervision more difficult and might make people visiting the pharmacy more reluctant to ask to speak to the RP. The PIP said that they were aiming to expand the size of the downstairs dispensary so that the RP would mainly be downstairs and more accessible for people. The RP knew the advice about pregnancy prevention that should be given to people in the at-risk group who took sodium valproate. But the pharmacy was not aware of the recent guidance about only supplying sodium valproate in original packs. The RP said that they would implement the guidance immediately.

On the day of inspection, the pharmacy was running a clinic providing the Covid-19 autumn booster and seasonal flu vaccinations. This was well run with a volunteer managing people arriving for the vaccinations, using two of three consultation rooms.

The pharmacy was also providing a travel vaccination clinic. The RP worked under a PSD written by the PIP to provide this as a walk-in service. The PSD had comprehensive information covering the key questions to ask before supplying the travel vaccine. The RP carried out the consultation and the PSD was signed by the prescriber to give authorisation for the RP to administer the treatment. In addition to the PSD the pharmacist made records of the vaccination such as batch number and expiry date which were maintained in a separate folder.

The PIP was prescribing for a range of clinical conditions including weight loss, UTIs and chest infections but they could not provide evidence that they had undertaken training in these areas. A prescription had been issued for a medicine liable to misuse. Although it was a small quantity, the PIP explained this was for muscle spasm and described the rationale for prescribing. The PIP explained that they had either checked the person's Summary Care Record (SCR) or contacted the person's doctor to confirm the person was prescribed this medication. But there was no evidence of these actions as the PIP did not document patient consultations or communication with other health care professionals. The PIP said that they used NICE guidelines and local antibiotic guidelines when prescribing antibiotics. However, prescriptions seen showed that they were prescribing five days' worth of antibiotics to women when local antibiotic guidelines recommended three days' worth of antibiotics for the relevant

condition. There was no documentation to explain the rationale for prescribing five days treatment. This increased the risk of antibiotic resistance and was not in line with national and local guidelines.

The pharmacy was providing a weight loss service. Most people had a face-to-face consultation, and a supply was made via a PSD 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. People had to have a BMI of above 30 to qualify for the various weight loss treatments. People were also able to access the weight loss service through the website. People completed an online questionnaire. The information from the online questionnaire for weight loss was comprehensive and covered the main points to help inform the PIP before making a prescribing decision. Completed questionnaires were reviewed by the PIP before the PIP decided if the person was suitable for the treatment. And they checked information, including weight, on the person's Summary Care Record (SCR). The PIP used their own professional judgement when prescribing. However, the SCR may not always provide an up-to-date record of the person's weight. And the PIP did not always use any other independent evidence to verify their weight. This meant that there was a risk of people receiving treatment that was not clinically appropriate. Examples were seen where orders had been rejected such as a person requesting weight loss medicine which was not appropriate. If the person's responses to the online questionnaire indicated that they qualified for the treatment, the PIP would contact them via the telephone or video call. The PIP explained they liked to contact people to make sure they understood the treatment they were receiving and counsel them on the medication being issued. But the PIP did not make any records of these conversations.

Some people were being supplied GLP-1 medication for weight loss such as Ozempic and Rybelsus. National alerts have been issued stating people should not be started on GLP-1 medication. The PIP explained that they were only continuing the supply of GLP-1 medication and not initiating it and said that people were asked if they had the medicine before. But the PIP was not independently verifying the information given by people which increased the risk of the medicines being prescribed outside of the guidelines. The use of Ozempic and Rybelsus for weight loss are both off-label. The PIP said that they informed people about this when undertaking the face-to-face service. But they did not make a record that this advice had been given.

The PIP explained that the pharmacy did not use an external company to confirm the identity of people using the online service for weight loss medicines, but the pharmacy checked the age and identity of people by asking to see their passport or driving license. If the pharmacy was not able to verify the person's identity or age the order was refunded. But the pharmacy did not keep any records to show that it had made this check. In addition, the pharmacy did not have any processes in place to screen for multiple accounts. The inspector signposted to the Identity Verification and Authentication Standard for Digital Health and Care Services, ICO’s website for guidance on consent and Payment Card Industry Data Security Standard (PCI DSS).

The pharmacy offered 'hay fever injections' which was advertised on the website and in the pharmacy. The PIP was directed to the MHRA guidance that advised that the pharmacy should not advertise this service. This service was provided via a PSD and the questions covered all the key points. However, the pharmacy was not telling people that this was an unlicensed indication for the medicine administered.

The pharmacy did not mandate people to give consent for their regular GP to be informed about the treatment they were receiving. The PIP stated that if a person did give consent, the pharmacy would send information to the GP about the medicines it had supplied, but there was no evidence of this being done. In the majority of cases, people did not consent so the pharmacy did not share any information to make their GP aware of what medicines had been supplied. This meant the pharmacy

did not have assurance that the treatment was being appropriately monitored. Furthermore, the pharmacy did not make records of any requests for copies of people's medication summary or SCR to identify any potential interactions or concerns. And if the PIP prescribed a medicine, they did not always record their reasons.

The RP had an awareness of the medicines that had a potential for misuse and explained that when he received a prescription he checked for inappropriate and unsafe quantities and would flag this up with the PIP if this was the case. He said that this had not yet happened, but the RP said that he would intervene if he needed should there be a cause for concern. In addition to the current prescription the RP said that he had access to the prescribing system so he could see the person's history.

The pharmacy used a dispensing audit trail which included use of 'dispensed by' and 'checked by' boxes on the medicine label to help identify who had done each task. Baskets were used to keep medicines and prescriptions for different people separate to reduce the risk of error. The pharmacy supplied medicines in multi-compartment compliance packs to people living in the community to help them take their medicines at the right time. The pharmacy spread the workload for preparing these packs across the month, using a tracker to make sure packs were prepared and supplied on time. Compliance packs seen included medicine descriptions on the packs to make it easier for people to identify individual medicines in their packs. The pharmacy was not routinely supplying patient information leaflets. The pharmacy manager said they would start supplying them.

Medicines were mainly stored on shelves in their original containers. But a few medicines that had been de-blistered by mistake had been put in brown bottles. The bottles did not record all the information required such as batch number, expiry date and the date they were put in the bottle. These bottles were subsequently put in pharmaceutical waste bins and the pharmacy manager said that she would make sure the required information was recorded in future. Opened bottles of liquid medications were marked with the date of opening so that the team would know if they were still suitable for use. The pharmacy manager explained the process for date checking medicines; each member of staff had their own section of the pharmacy shelves to manage. The pharmacy did not keep a record of date checking. A check of a small number of medicines did not find any that were out of date. CDs were stored appropriately. A record of invoices showed that medication was obtained from licensed wholesalers. Aesthetic products were supplied from reputable sources and stored appropriately. The pharmacist explained the process for managing drug alerts which included a record of the action taken.

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. The pharmacy maintains its equipment and facilities adequately.

Inspector's evidence

The pharmacy used suitable measures for measuring liquids. The pharmacy had up-to-date reference sources. The pharmacy team checked fridge temperatures daily to make sure medicines were stored within the required range of 2 and 8 degrees Celsius. However, there were gaps in the electronic fridge temperature record. The pharmacy manager explained that she had just returned from holiday and staff had recorded the temperatures on pieces of paper in her absence. She intended to enter these on the electronic record on her return. She could not find all the notes and said she would train other staff on how to enter the records electronically. The pharmacy's portable electronic appliances looked in reasonable condition. The pharmacy had the appropriate equipment to be able to provide the vaccination services safely.

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.