

Registered pharmacy inspection report

Pharmacy Name: HealthNet Homecare, Unit 1 & 2, Orbit Business Park, Alfred Eley Close, Swadlincote, Derbyshire, DE11 0WU

Pharmacy reference: 9011236

Type of pharmacy: Internet / distance selling

Date of inspection: 13/05/2021

Pharmacy context

This specialist homecare pharmacy started operating in October 2019. It is situated in a large, purpose built industrial unit on the outskirts of Swadlincote. The pharmacy specialises in delivering medicines and ancillary items directly to people across the UK on behalf of various NHS Trusts. This is the second pharmacy to be owned by HealthNet Homecare. The company also provides nursing services to support people in using their medicines correctly.

Overall inspection outcome

✓ Standards met

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	1.1	Good practice	The pharmacy carries out regular and robust risk assessments to make sure the services that it provides are safe. Pharmacy staff receive specific training on standard operating procedures and the pharmacy monitors this. The pharmacy helps develop the contracts with NHS Trusts which promote good practice for home healthcare.
		1.2	Good practice	The pharmacy regularly audits its services to ensure they are safe. It has robust processes in place to make sure it completes action plans and makes improvements in the time scales specified.
		1.8	Good practice	The pharmacy team receive regular training on safeguarding and the level of training is dependent on their role within the pharmacy. Staff know their responsibilities and know to refer to one of the designated safeguarding leads if they have a concern.
2. Staff	Standards met	2.1	Good practice	There are enough staff to manage the workload and the pharmacy's management effectively plan for new business by reviewing and adjusting staffing levels in advance.
		2.2	Good practice	The pharmacy team have completed accredited training and undertake a programme of additional training to support their specialist roles. There is scope for personal development and pharmacy staff are suitably supervised and supported during their training courses.
		2.3	Good practice	The pharmacy team are empowered to use their professional judgement in the best interests of the patient and regularly contact prescribers when they have a query about prescriptions. And they liaise with other healthcare professionals involved in their care. These are recorded as evidence and to support other pharmacists, rather than asking the same question on multiple occasions.

Principle	Principle finding	Exception standard reference	Notable practice	Why
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	4.1	Good practice	The pharmacy service is well designed so people living with long term medical conditions can manage their medicines and obtain regular supplies without a significant impact on their everyday life.
		4.2	Good practice	The pharmacy operates a safe and efficient service. Its processes are well controlled and managed. The prescription journey is well designed so progress can be tracked. And the dispensing team receives support from a much larger team, and this allows them to focus on their work.
		4.3	Good practice	The pharmacy manages and stores medicines in a secure, well controlled and organised manner. It obtains medicines and ancillary items from licensed suppliers and it stores them in an MHRA licensed warehouse. Ambient and fridge temperatures are closely monitored and there are systems in place to address temperature deviations.
		4.4	Good practice	The pharmacy team works closely with manufacturers to alert them to any possible side effects or issues with their medicines in order to improve their knowledge of these medicines. The pharmacy tracks batch numbers to an individual patient level so they can act quickly if there are any product recalls or concerns about batches.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✓ Standards met

Summary findings

The pharmacy effectively manages the risks associated with the services to make sure people receive appropriate care. It uses regular audits and risk assessments to help make changes or improvements to the services and the way the pharmacy operates. Members of the pharmacy team work to professional standards and they follow written procedures to make sure they work safely. They record their mistakes so that they can learn from them. And they make changes to stop the same sort of mistakes from happening again. There are clear safeguarding procedures in place and the team knows its responsibilities in keeping vulnerable people safe.

Inspector's evidence

This pharmacy opened in October 2019 and was the second pharmacy to be operated by HealthNet Homecare. The original pharmacy in Featherstone was reaching its physical capacity so the owners decided to open another pharmacy. This has allowed the company to continue to grow and work with additional NHS Trusts and dispense a wider range of products. The transfer of part of the workload from Featherstone to Swadlincote had been carefully controlled and this gave the management team at this pharmacy the time to recruit and train new members of staff on the company processes. The dispensing team was part of a much larger team working on site which included business development, finance, I.T., administration, warehousing and a small customer services team. There was a dedicated nursing team that specialised in supporting people with how to administer medication at home by providing face-to-face or virtual visits. HealthNet Homecare's business development managers worked directly with NHS Trusts on the contracts and service level agreements. There were nationally developed standards for Home Healthcare Services which the pharmacy worked to. The pharmacy was registered and inspected by Medicines and Healthcare Regulatory Authority (MHRA) and Care Quality Commission (CQC).

The different teams were linked using a series of bespoke computer systems to manage the end to end processes and governance. The systems had various functions which included; sending prescription requests to NHS Trusts, storing scanned copies of original prescriptions, electronic audit trails for each prescription, details of telephone conversations with patients or prescribers, details about home deliveries, workload planning information and invoicing. Each computer terminal required the member of staff to sign in using their individual sign-on so that every activity could be audited. A computer system supported the pharmacy leadership team with management information, and this provided lists of activities, reports, records and tasks.

A range of standard operating procedures (SOPs) were in place which covered the operational activity and the services provided. SOPs were reviewed regularly by the superintendent (SI) and the computer system was configured so that it alerted the SI when a SOP was due for review. Each SOP was auditable and showed who had been involved in writing and reviewing the document and when this had last taken place.

New and updated SOPs were uploaded to each staff members' individual online learning platform and a task was created to prompt them to undertake the training. Mini tests were attached to each SOP so that understanding could be checked, and the pass mark was 100%. One of the pharmacy management

team also observed staff working to that SOP to ensure they were working in accordance with the updated process. Pharmacy management tracked outstanding SOP training and asked staff members to complete anything that was overdue. Each member of staff had their own online learning platform and training was uploaded according to their job role.

The system for recording near misses had quite recently been updated from a paper-based to a electronic system. The team were running the two processes together and the pharmacy manager was validating the new system by comparing the quality of the data produced by the electronic system to the existing one. Original prescriptions were stored electronically and the prescription was tracked through the dispensing process using a 'pick note'. The barcodes on the pick note were scanned at each stage of dispensing process and this linked the different computer systems together and created the audit trail. Each member of staff's involvement in the prescription journey were recorded electronically. In order to record near misses, the system could tell if an accuracy checking technician (ACT) had returned the prescription back to a dispenser to be amended. The reason was recorded by hand on the pick note and this is what was being checked by the pharmacy manager to ensure that the new system gave sufficient details to undertake a review.

The pharmacy management team carried out a wide range of audits and risk assessments. They created action plans as part of these processes, and these were added to the management information system to ensure the actions were completed in accordance with the time scales specified. Risk assessments were carried out as a team activity to ensure all the relevant people were involved in the process. The company had a specific pharmacovigilance (PV) department and members of the team completed PV forms if they encountered any issues. Some PV training was done during the induction period. A customer service advisor who had only been in role for two weeks explained that she had identified a PV issue whilst talking to a patient and had completed a PV form to report this. Pharmacy incidents, including dispensing errors and complaints, were recorded and investigated. The management information system was used to record the incident and additional documents could be attached to the report for a full and complete record. The SI often led the internal investigation and the steps that were taken to investigate were dependent on the scenario. For example, personal reflection logs were completed by the team members involved if there had been a dispensing error.

The pharmacy could be contacted by telephone and email. There were customer services departments based at both pharmacy sites and a customer services manager worked across them. A new customer services advisor explained how she contacted people to arrange their next delivery. She had received some product training so that she had knowledge on the medicines that she was contacting people about and how they are administered. The pharmacy had dummy devices so that the team could see and feel them and understand how they work as part of their product training. More experienced members of the team were taking incoming calls as these required a broader knowledge. A link to an anonymised patient survey was available to people that used the online ordering system, and paper surveys were sent out. The online ordering system was developed as a direct result of patient feedback.

A certificate of professional indemnity insurance was displayed. The Responsible Pharmacist (RP) notice showed the correct details and was prominently displayed. The RP log was recorded in accordance with legislation. Records for prescription interventions were made on the patient medication record (PMR) system which was held online so could be viewed from any of the company computers.

All computers were password protected and staff members had individual sign in details which they did not share. Emails to NHS Trusts were sent from NHS.net email addresses. Confidential waste was destroyed securely. The team were aware of data protection when sending emails and redacted ore

removed information that they did not think was relevant. The customer services team confirmed that they were talking to the right person on the telephone before discussing medication details. Access to the premises was controlled and visitors were required to sign in and wear a visitor's lanyard. Visitors were asked to show their ID if they were not known to the team. Staff wore their ID on a lanyard and this was used to open internal doors, this controlled access to certain parts of the premises for security purposes.

There were two safeguarding leads at this site; one nursing lead and one pharmacy lead. The team completed different levels of safeguarding training which was dependent on their job role. Examples of training include Centre for Postgraduate Pharmacy Education (CPPE), Health Education England (HEE) or in-house training on the online learning platform. An example was given where a safeguarding referral had been made. A member of the team had been informed of an issue which he thought was an immediate patient safety risk, so he had contacted the pharmacy safeguarding lead who assessed the information and managed the issue.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough suitably trained and qualified team members to manage the workload and the services that it provides. The pharmacy considers staffing levels as part of future workload planning. It makes sure it completes recruitment and training before any additional work is undertaken. The team members plan absences in advance, so they always have enough cover to provide the services. They work well together in a supportive environment and they can raise concerns and make suggestions.

Inspector's evidence

The dispensary team comprised of two pharmacists, a pharmacy manager (accuracy checking technician), a supervisor (accuracy checking technician), four accuracy checking technicians, a trainee pharmacy technician and seven dispensing assistants. The dispensary team were supported by various other people and departments. There was an expectation that the customer services team did product training as part of their induction and then they were enrolled onto an accredited pharmacy related course. The customer services department were new at this site and the team members were still in their induction period. The superintendent was based at Featherstone and worked at the pharmacy at least once a week to support the team's training and development. A Head of Quality had recently been recruited to support the superintendent and share some of the workload. The superintendent was also the Head of Compliance.

The pharmacy manager was responsible for the day-to-day operations of the dispensary and this included organising the workload and allocating people to various tasks. He was supported in this by the supervisor. The team members were trained to undertake the various stages of the dispensing process, rather than just one part of it. They thought that this had been very useful during the pandemic as it meant that there was contingency cover for sickness or to ease any 'bottlenecks'. The pharmacy business had grown by moving different therapies from the Featherstone site. As the growth had been carefully planned and managed, the pharmacy had been able to recruit team members and train the pharmacy team in advance of making any changes. Annual leave was booked in advance using a website or smartphone app and this was authorised by the pharmacy management team.

In-house training, such as new SOPs, were uploaded to the online learning platform. Additional training was provided by manufacturers and virtual training sessions had allowed this to continue during the pandemic. Printed training materials and dummy devices were also available to aid ongoing training. The SI and pharmacy manager used feedback from the team to identify if additional product training was required and liaised with the manufacturers to organise this. Training certificates were scanned and uploaded onto the online learning platform as evidence of training. The Responsible Pharmacist (RP) had previously worked in a hospital pharmacy so she was familiar with the majority of the specialist medicines supplied. She said that additional training was available from the manufacturers and she just needed to ask if she required any additional training or product information.

The dispensary team had a morning meeting to discuss the day's work, allocate tasks and discuss any pharmacy matters. The team explained that they felt comfortable speaking to the rest of the team, or one-on-one with the pharmacy managers if they had any comments, concerns or suggestions and the

management team were very receptive to feedback.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy provides a safe, secure and professional environment for the provision of healthcare services. The premises are secure and safeguarded from unauthorised access. The pharmacy is clean and properly maintained.

Inspector's evidence

The premises were smart in appearance and well maintained. The premises had been purpose built and designed to future proof the business as there was room to expand if required. Any maintenance issues were reported to a maintenance contractor that had been screened, as this was a MHRA requirement. The pharmacy, offices and warehouse were clean and tidy.

The pharmacy was registered with MHRA and they had Responsible Persons who were accountable for the MHRA activity. The building temperature was carefully monitored. A second unit on the industrial estate had been leased and was going through the MHRA registration process. This was going to be used for MHRA activity only.

Access to each part of the building was monitored and controlled. Staff were only allowed in the parts of the building relevant to their role.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy manages its services well and it supplies medicines safely. It gets its medicines from licensed suppliers, and it stores them securely and at the correct temperature, so they are safe to use. People receive detailed information about their medicines, and they can seek advice from a healthcare professional. The pharmacy works closely with manufacturers to report and resolve any problems it identifies relating to medicines.

Inspector's evidence

As a specialist home healthcare pharmacy, the pharmacy had contracts with various NHS Trusts to supply people with their medicines and ancillary items, such as sharps boxes. The contract specified which medicines would be supplied from the pharmacy and there was a specific formulary of medicines that the pharmacy could supply. The pharmacy had contracts with manufacturers so they could directly obtain medicines from them. Many of the medicines supplied were specialist and could not be obtained from the usual pharmacy wholesalers.

The pharmacy classed the NHS Trust as their 'customer' and it was dispensing prescriptions to patients on behalf of the NHS Trust. When a patient was first prescribed a medicine to be supplied from the pharmacy, the hospital explained how home healthcare worked and that prescriptions would be supplied by HealthNet Homecare. The hospital gained the patient's consent and passed the details to the pharmacy together with the prescription. The pharmacy used a central postal address to make it easier for the hospitals to send information through. Incoming post was sorted and prescriptions were scanned into a computer system, and the original was archived.

New patients were contacted by the pharmacy to organise their delivery and a nurse visit was arranged if required. Nurse visits covered matters such as administration technique, troubleshooting and disposal of clinical waste. During the pandemic, these nurse visits had been available as telephone calls, video calls or face-to-face. The pharmacy had a range of patient information and this was supplied with the first supply and again if requested.

Further deliveries were either arranged by telephoning the person, or the person could choose to use an online ordering system to order their own. The online ordering system had been available for a few years and had been developed as a result of patient feedback. People could register for the online system and were prompted to log in and order their next delivery around two weeks before it was due. The system was configured so that the person could select the ancillary items from a list that was matched to their prescription. This could range from a single item, such as a sharps bin, to a much longer list for some of the more complex therapies. The system also captured how much medicine the person had in their home, to identify any compliance issues. The person was given a choice of delivery options and could choose to have their prescription delivered to an alternate address if they preferred. People who opted not to use the online ordering system and people that had not placed their next order were contacted directly by the customer services team to organise their next delivery.

The pharmacists carried out clinical screening of all prescriptions. There were different checks completed dependent on the prescription type and the system allowed the pharmacists to see previous prescriptions for that person, and records of interventions or queries to support the clinical check. The pharmacy did not have access to the patient's hospital or NHS notes. The National Standard required a pharmacist at the NHS Trust to perform a clinical screen of the prescription before it was sent to the pharmacy, this was to check matters such as blood test compliance, blood test results and interactions with other prescribed medicines. The pharmacist marked the prescription if the hospital pharmacist had not carried out a check. Exception reports were created and fed back to the Trusts to improve compliance with national quality standards for homecare and the service level agreements. The pharmacists made interventions with the NHS Trusts and they telephoned or emailed their queries to the prescribers as necessary, and these were recorded on the pharmacy's computer system.

Workload was organised by delivery date and the pharmacy manager could view the upcoming work due to be completed. The team were allocated to different tasks dependent on the workload for that day. The prescription journey was demonstrated during the inspection; prescriptions were clinically checked by a pharmacist, a request for delivery added to the system, the request was sent to the warehouse for picking, the prescription was labelled and the details already imputed were checked, the prescription was assembled, accuracy checked and then packed and labelled for dispatch. As many of the prescriptions contained medicines that needed to be stored in the fridge, there were large walk-in fridges in the warehouse to store completed prescriptions that were awaiting collection by the logistics companies.

The prescriptions contained directions for the pharmacy to make a number of supplies against that prescription, such as four supplies at eight-week intervals. Each prescription had a unique reference which recorded all of the information about the prescription, including how many supplies were permitted and had been made. Towards the end of the prescription, an automated prompt email was sent to the NHS Trusts to ask them to contact the individual prescribers within their Trust and start the process for a new prescription to be generated. This was sent to the central postal system and the cycle started again.

A number of logistics companies were used to deliver the prescriptions. Delivery risk assessments were carried out and different styles of packaging were used dependent on the company. The deliveries could be tracked and audited. The warehouse and fridges were temperature controlled and constantly monitored. Alarms and management alerts were sent if any of the temperatures went out of range so that action could be taken quickly. There was an on-call rota for the pharmacy and someone would attend if the temperature went out of range. There were pharmaceutical waste contracts in place and waste was segregated within the warehouse. A specialist contract was required for sharps containers due to the volume of sharps bins that were returned by patients.

Medicines were obtained directly from the manufacturers as some of the novel treatments could only be supplied by home healthcare pharmacies. The pharmacy recorded which batch numbers had been supplied to which patient so it could directly contact people in the event of a product recall. PV reports were created for every reported side effect or issue, however minor, and these were reported back to the manufacturer. This supported the manufacturer with their post-launch safety monitoring. People were sent links to demonstration videos if the pharmacy team thought that the person needed support with administration technique. The SI was 'hands-on' with speaking to patients and gave examples of when she had telephoned people to discuss their injection technique if they had complained about faulty injection devices.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely.

Inspector's evidence

The pharmacy team had access to a range of up to date reference sources, including the BNF. Internet access was available. Patient records were stored electronically and there were enough terminals for the workload currently undertaken. Computer screens were not visible to the public as members of the public were excluded from the premises. Large computer screens were used to allow for several documents to be open and visible on the same screen.

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.