# Registered pharmacy inspection report

**Pharmacy Name:** Calea Uk Limited, Cestrian Court West, Eastgate Way, Manor Park, RUNCORN, Cheshire, WA7 1NT

Pharmacy reference: 1092153

Type of pharmacy: Closed

Date of inspection: 02/09/2019

## **Pharmacy context**

This is a distance-selling pharmacy situated on an industrial estate. It mainly prepares enteral and parenteral nutrition (EN and PN) feed bags against prescriptions from NHS Trusts which it delivers to people across England and Wales. It works in partnership with the pharmacy owner's feeds manufacturing facility located on the same site. The pharmacy also supplies infusion devices and any ancillary equipment that people need to use with their feed, and immunoglobulin vials.

## **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	1.8	Good practice	The pharmacy team effectively protects and supports vulnerable people.
2. Staff	Good practice	2.1	Good practice	Staff complete tasks properly and effectively in advance of deadlines. And the pharmacy reviews its staffing levels so that they remain appropriate.
		2.2	Good practice	Members of the pharmacy team are fully trained and the pharmacy supports newer members while they are undergoing training. Staff complete regular ongoing training relevant to their roles to help keep their skills and knowledge up to date. And they have protected time to learn when they are at work.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

## Principle 1 - Governance Standards met

#### **Summary findings**

The pharmacy generally manages its risks well. The pharmacy team follows written instructions to help make sure it provides safe services. The team reviews its mistakes which helps it to learn from them. Pharmacy team members receive training on protecting people's information, and they have a clear understanding of their role in protecting and supporting vulnerable people.

#### **Inspector's evidence**

The pharmacy had written procedures that were regularly reviewed and covered safe dispensing and the responsible pharmacist (RP) regulations. Records indicated that all the other staff had read and understood the procedures relevant to their role and responsibilities.

The pharmacy had systems in place for identifying who was responsible for each prescription medication supplied, which assisted with investigating and managing mistakes. The pharmacy team discussed any mistakes it made. It had an electronic system for recording them, and staff usually recorded the reason why they thought they had made each mistake. The team reviewed the records each month, which gave it an opportunity to learn and mitigate against risks in the dispensing process. The pharmacy also produced weekly clinical governance reports that it shared with the rest of the organisation to help it collectively improve its services.

The team received positive feedback in key areas in its last annual satisfaction survey of people and NHS Trusts who used its services. It met with each of the NHS Trusts every three to twelve months depending on the scale of the service, to discuss service delivery. People could raise a complaint via the pharmacy owner's customer service helpline. The superintendent accepted that there were occasions when its communications with people could be more effective. So, the pharmacy had recently arranged for temporary staff and employees from its parent company to be available at short notice to handle telephone queries if there was a sudden increase the number of calls. This meant people's concerns and complaints could be addressed more efficiently. It had an online forum and a panel that met quarterly, so people could discuss any issues about the quality of the services. And the pharmacy also discussed complaints about the delivery service with its national courier, who provided documented corrective actions that addressed these concerns.

The pharmacy had professional indemnity insurance for the services it provided. It maintained its records for the RP, and the RP displayed their RP notice, as required by law. The pharmacy kept records of people's hospital medication referral form, prescriptions, and feed formulation. In addition, it recorded details of who had compounded and carried out the quality check on their feed, date-checked their feed, dispensed and accuracy checked their feed and associated products. It also kept records that clarified the stage each prescription was at in the compounding and dispensing process, which helped to make sure it supplied people with their products in good time.

All the staff had signed agreements about keeping people's information confidential and they completed the pharmacy's data protection training. They securely stored people's information and used passwords to protect access to people's electronic data. The pharmacy had audited how well it protected people's data in January 2018 and it had addressed any deficiencies that it had identified.

The pharmacy had its own safeguarding policies and procedures. All the pharmacists had level two

safeguarding accreditation and staff had completed the pharmacy's safeguarding training. The pharmacy's external courier drivers had also completed safeguarding training and reported any safeguarding concerns such as people exhibiting signs of confusion. The team worked closely with the pharmacy owner's nursing team and hospitals, which helped to identify and facilitate supporting people who could be vulnerable.

The pharmacy discussed people's welfare arrangements with the Trust's clinical nutrition teams. And the owner's nursing staff, who had all completed safeguarding training, regularly visited those people who needed care at home. The nursing staff kept records that included information about these people's wellbeing, nutritional status and weight, which helped to inform discussions about their overall care.

## Principle 2 - Staffing Good practice

#### **Summary findings**

The pharmacy has enough staff to provide safe services and it reviews staffing levels in response to changes in the workload. The team members have the skills and experience needed for their roles. Each team member has a performance review and completes relevant training on time, so their skills and knowledge are up to date.

#### **Inspector's evidence**

The pharmacy had the equivalent of fifty-two full-time staff, three dispenser vacancies recently created by either staff promotion or its owner allocating additional staffing resource. It usually filled these vacancies within a few weeks and had a low staff turnover. The superintendent pharmacist, whose specialism was in aseptic services and had been a resident pharmacist for around six years. The deputy head of pharmacy, who was also a pharmacist, and two senior resident pharmacists took responsibility for operational management of the team and reported to the superintendent. The senior pharmacists each led the two teams of pharmacists. Three registered technicians, who reported to the deputy head of pharmacy, each led their own sub-team of dispensers and accredited checking technicians (ACTs). These arrangements helped to make sure that all the staff had regular opportunities to develop their skills by working alongside other more experienced team members who had higher qualifications.

The pharmacy had enough staff to comfortably manage its workload. It had made sure it had dispensed and dispatched all the products scheduled to be prepared by the end of the working day. The team monitored how long it took to complete the manufacturing and dispensing process for each feed and used this data to measure whether it was meeting its efficiency targets.

The pharmacy planned a daily timetable which made sure there were enough staff allocated to each part of the preparation process for feeds and their associated products. It arranged pharmacist cover two months in advance, and four months in advance for the rest of the team. The pharmacist's working hours were carefully planned around service demand levels.

The pharmacy also effectively planned its staffing over the long term. It had an automated model that predicted the pharmacy's workload over the next two years, calculated the planned and unplanned leave that staff could take at any time without affecting service efficiency, which the superintendent and deputy head of pharmacy regularly reviewed. The model also accounted for the pharmacy's total staff head count needs, which helped make sure there was always enough staff available to efficiently provide services. And the pharmacy owner's operations director had agreed to the pharmacy's projected long-term increased staffing needs under the model. An increase in demand for PN feeds meant the pharmacy had plans to recruit another pharmacy was not accepting any new or returning patients until the end of 2019 at the earliest so that it could safely and efficiently service its existing people. Several members of the team were also trained to work in various roles within the pre-production and dispensing units within the pharmacy, which meant they could be called on when there was a need to increase feed production.

Each member of the pharmacy team received the specialist training relevant to their role that was needed to dispense EN and PN feeds. Pharmacists completed specialist training on formulating and dispensing feeds, and several courses including one on aseptic services that Leeds University in

partnership with the NHS provided. From their recruitment onwards, each pharmacy team member had their skills assessed then built a portfolio of evidence to demonstrate they had attained specific skills. Staff had completed aseptic medication preparation training that Leeds University in partnership with the NHS also provided. Each staff member also completed training on specific feeds and the associated products that people needed to use their feeds. And the pharmacy had a strategy for many of its staff to become ACT accredited in three to five years, which would help to increase the teams overall skills and expertise in feed manufacturing and dispensing. It also provided a guide for any temporary employed pharmacists who were new to its service. And it limited their function to accuracy checking medication, so they only worked within their ability.

The pharmacy had a clear plan to make sure it had a robust staff skill mix. Each team member spent one week working on each stage of the dispensing process, which helped to maintain their skills. The number of employed pharmacists had also been increased to thirteen, which led to a significant reduction in the number of temporary pharmacists to one who was previously permanent employee, and the pharmacy only required them occasionally for its basic functions. The number of ACT members of the team had greatly increased, with eight effectively used in the EN and PN dispensing processes. Two more staff were in training to become ACTs, and three more would start the training in the next twelve months. So, the increased number of permanent higher skilled staff should help the team to perform better.

The pharmacy effectively developed each member of the team. New staff member's training was progressing well, and they were on schedule to complete it within twelve months. They had an initial six-month trial period and discussions with their line manager about their progress every four to six weeks. The pharmacy also had its own bespoke four level training programme where qualified dispensers received accreditation to carry out additional tasks when they had mastered other specialist skills needed for the services provided. And it had a tailored three level training programme for building the ACT's skills, where they were given increasingly larger numbers of products to accuracy check, leading to them being authorised to check feed formulations pre-production. Staff had protected study time for any training that the pharmacy required completing. They all participated in annual performance reviews, which included personal development and training plans. They also had less formal regular one-two-one discussions with management every four to six weeks about their performance and any remedial training they needed to improve their knowledge and skills. The pharmacy's training support officers, who were registered technicians, regularly reviewed each team member's file to identify any outstanding training that needed to be discussed with them, the senior or superintendent pharmacists. The superintendent and pharmacy management team reviewed the pharmacy's strategic training plan twice yearly and monitored the progress towards completing it every month. This had helped to identify a significant gap in the team's overall skills in formulating feeds, which led to it increasing the number of trained staff from five to twelve.

The pharmacy team held operational review meetings twice each weekday that all senior pharmacy staff attended, during which it addressed any outstanding feed orders, staffing, or indirect issues that affected the pharmacy's service efficiency, such as the manufacturing unit's ability to produce feeds. All the staff participated in regular reviews of the team's performance on service quality, efficiency and safety every week.

Members of the pharmacy management team each participated in attending the pharmacy owner's quarterly multi-disciplinary clinical governance and executive team meetings, which helped to share learning to improve services across the organisation. The clinical governance meetings included the organisation's head of quality, head nurse, superintendent pharmacist, deputy head of pharmacy, operations director, customer services, warehouse and distribution managers. These meetings happened on a daily basis when there had been periods of increased service demand or complications

in feed production.

The team had incentives to improve service quality in relation to supplying products correctly, on time and the number of complaints that people made. The Superintendent explained that by setting incentives for the whole team, rather than individual members, staff had supported each other to maintain and improve standards. The pharmacy was exceeding its target for ninety-eight percent of the feeds passing its quality control checks, and was recently achieving ninety-nine point nine-eight percent. It had recently resumed meeting NHS performance targets for supplying feeds to people on time after a short period of interruption to the service. The team also had a target to make sure staff training was up-to-date.

## Principle 3 - Premises Standards met

### **Summary findings**

The premises are clean, secure and spacious enough for the pharmacy's services. Plans to expand the available space in the future will significantly increase service capacity.

#### **Inspector's evidence**

The level of cleanliness was appropriate for the services provided. The premises had the space that the team needed to dispense feeds and associated products safely. And staff could secure it to prevent unauthorised access. The pharmacy's parent company were building a second pharmacy on the same site as the pharmacy. People did not visit the premises, which meant the pharmacy did not need private areas to hold confidential discussions with them.

## Principle 4 - Services Standards met

## **Summary findings**

Overall, the pharmacy's working practices are effective, which helps make sure people receive safe services. It gets its medicines from licensed suppliers and manages them effectively to make sure they are in good condition and suitable to supply.

#### **Inspector's evidence**

The pharmacy was open from early morning to late night Monday to Friday, and over the weekend. People could order and arrange standard delivery of their products up to 11pm. An on-call pharmacist was available on-site from 8am on Saturday to 8am on Monday. And the pharmacy supplied urgently required feeds overnight to make sure people had them early the next day. They could also contact an out-of-hours nurse in emergencies if, for example, their feed bag had punctured.

The hospital usually issued people's prescriptions that covered six to twelve months' supply, which the pharmacy could access electronically. The pharmacy owner's customer services department contacted people one week before their scheduled delivery date to confirm the feeds and associated products that they required.

The pharmacy kept a supply priority list of people who were higher-risk that included infants and children, because their feeds had a limited shelf-life of eight days. However, there was a period recently when it had not always managed to deliver feeds to these people every seven days as normal. This was due to unexpected changes to regulatory standards for products being used in manufacturing feeds being suddenly raised, which the pharmacy had since addressed. The pharmacy also kept a priority list for people who were receiving palliative care, diabetics, or had a stoma. Some of these groups of people had more complex feed formulations, so the pharmacy had reserved extra stock to make sure it avoided running out of their feed. The pharmacy also supplied an additional feed to two-thirds of its patients in case of damaged future supplies or them unintentionally delaying their next order.

The pharmacy had a written procedure to assess the stability and shelf life of each feed and used a bespoke stability matrix for each feed that the owner's medical information team had produced in partnership with Cardiff University. The pharmacy also discussed feed stability with the Trusts, with the aim of extending their shelf-life. It also had written procedures for the feeds it obtained from the manufacturing unit, which included a risk assessment, quality control and audit.

Pharmacists clinically checked each prescription for before the corresponding EN or PN feed was manufactured or dispensed. The ACTs referred to people's files and their prescriptions when they checked their prepared feeds and products.

The pharmacy owner's electronic data management systems meant it could efficiently and accurately transfer information about people's feeds and associated products between the customer services department and the pharmacy. The pharmacy's electronic template for formulating PN feeds helped the team to make sure the manufactured products were stable and could be used to accuracy check the dispensed feed. The team sent details of feed formulations to the NHS Trusts, which helped them to issue an appropriate prescription.

The pharmacy's electronic delivery note system helped it to efficiently plan the production and delivery

of each feed and their associated products. The hospital informed the pharmacy electronically of the associated products such as needles and infusion device flushes that people would need with their feed. And the pharmacy owner's warehouse facility located next to the pharmacy supplied all the associated feed products to it.

The pharmacy obtained its medicines from a range of MHRA licensed pharmaceutical wholesalers. The manufacturing unit from which it obtained all its feeds had the appropriate MHRA manufacturing and wholesale licences. All the staff had completed Falsified Medicines Directive (FMD) training and the pharmacy had a system to comply with FMD.

The team monitored its feed and medicine refrigerator storage temperatures. Feeds were manufactured and supplied to people shortly after they had ordered them, which meant the pharmacy did not hold any stock and a stock expiry date check programme was not necessary. Over eighty-five percent of the feeds had a thirty-day shelf life, which helped to reduce the number of times most people had to order them, and they remained suitable to use long enough for them to be consumed. The team checked immunoglobulin expiry dates during the accuracy check stage of the dispensing process. Staff also contacted people to confirm whether they would use this medication before they reached their expiry date and they made corresponding records that supported this.

At 5pm each weekday the pharmacists on duty reviewed the list of outstanding prescriptions that were for people who were a priority. They immediately contacted these people to identify any products they urgently required. The manufacturing unit had up until 10.30pm to supply urgent products to the pharmacy for it to dispense that people needed by the next day. The pharmacy also had a delivery service that it could contact twenty-four hours a day for any unexpected urgent requests for products.

The pharmacy offered people two-hour time slots in which they could have their products delivered on a weekday up to 11pm and sometimes on Saturday. So, people usually obtained their items at a time convenient to them. It delivered within the agreed time slot around ninety-percent of the time.

The pharmacy used two national couriers to deliver all its products to people, one of who was a specialist cold-chain transporter that was required for parenteral feeds. It met them monthly and quarterly to discuss their service performance and initiate action plans to improve performance, which had been overall positive. The couriers had also responded quickly to a recent and sudden doubling of standard and ten-fold increase in urgent deliveries. The delivery drivers had completed an in-depth training programme that covered good distribution practice, maintaining the cold-chain, recognising and handling any safeguarding concerns, which supported an efficient and effective service. The pharmacy used an electronic system that tracked people's products out for delivery from dispatch at the pharmacy to handing it over to them. Records indicated that delivery drivers obtained people's signature at the point of delivery, which helped to confirm safe and secure delivery of feeds and other products. They also completed a checklist to make sure feed expiry dates were suitable and the assigned number of feeds and any associated products had been delivered.

The pharmacy had a standard one-week delivery lead time to supply people their products. It occasionally supplied a small proportion of people's parenteral feeds over two separate deliveries if the team had found a feed that did not pass its quality checks for urgent orders received late during the working day. People were not always informed that the pharmacy owed them some of their order until part of it was delivered. This was because the pharmacy owner's customer services department, who informed people about owed products, may not have had the opportunity to check its records for people who placed an urgent order late-night the previous day to be delivered at 8am the next day. However, this only represented one percent of all orders.

The pharmacy used its parent company's quality management system for all the products it supplied to people. This meant any reports from people about their products were recorded and forwarded to the parent company's pharmacovigilance department, who identified any suspect items that required addressing.

## Principle 5 - Equipment and facilities Standards met

## **Summary findings**

The pharmacy has the equipment that it needs to provide its services effectively. It properly maintains its equipment and it has the facilities to secure people's information.

#### **Inspector's evidence**

The team had the facilities it needed to dispense feeds. Staff could report equipment issues to the contracted maintenance company, which helped to sustain service continuity.

The pharmacy had the facilities needed to secure people's written and electronic information. The premises were access controlled, which meant unauthorised persons could not easily enter it or view people's information. The pharmacy regularly backed up its people's data on its patient medication record (PMR) system, so it secured patients' electronic information and could retrieve their data if the PMR system failed.

## 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.	