Nationwide Pharmacies Limited

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Inspection report

Nationwide Pharmacies Ltd
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Overall summary

Letter from the Chief Inspector of General Practice

We carried out an announced comprehensive inspection at Nationwide Pharmacies Ltd on 6 February 2017.

Nationwide Pharmacies Ltd provides an online GP consultation and medicines ordering service. Patients register for the service on the provider's website, select the medicines they require, complete an online consultation form which is reviewed by a GP, and if approved, the affiliated pharmacy (which we do not regulate) sends the medicines to the patient by secure post.

We found this service was not providing safe, effective, caring, responsive and well-led services in accordance with the relevant regulations.

Our key findings were:

- Staff we spoke with were aware of the organisational ethos and philosophy and told us they felt well supported and that they could raise any concerns.
- There was a clear business strategy and plan.
- Prescribing was not routinely monitored to prevent any misuse of the service by patients and to ensure GPs were prescribing appropriately. We found patients being prescribed large quantities of medicines for erectile dysfunction and painkillers but there was a lack of monitoring or follow up for these patients.
- When prescribing was found to be inappropriate, there was no evidence that actions were taken to prevent re-occurrence or that learning was disseminated.
- There were no systems to mitigate safety risks including analysing and learning from significant events.
- Medical records were maintained, however recording was not always adequate. For example, medical records did not show any evidence of clinical diagnoses being made or how care and treatment had been determined.
- There were no systems to ensure that emergency services could be directed to the patient in the event of a medical emergency during a consultation.
- Appropriate recruitment checks had not been conducted for staff recruited from an agency. There was a lack of systems to ensure that staff recruitment information and relevant checks were maintained.
- There was no formal induction programme for newly employed staff.
- There was a lack of policies and procedures to govern activity such as incident reporting and safeguarding adult and children.

Summary of findings

- Staff had not received training in all areas needed to ensure they could carry out their role such as the Mental Capacity Act 2005, health and safety, safeguarding children and adults, information governance and fire safety training.
- Patients were not always treated in line with clinical best practice guidance.
- There were limited systems in order to verify a patient's identity.
- There was a lack of systems and processes in order to assess, monitor and improve the quality and safety of the services provided.
- The service encouraged and acted on feedback from both patients and staff. However, there was no formal process to record, manage and monitor feedback obtained.
- The provider was aware of the requirements of the duty of candour. However, systems were not established to ensure compliance with the duty of candour.
- Patients were not able to access enough information about the GP available.
- The systems to protect personal information about patients were not always adequate. For example, email accounts were not encrypted in order to ensure security of emails sent and received. The company registered with the Information Commissioner's Office during our inspection visit.
- Information for patients about services and how to complain was available. However, a formal complaints process for staff had not been adequately established.

The areas where the provider must make improvements are:

- Ensure that information about safety is used to promote learning and improvement by introducing formal arrangements for monitoring safety, significant events, incidents and concerns.
- Ensure the safe and proper use management of medicines in line with evidence based and national guidance and/or best practice.
- Ensure systems and processes are established and implemented in order that care and treatment is provided in a safe way.
- Ensure patient records relating to care and treatment are accurate, complete and contemporaneous, and include a record of the care, treatment and decisions taken.
- Ensure systems and processes are implemented in order to take appropriate action if there is a clinical or medical emergency.
- Ensure care and treatment is provided with the consent of the relevant person and that policies and procedures implemented reflect current legislation and guidance.
- Ensure recruitment arrangements include all necessary employment checks for all staff.
- Ensure that staff employed by the service receive appropriate support, training, professional development, supervision and appraisals; as are necessary to enable them to carry out the duties.
- Ensure that systems and processes are implemented for the purpose of identifying, receiving recording, handling and responding to complaints.
- Ensure that processes and procedures are implemented in order to assess, monitor and improve the quality and safety of services provided.
- Ensure that processes and procedures are implemented in order to assess, monitor and mitigate the risks relating to the health, safety and welfare of staff and service users.
- Ensure that systems and processes are implemented in order to promote a culture that encourages candour, openness and honesty at all levels.

We have issued Warning Notices requiring the provider to take action to improve its services by 28 March 2017. Further details are shown in the table at the end of this report.

Professor Steve Field CBE FRCP FFPH FRCGP

Chief Inspector of General Practice

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found this service was not providing safe services in accordance with the relevant regulations.

- Prescribing of medicines were not routinely being monitored. Where the prescribing had been found to be inappropriate there was a lack of evidence to show that actions were taken to prevent re-occurrence or that learning was disseminated.
- There were no systems or processes in order to mitigate safety risks including analysing and learning from significant events.
- Medical records showed that notes had not always been adequately completed. For example, medical records did not show any evidence of clinical diagnoses being made or how care and treatment had been determined.
- Appropriate recruitment checks had not been carried out for any staff.
- Staff working at the location had not had fire safety or health and safety training.
- The provider's current system for checking the identification of a patient when they registered for the service was limited to a basic credit card check.
- There were no systems to ensure emergency services were directed to the patient in the event of a medical emergency occurring during a consultation.
- The systems to protect all patient information did not always ensure records were stored securely. The service was registered with the Information Commissioner's Office.
- The service had a business contingency plan.
- The provider was aware of the requirements of the duty of candour. However, systems had not been established to ensure compliance with the duty of candour.
- There was one GP to meet the current demand of the service. However, there was a lack of appropriate contingency planning if the GP was absent.
- Not all staff had received safeguarding training appropriate for their role. All staff had access to local authority information if safeguarding referrals were necessary. There was a safeguarding lead but not all staff we spoke with were aware of who the safeguarding lead was.

Are services effective?

We found this service was not providing effective services in accordance with the relevant regulations.

- Consent to care and treatment was not sought in line with the Mental Capacity Act 2005 and staff had not received Mental Capacity Act training.
- We were told that the GP assessed patients' needs and delivered care in line with relevant and current evidence based clinical guidance and standards. For example, National Institute for Health and Care Excellence (NICE) best practice guidelines. patients were not always treated in line with best practice guidance.
- The service did not have effective arrangements in order to coordinate care and share information appropriately. For example, when patients were referred to other services. Consent to share information with the patient's own GP was not routinely sought on the consultation forms.
- There was no policy or guidelines for staff to refer to for the management of sexually transmitted infection (STI) testing results. Additionally, there was no process or system to reconcile tests requested and results received.

Summary of findings

- There were no arrangements for induction, monitoring and appraisal in order to ensure staff had the skills, knowledge and competence to deliver effective care and treatment. We identified there were shortfalls in staff training. For example, staff had not received training relating to the Mental Capacity Act 2005, safeguarding children and adults, health and safety and fire safety training.
- If the provider could not deal with the patient's request, this was adequately explained to the patient and a record kept of the decision.
- The service's web site contained information to help support patients to lead healthier lives.

Are services caring?

We found that this service was not providing caring services in accordance with the relevant regulations.

- Systems to ensure that all patient information was stored and kept confidential were not always effective.
- We did not speak to patients directly on the days of the inspection. We reviewed the previous six months of online reviews from patients (approximately 200), the majority of which were positive about the service. Patients commented on the excellent, fast and professional service they received from the service. Where there had been negative comments these related to the non-receipt of medicines or requests being declined.

Are services responsive to people's needs?

We found that this service was not providing responsive care in accordance with the relevant regulations.

- There was information available to patients to demonstrate how the service operated.
- Patients could access the service by phone from 8.45am to 5.45pm, Monday to Friday.
- The service gathered feedback from patients through an online review website. Where there was negative feedback received, we found that the provider had generally responded to these in a timely way. The provider had not analysed trends, identified actions to improve the service or lessons learnt.
- Patients could access a brief description of the available GP on the provider's website.
- There was no complaints policy established in order to provide staff with information about handling both formal and informal complaints from patients.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations.

- There was a clear staffing structure and staff were aware of their own roles and responsibilities. However, there was no overarching clinical governance and there was a clear lack of clinical leadership.
- There was a lack of policies and procedures to govern activity in relation to: significant event and incident reporting, safeguarding adults and children, managing and monitoring complaints, data protection, recruitment checks, MHRA and patient safety alerts, managing and monitoring consent and mental capacity, responding to medical emergencies, staff training, supervision and appraisal.
- Where policies and documents were present these had not been routinely reviewed and updated. Where policies had been updated, these did not always cover areas appropriately. For example, the security policy dated May 2016 covered the security of a patient's credit/debit card details but did not include information about the security of a patient's personal/medical data.
- There was no evidence of quality improvement activity. For example; audits, monitoring feedback from patients and learning lessons from incidents.
- Management meetings were held between two and three times a year but they did not show where learning from the meetings, for example discussions held and actions to be taken had been shared with all staff.

Summary of findings

- The arrangements for identifying and recording risks, issues and implementing mitigating actions in order to keep patients safe were insufficient. For example, the lack of routine identity checks and the over prescribing of some medicines.
- The service encouraged patient feedback via an online review process.
- The provider told us they were committed to making access to healthcare easier where patients were in control of their own health.

Nationwide Pharmacies Ltd

Detailed findings

Background to this inspection

Background

Nationwide Pharmacies Ltd is based in High Wycombe in Buckinghamshire. Nationwide Pharmacies Ltd set up an online service in October 2012 and provide private prescription treatments following an online consultation with a GP. We did not inspect the provider's affiliated pharmacy (which is not within the remit of registration with CQC). We inspected the online service which is also known as Nationwide Pharmacies Ltd at the following address:

Unit 1, Riverside Business Centre, Victoria Street, High Wycombe, HP11 2LT.

The service employs staff who work on site including staff employed by the affiliated pharmacy and administrative staff. At the time of the inspection, the service had approximately 40,000 patients registered. However, although all those patients registered with the service, not all of them may have been prescribed medicines. The service issues prescriptions for an average of 1600 items per month.

The service can be accessed through their website, www.nationwidepharmacies.co.uk where patients can place orders for medicines seven days a week. The service is available for patients in England and overseas (mainly Germany). Patients can access the service by telephone from 8.45am to 5.45pm, Monday to Friday. This is not an emergency service. Subscribers to the service pay for their medicines when making their on-line application. Once approved by the GP a prescription is sent to the affiliated pharmacy which supplies the medicines.

Nationwide Pharmacies Ltd was registered with Care Quality Commission (CQC) on 31 January 2012 and has a registered manager. A registered manager is a person who is registered with the CQC to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run. The service is registered to provide the regulated activities: Treatment of disease, disorder or injury and Transport services, triage and medical advice provided remotely.

How we carried out this inspection

Our inspection team was led by a CQC Lead Inspector accompanied by a second CQC Inspector, a GP Specialist Advisor, a second specialist advisor and a pharmacist specialist.

Before visiting, we reviewed a range of information we hold about the service and asked other organisations to share what they knew.

During our visits we:

- Spoke with a range of staff including the Managing Director, the superintendent pharmacist, a pharmacy technician, the GP and two non-clinical staff.
- Reviewed organisational documents.
- Reviewed a sample of patient records.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

Detailed findings

Why we carried out this inspection

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

Are services safe?

Our findings

We found that this service was not providing safe services in accordance with the relevant regulations.

Safety and Security of Patient Information

Nationwide Pharmacies Ltd provides an online doctor consultation and medicines ordering service. Patients register for the service on the provider's website. The service was not intended for use for patients with either chronic conditions or as an emergency service. All patient information was stored on the provider's computer system.

The IT systems protected the storage of all patient information. There was a system for private prescriptions which was backed up on a server which was protected. We were told by the provider that all patients could be contacted if there was a problem with issuing their medicines. For example, a fire at Nationwide Pharmacies Ltd premises. However, the service could not provide a clear audit trail of who had access to records and from where and when. Additionally, there was a lack of policies and procedures for the security of patients' medical records maintained and held by Nationwide Pharmacies Ltd and we found that patients' records could be altered. We were told by staff that patients' records were auditable but we were not provided with evidence to support this.

The service was not registered with the Information Commissioner's Office at the start of our visit. We raised this with the provider and they addressed this at the time of the inspection. We subsequently received documentary evidence to show that the company was now registered appropriately. There was a business contingency plan to minimise the risk of losing patient data.

The provider's current system for checking the identification of a patient when they registered for the service were not effective. On registering with the service, patient identity (ID) was only verified through a credit card check. However, minutes from the provider's management meeting dated 12 April 2016, stated that photographic ID checks were conducted only if there were issues with processing credit card payments. Additionally, there were no identity checks conducted in relation to medicines purchased for children (with the patient's parent completing the purchase on the child's behalf), in order to help ensure both the child and parent's identity could be proven nor that the person making the order had parental responsibility for the child.

Prescribing safety

Not all medicines prescribed to patients from online forms were monitored by the provider to ensure prescribing was appropriate.

We did not see any evidence of contemporaneous clinical records for changes in medication. For example, a medicine may have been ordered for a condition for which it wasn't indicated. Any issues that arose between the GP, the pharmacy or the patients requesting prescriptions were not systematically recorded as they arose.

If a medicine was deemed necessary following completion of the on-line request form, the GP issued a private prescription. The GP was only able to prescribe from a set list of medicines that were advertised on the provider's website. There were no controlled drugs on this list. The provider told us that they had very few overseas patients and their website page made it clear that they do not deliver specific medicines, for example codeine based medicines, overseas.

Once the patient selected the medicine and a prescription was issued, no relevant instructions were given to the patient regarding when and how to take the medicine, the purpose of the medicine and any likely side effects and what they should do if they became unwell. This was provided by the affiliated pharmacy.

We noted that the provider prescribed unlicensed medicines. Medicines are given licences after trials have shown they are effective and safe for use in treating a particular medical condition. If a medicine is used in a way that is different from that described in its licence, this is called 'off-label'use.Treating patients with medicines for a medical condition that is not described in its licence is higher risk because less information is available to show the benefits and less is known about the potential risks. We noted that medicines were prescribed for off-label use (for example, a medicine used to treat jetlag); there was a statement on the website which informed people that there was no licensed preparation for this use. The manufacturer's patient information leaflet was available to view on the website, this only referred to the licensed use of this product and no further information was provided. We

did not see evidence of consent by the patient to acknowledge and accept that they were receiving a medicine for use outside of its licence.This posed a risk to the patients and was not in accordance with General Medical Council guidance.

We looked at patient consultation records and were concerned at some prescribing decisions. We found that there had been over prescribing of some medicines. For example, Sildenafil, a medicine used to treat erectile dysfunction. We were told that the provider's threshold was 40 tablets per month, which exceeded the quantity that would be needed to provide the maximum dose of one tablet in 24hours, that the product was licensed for. However, there was no written documentation to formally support the provider's policy. We found evidence that one patient had been prescribed excessive amounts of Sildenafil, more than the appropriate licensed use for this medicine. In 2013 we found two examples when this had been particularly excessive. We also saw evidence of a patient being prescribed Trimethoprim (an antibiotic) for a three day period for a urinary tract infection. We were told that the provider's policy was that no further prescriptions would be honoured after this if requested. We found that the same patient had been prescribed a further dose of Trimethoprim within seven days of their first prescription. There was no written documentation to support what we were told was the provider's threshold policy regarding the prescribing of this medicine. The provider did not follow the principles of antibiotic stewardship as they did not consider local or the Royal College of General Practice and Public Health England guidance on antibiotic prescribing.

We did not find evidence to show that patients requesting a monthly repeat prescription (for example, inhalers, high strength co-codamol 30/500 only available on prescription) had been reviewed in order to establish that they were taking the medicine correctly or the reason they required it had been considered as part of the repeat prescribing process. We found that where medicine reviews were being completed, these were done so only in cases where issues were identified involving higher risk medicines. For example, co-codamol and requests for amounts over the amount authorised by the provider, 40 per month. Additionally, we found evidence of patients providing a copied or repeated history or with known duplicate accounts (registered with the service more than once but using different addresses, for example). There were no risk assessments or systems to routinely identify these or action having been taken to address them.

There were no systems or processes to routinely communicate with a patient's own GP. This is very important to make sure that medicines were not being abused. For example, requests for repeat prescribing of asthma medicines, co-codamol, antibiotics and medicines prescribed for off label use.

Management and learning from safety incidents and alerts

The systems for identifying, investigating and learning from incidents relating to the safety of patients and staff members were limited. We saw minutes of management meetings which discussed incidents and significant events. However, there was a lack of staff knowledge of what constituted an incident and/or significant event. Additionally, there was a dependency on staff vigilance and a lack of systems and processes in order to underpin how incidents and significant events should be managed and monitored appropriately.

The provider was aware of the requirements of the duty of candour. (The duty of candour is a set of specific legal requirements that providers of services must follow when things go wrong with care and treatment). However, there were no systems to ensure compliance with the duty of candour. For example, support training for all staff on communicating with patients about notifiable safety incidents. The service did not have a system to ensure that when things went wrong with care and treatment, they would give affected people reasonable support, truthful information and a verbal and written apology.

There was limited knowledge of and access to The Medicines and Healthcare Products Regulatory Agency (MHRA) and National Patient Safety (NPS) alerts. We were told by the superintendent pharmacist and the provider that all alerts (either MHRA or NPS) went directly to the affiliated pharmacy who acted on them accordingly and the GP received these through their own GP practice. However, there was a lack of formal systems and process to underpin how MHRA and national patient safety alerts should be managed and monitored appropriately.

Safeguarding

Are services safe?

Not all staff had received safeguarding training appropriate for their role. We found that customer service staff (likely to identify vulnerable people) had not received training in safeguarding adults or children. There was an identified safeguarding lead. However, there was a lack of knowledge amongst staff as to who this was. We were unable to establish at the time of the visit that the safeguarding lead had received the appropriate level of training in order to conduct this role (level 3). In view of the service providing services throughout England, there was a lack of information accessible to staff in relation to safeguarding authorities across the country. We found a lack of systems to conduct appropriate identify checks which underpin safeguarding measures. Additionally, we found that there were no identifiers in the online form regarding coercion of a patient and/or where there may have been concerns. For example, male partners paying for female patients' contraception. The service had not considered that this may be a safeguarding issue, causing a clear risk to patients.

We found that staff lacked knowledge of the Mental Capacity Act 2005 and the impact of it in their work. Additionally, there was a lack of lack of systems and processes to monitor and manage mental capacity assessment, if required. There were no formal processes for checking consent of the patient on their online forms or that consent for care and treatment was sought at each stage of the online process. There was no evidence consent was sought from patients who made a request for medicines and consultation through a family member. For example, anti-malarial medicines being purchased for children (with the patient's parent completing the purchase on the child's behalf).

Staffing and Recruitment

We had concerns that there were not enough clinical staff, to meet the demand of the service. There was a separate administration team but there was only one GP who also worked as a part time senior partner at an NHS GP practice and there was a reliance on this one individual to assess and deal with all the prescriptions requested. We also had concern as to how this was managed and monitored as there was a lack of formal clinical peer review, discussion and oversight of the GPs role.

We did not see any evidence of personnel files for staff recruited held by the service. We found there was a lack of a system to routinely conduct recruitment checks when a newly appointed staff member had been recruited from an agency. We were told that these documents were held by the agency. However, the service did not obtain copies of these, in order to ensure that staff recruited were suitably experienced and qualified for the role they were employed for.

We found that Disclosure and Barring Service (DBS) checks were not routinely obtained for all staff employed or appropriate risk assessments completed where DBS checks may not be deemed necessary. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable). Additionally, there was no system or process for the routine checking of the registration with the appropriate professional body for the GP and pharmacy professionals.

Monitoring health & safety and responding to risks

The provider informed patients what the limitations of the service were on their website. The service was not intended for use as an emergency service. However, there were no processes to manage or monitor any emerging medical emergencies during a consultation or information on the website.

Clinical meetings were held between two and three times a year. However, minutes from these meetings did not show how the learning from incidents, for example discussions held and actions to be taken, had been shared with all staff, as they had not been included in the minutes.

The provider provided regulated activities from a purpose built industrial unit which accommodated the management and administration staff. Patients were not treated on the premises and the GP reviewed the on-line request forms and prescribed from a remote location. We found there were systems to check that there was an up to date fire risk assessment, records of regular fire equipment testing and testing of electrical equipment to ensure the equipment was safe to use and working properly. However, we found that staff had not received training in health and safety or fire safety awareness.

Are services effective?

(for example, treatment is effective)

Our findings

We found that this service was not providing effective services in accordance with the relevant regulations.

Consent to care and treatment

There was clear information on the service's website with regards to how the service worked and the costs of a consultation and of medicines available, and a set of frequently asked questions for further supporting information. The website had a set of terms and conditions and details on how the patient could contact them with any enquiries. Information about the cost of the consultation and prescription was known and paid for in advance.

We found that consent was not routinely sought to contact the patient's own GP or advise the patient that if consent is not given, services would not be provided. There was no system or process to routinely record who the patient's registered GP was at any stage during the purchase. This was completed only when the doctor had initiated a medicine review. There was no system to ensure patients' consent to care and treatment was in line with legislation or guidance for patients who made a request through a family member. The service processed anti-malarial medicines for parents if they requested this for their children. However, there was no system to verify parental responsibility or identity of the child, when processing such requests.

Assessment and treatment

We reviewed 46 medical records and were concerned about some of the prescribing decisions. For example, for the patient over prescribed Trimethoprim (an antibiotic) there was no record that consideration had been given to the fact that the infection may be resistant to the Trimethoprim prescribed or that the patient did not have a urinary tract infection. The patient had not been contacted to discuss their symptoms. This was inappropriate as the patient should have been referred for further investigation; prescribing was not in accordance with best clinical practice and national guidance.

We found that medical records did not show any evidence of clinical diagnoses being made or how care and treatment had been determined. There was limited detail recorded in patient medical records about the content of emails sent between the GP and the patients. Emails sent were not being accurately transferred to patients' medical records. There was no structure or detail for these. For example, the medical record entry by the GP stated 'email sent' and there was no summary of the content of the email. We saw that emails were saved to the GP's email account and were not accessible to other staff that may require access to the clinical information contained within them. For example, the pharmacists at the affiliated pharmacy, clinically reviewing the prescription before make a supply.

We were told that the GP reviewed the online forms filled in by patients and if they were unable to reach a decision as to the appropriateness of prescribing the medicine, there was a system where the GP could contact the patient for further information. We found that the online forms were not comprehensive enough to enable a clinical diagnosis or to identify any contra-indications (reasons why a medicine should not be prescribed due to other medicines being taken by the patient) and there was no automated system to flag these up. Additionally, we found that the questionnaires often contained medical terminology and were not based on current guidance/evidence of best clinical practice.

Patients completed an online form which included their past medical history. However, we found that there were instances of patients providing a copied or repeated history but there was no system to routinely identify this or review where this was detected. There were no risk assessments or systems noted for patients with known duplicate accounts. In both instances there was a dependency on staff vigilance and no automated system to highlight accounts of concern. Additionally, the forms were designed to prompt the patient to supply a correct answer. For example, if a patient had answered 'no' to a question when the answer should have been 'yes', the system asked the patient to review their answer. There was no automated system to alert the service that patients had initially answered questions incorrectly and trigger that a review may be necessary.

The GP providing the service was aware of both the strengths (speed, convenience, choice of time) and the limitations (inability to perform physical examination) of working remotely from patients. However, they failed to assess and minimise the risks for patients. For example,

Are services effective?

(for example, treatment is effective)

there was no policy or guidelines for staff to refer to for the management of sexually transmitted infection (STI) testing results. There was no process or system to reconcile tests requested and results received.

The service did not routinely monitor consultations or carry out consultation or prescribing audits to improve patient outcomes.

We asked to see examples of quality improvement activity, for example clinical audits. The doctor told us that each prescription was considered individually and that they did not audit their prescribing overall. This means that the provider did not undertake a systematic review of prescribing patterns against best practice standards and did not have a process for identifying improvements.

Coordinating patient care and information sharing

There was no evidence of communication with the patient's registered GP in order to help ensure risks were appropriately identified and mitigated. When a patient contacted the service they were not asked if the details of their consultation could be shared with their NHS GP.

Where the patient requested to have an STI test, the testing kit was sent to the patient by post with instructions on how to provide a sample. The testing kit included a pre-paid envelope to be sent to a laboratory. Results from the test were then sent back to the provider. Staff reported that positive results were given to the patient by the GP but there was no routine system regarding contact being made with patients when the results were negative or for signposting them to other services.

Supporting patients to live healthier lives

The service did not always identify patients who may be in need of extra support, although they had a range of information available on the website. For example, self-treatment of a common cold, weight loss and smoking cessation. We found that the website directed patients to NHS Direct for further advice and support. However, NHS Direct has not been in existence since 2014. We raised this at the time of the inspection and the website was updated to direct patients to NHS Choices.

Staff training

Staff told us they were supported by the management team. There was no formal system to ensure that staff received ongoing support, appraisals, mentoring, and clinical supervision.

We found that there was a lack of a formal process of induction for newly appointed staff, as well as no formal or consistent structured meeting process following employment probation periods. We were told by a member of staff recruited four and a half months prior to our inspection that they had a meeting with the provider after their three month employment probation; however this had not been documented. Whilst another member of staff recruited six months prior to our inspection had not had a meeting in order to establish how they had progressed during this period.

We also found that staff (both clinical and non-clinical) had not received information governance training and that not all staff had been trained in safeguarding adults and children or The Mental Capacity Act 2005.

We found that the GP kept a record of their own training and appraisal. However, there was no system or process for the provider to assure themselves that the GP had been appraised or undertook CPD.

The provider funded training for staff and we were told decisions about this were based on staff development and provider need. However, there was no formal supervision of staff, in order to underpin how staff development was appropriately managed and monitored.

Are services caring?

Our findings

We found that this service was not providing caring services in accordance with the relevant regulations.

Compassion, dignity and respect

The systems to ensure that all patient information was stored and kept confidential were not always effective. We found that the provider had not ensured that email accounts used had sufficient protections for the storage and transmission of personally identifiable information, for example passport details, as staff email accounts were not encrypted in order to ensure security of emails sent and received. There had been no risk assessments conducted to help ensure that where accounts were not required to be encrypted, for example administrative staff who did not handle patients confidential information, these had been assessed and considered.

The service engaged with an online review website on which they are rated by customers. We reviewed the previous six months of online reviews from patients, the majority of which were positive about the service. Patients commented on the excellent, fast and professional service they received from the service. Where there had been negative comments these related to the non-receipt of medicines or requests being declined (at the time of our inspection visit 17 out of 20 negative comments had been responded to). They had an overall rating of 9.2 out of 10. There had been no consideration given to patients not wishing to use this system to provide confidential feedback, due to its open/public nature.

Involvement in decisions about care and treatment

Patient information guides about how to use the service and technical issues were available. There were dedicated staff members to respond to any enquiries. Information on the provider's website informed patients about each medicine that was available, the cost of the medicine, how to use a medicine and the potential side effects.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was not providing responsive services in accordance with the relevant regulations.

Responding to and meeting patients' needs

There was information available to patients to demonstrate how the service operated. Patients could access the service by phone from 8.45am to 5.45pm, Monday to Friday. Help and support from the service could be accessed either by e-mail or by phone.

We were told that patients who had a medical emergency were advised on the provider's website to ask for immediate medical help via 999. However, we found that there was no clinical emergency policy or procedure for staff to follow and the website did not signpost patients to emergency services or their own GP if they required an urgent consultation.

The digital application provided by the service allowed patients to contact the service from abroad (mainly Germany). The GP was based in England but continued to provide the consultation service when they were abroad, for example on holiday. Any prescriptions issued were delivered using the Royal Mail parcel delivery service.

Tackling inequity and promoting equality

The provider offered services to anyone who requested and paid the appropriate fee, and did not discriminate against any client group.

Patients were not able to access enough information about the GP, as there was only a brief description available. At the time of our inspection, patient could access one GP.

Staff told us that translation services were not available for patients who did not have English as a first language. The provider's website only had information and application forms in English. The provider told us they were considering the website being translated into German. The provider had not performed any accessibility testing on their website for patients with sensory impairments or disabilities.

Managing complaints

Information about how to make a complaint was available on the service's web site. However, there had been no complaints recorded in the last 12 months. Information on the website did not contain information for patients regarding the timescales for dealing with the complaint or how they may be escalated if the patients' complaint had not been resolved satisfactorily.

The service gathered feedback from patients through an online review website (Trust Pilot). Where there was negative feedback received we found the service had generally responded to these in a timely way (at the time of our inspection visit 17 out of 20 negative comments had been responded to). The service had not formally analysed trends, identified actions to improve the service or lessons learnt. However, many negative comments related to the non-receipt of medicines or requests being declined and were not considered by the service to be complaints. The provider told us that people could complain directly to him and this was supported by information provided to people on the website.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

We found that this service was not providing well led services in accordance with the relevant regulations.

Business Strategy and Governance arrangements

The provider told us they had a clear vision to work together to provide a high quality, responsive service that put care and patient safety at its heart. We reviewed business plans that covered the next two years. The provider was committed to making access to healthcare easier where patients were in control of their own health.

There was a clear staffing structure and staff were aware of their own roles and responsibilities. However, there was no overarching clinical governance and there was a clear lack of clinical leadership.

There was a limited range of service specific policies which were available to all staff. We found that the service had a staff handbook, which included details of personnel related policies. However, there was a lack of policies and procedures to govern activity in relation to: significant event and incident reporting, managing and monitoring complaints, data protection, recruitment checks, MHRA and patient safety alerts, managing and monitoring consent and mental capacity, responding to medical emergencies, staff training, supervision and appraisal. Where policies were available, hard copies of policies and standard operating procedures were available in the service.

We also found that those policies/documents which were present had not been routinely reviewed and updated. For example, the statement of purpose was dated 2011 with a review date of 2012. This review had not been undertaken. Where policies had been updated, these did not always cover areas appropriately. For example, the security policy dated May 2016 covered the security of a patient's credit/debit card details but included no content regarding the security of a patient's personal/medical data.

There was no evidence of quality improvement activity. For example; clinical audits, monitoring feedback from patients and learning lessons from incidents.

The supporting team carried out a variety of checks either daily or weekly. Management meetings were held between two and three times a year. However, whilst the minutes from these meetings were adequate, they did not show how the learning from the meetings, for example discussions held and actions to be taken, had been shared with all staff, as they had not been included in the minutes.

The arrangements for identifying and recording risks, issues and implementing mitigating actions did not keep patients safe. Systems and processes had not been established to effectively identify the issues raised within the safe, effective, caring, responsive and well-led domains. For example, Safeguarding children and adults, recruitment procedures, governance arrangements.

From the 46 medical records we reviewed we saw that notes had not always been adequately completed. For example, medical records did not show any evidence of clinical diagnoses being made or how decisions on care and treatment had been made. There was limited detail recorded in patient medical records about the content of emails sent between the GP and their patients and patient records could be altered. We were told changes to patients' records were auditable but saw no evidence at the time of the inspection to support this.

Leadership, values and culture

The provider had responsibility for any medical issues arising. They attended the service daily. The provider realised that the service had grown considerably and had plans for improving online access being available for patients using the service in the future.

The values of the service were to focus on a traditional family run business values whilst adapting to modern day demands and rapid change in technologically.

The service had an open and transparent culture. We were told that if there were unexpected or unintended safety incidents, the service would give affected patients reasonable support, truthful information and a verbal and written apology. However, this was not supported by an operational policy or an established process.

Seeking and acting on feedback from patients and staff

Patients could rate the service they received via an online review website (Trustpilot). This was constantly monitored and if they fell below the provider's standards, it would

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

trigger a review of the issue raised in order to address any shortfalls. In addition, patients were emailed at the end of each consultation with a link to complete an online review. Patient feedback was published on the service's website.

Staff told us they could feedback about the quality of the service and any change requests were discussed. However, there was no formal process for recording, monitoring or managing such discussions.

The staff handbook contained guidance for staff in relation to whistleblowing. A whistle blower is someone who can raise concerns about practice or staff within the organisation. The provider was the named person for dealing with any issues raised under whistleblowing. However, there was no formal policy for how whistleblowing would be managed and monitored or contacting other whistle blowing advisory agencies.

Continuous Improvement

The provider told us that they were open to suggestions for improvement from staff but we saw no evidence of any service improvements.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Safeguarding service users from abuse and improper treatment. **How the regulation was not being met:** The provider was failing to ensure service users must be protected from abuse and improper treatment in accordance with this regulation. In that: • There were no systems or processes established in order to prevent abuse of service users. • There were no formal processes for checking consent, especially in relation to children (with the patient's parent completing the purchase on the child's behalf). • There was no safeguarding policy for all staff to access, nor was there a structured formal process for reporting safeguarding issues. • Customer service staff likely to identify vulnerable people had not received training in safeguarding adults or children. • There was an identified safeguarding lead; however there was a lack of knowledge amongst staff as to who this was. We were unable to establish that the lead had received appropriate training in order to conduct this role. • There was a lack of nationwide safeguarding authorities for staff to access. • Poor identify checks underpinned that safeguarding measures were not a priority and patients could be put at risk of harm.

This section is primarily information for the provider

Requirement notices

- There were no identifiers in the online form regarding coercion of a patient/concern.

This was in breach of regulation 13 (1) and (2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely Treatment of disease, disorder or injury	Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints Regulation 16 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Receiving and acting on complaints. **How the regulation was not being met:** The provider had failed to establish and operate effectively an accessible system for identifying, receiving, recording, handling and responding to complaints by service users and other persons in relation to the carrying on of the regulated activity. In that: • There was no formal complaint policy established for staff to refer to or to underpin how complaints should be managed, monitored and responded to. • Information on the website did not adequately inform patients how complaints should be managed, monitored and responded to. **This was in breach of regulation 16 (2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.**

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed Regulation 19 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Fit and proper persons employed.

This section is primarily information for the provider

Requirement notices

How the regulation was not being met:

The provider did not have an established and effective recruitment procedure.

In that:

- There were no DBS checks or risk assessments for staff (where appropriate).
- There was no system or process for the routine checking of the registration with the appropriate professional body for the pharmacists and the GP.
- Where staff had been recruited by a recruitment agency, there was no system or process to ensure copies of recruitment checks had been verified by the provider.

This was in breach of regulation 19 (1), (2) (3) and (4) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely Treatment of disease, disorder or injury	Regulation 20 HSCA (RA) Regulations 2014 Duty of candour Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Duty of candour.

How the regulation was not being met:

The provider was failing to ensure a culture which encouraged candour, openness and honesty at all levels.

In that:

- There were no systems to ensure compliance with the duty of candour, which included support training for all staff on communicating with patients about notifiable safety incidents.

This section is primarily information for the provider

Requirement notices

- The service did not have a system to ensure that when things went wrong with care and treatment, they would give affected people reasonable support, truthful information and a verbal and written apology.

This was in breach of regulation 20 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely Treatment of disease, disorder or injury	Regulation 11 HSCA (RA) Regulations 2014 Need for consent Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Need for consent **How the regulation was not being met:** The provider was failing to ensure that care and treatment of service users is only provided with the consent of the relevant person. In that: • There was a lack of effective systems and processes for obtaining informed consent in regard to unlicensed medicines prescribed. **This was in breach of regulation 11 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.**

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Regulation 12 HSCA (RA) Regulations 2014: Safe care and treatment **How the regulation was not being met:**

This section is primarily information for the provider

Enforcement actions

The provider was failing to provide care and treatment to service users in a safe way as they were failing to ensure they assessed and mitigated the risks to the health and safety of service users of receiving the care or treatment.

In that:

- Systems to confirm a patient's identity were not adequate.
- Medical questionnaires used to gather information on the service user's condition prior to prescribing did not ensure; essential and appropriate information has been obtained or include appropriate identification of contra-indications.
- Medical records did not show any evidence of clinical diagnoses being made or how care and treatment has been determined.
- There was no process or system to reconcile tests requested and results received.
- There were no appropriate policies or guidelines for staff to refer to for the management of sexually transmitted infection (STI) testing results.
- There were no systems to assist patients in the rare event of a medical emergency occurring during consultation.
- Over prescribing of medicines was identified.
- Medicine reviews are not routinely conducted in all cases where long term purchases are being made.
- Service users requesting a monthly prescription had not routinely been reviewed in order to establish they were taking the medicine correctly or the reason they required it had been considered as part of the repeat prescribing process.
- Safety concerns identified did not provide assurance that there were systems or processes in order to ensure the GP employed was operating in accordance with General Medical Council (GMC) guidance on remote consulting and prescribing.
- There were no risk assessments or systems noted for service users with known duplicate accounts.
- There was no system or process to routinely record who the service user's registered GP was at any stage during the purchase.

This section is primarily information for the provider

Enforcement actions

- The web-based ordering system used by Nationwide Pharmacies Ltd did not allow the information relating to a service user's medical record to be shared with another healthcare professional in a timely and secure manner and information was not being shared with a patient's own registered GP to ensure prescribing was safe, appropriate and in accordance with General Medical Council guidance.
- There was no contingency planning for the absence of the GP.

This was in breach of regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance Regulation 17 HSCA (RA) Regulations 2014: good governance **How the regulation was not being met:** The provider was failing to ensure they assessed, monitored and improved the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services). In that: • There was no overarching clinical governance, a clear lack of clinical leadership and there were no systems to ensure that patients using the service are kept safe. • There was a lack of formal arrangements for managing policies and procedures in order to ensure staff were aware of standard procedure and protocol. • Policies and procedures which were present had not been routinely reviewed and updated. • Where policies have been updated, they had not been done so appropriately.

This section is primarily information for the provider

Enforcement actions

- There was a lack of knowledge about the issues affecting the service (such as patient satisfaction, complaints, NICE guidance and safety alerts) and insufficient action has been taken to formally share them with staff working at the service.

The provider was failing to ensure they assessed, monitored and mitigated the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.

In that:

- There was a lack of systems and processes to underpin the services provided and information about safety was not being used to promote learning and improvement. For example; significant events, complaints, data protection, recruitment checks, The Medicines and Healthcare products Regulatory Agency (MHRA) and National Patient Safety (NPS) alerts, policies and procedures.
- There was a lack of staff knowledge of what constituted a significant event or how to cascade them should one occur. Additionally, there was no significant event policy which informed staff of when and how a significant event should be reported and formally documented.
- There was a lack of Mental Capacity Act 2005 awareness amongst staff and there was a lack of systems and processes to monitor and manage patients mental capacity testing.
- Information about consent was not being used to promote good practice and there was no consent policy or procedure written to inform staff as to current guidance or evidence of best practice.
- There were no formal arrangements for monitoring safety and there is limited knowledge and access to MHRA and NPS alerts. Additionally, there was no formal process to underpin how these are received, managed and monitored.
- There was no system for routinely conducting recruitment checks. Recruitment records were not maintained in order to help ensure that recruitment checks have been conducted appropriately.

This section is primarily information for the provider

Enforcement actions

- There was no policy or procedure to routinely collaborate with the patients own GP.

The provider was failing to maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided.In that:

- There was no policy or procedure for the security of or monitoring and management of patients' medical records maintained by Nationwide Pharmacies Ltd.
- Patients' records could be altered and were not clearly auditable.
- Email accounts were not encrypted in order to ensure security of emails sent and received by the service. There had been no risk assessments conducted to help ensure that the email accounts had been assessed

The provider was failing to ensure they sought and acted on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services.In that:

- Reports from other stakeholders or registered bodies had not been used to evaluate and improve the overall service provision.
- There was no evidence of quality improvement activity to show that the learning from incidents had been used to inform processes for all other medicines prescribed.
- There was no formal process for staff supervision (either clinical or non-clinical) or a system for regular staff appraisal and the staff meeting structure did not include the whole staff team and issues such as significant events, safety alerts, complaints and updates to guidance having been formally cascaded to all staff.
- There was no policy or procedure for the monitoring and management of complaints and there had been no formal analysis of these negative comments to look for trends and identify lessons learnt.

This section is primarily information for the provider

Enforcement actions

- There was no system to conduct clinical audits routinely and there was no on-going programme of clinical audits which could be used to monitor quality and systems in order to identify where action should be taken.

This was in breach of regulation 17 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Transport services, triage and medical advice provided remotely Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing Regulation 18 HSCA (RA) Regulations 2014: Staffing **How the regulation was not being met:** The provider was failing to ensure that persons employed in the provision of the regulated activities are receiving appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform. In that: • There was no formal process of induction for newly appointed staff and there was no evidence to suggest that a formal process had been conducted in order to ensure staff received appropriate support, following their probation period. • There was no evidence of staff (both clinical and non-clinical) having received appropriate training and there was no staff training programme that could be routinely monitored and managed in order to ensure staff were appropriately trained in order to perform their roles. • There was no system or process to assure the GP had been appraised or undertook Continued Professional Development (CPD).

This section is primarily information for the provider

Enforcement actions

This was in breach of regulation 18 (2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.