

Nationwide Pharmacies Ltd

Quality Report

Nationwide Pharmacies LTD

Unit 1

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Summary of findings

Ratings

Overall rating for this service

Are services safe?	
Are services effective?	
Are services caring?	
Are services responsive to people's needs?	
Are services well-led?	

Summary of findings

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Summary of findings

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. We found this service was not providing safe, effective, caring, responsive or well led services in accordance with the relevant regulations. The full comprehensive report on the February 2017 inspection can be found by selecting the 'all reports' link for Nationwide Pharmacies LTD on our website at www.cqc.org.uk.

This inspection was an announced focused inspection carried out on 27 June 2017 to confirm that the provider had carried out their plan to meet the legal requirements in relation to the warning notices issued following our previous inspection on 6 February 2017. This report covers our findings in relation to the enforcement action we took.

We found this service had not met all the requirements as outlined within the warning notices issued specifically;

- The provider was unable to demonstrate that opioids (a potentially highly addictive medicine) was being safely managed as systems were in their infancy.
- The provider was unable to demonstrate how they had shared information with patient's GPs with their consent.
- The provider and GP were unable to demonstrate quality improvements.

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.

Our key findings were:

- The service had systems to keep people safe however these had not yet all been fully embedded.

- The service had systems to keep people safeguarded from abuse.
- There was a comprehensive system in place to check the patient's identity.
- There were systems in place to mitigate safety risks including taking action as a result of significant events.
- There were appropriate recruitment checks in place for all staff.
- Systems had been introduced to monitor prescribing practices and to prevent any misuse of the service by patients.
- There were some systems in place to ensure staff had the information they needed to deliver safe care and treatment to patients.
- The service learned and made improvements when things went wrong. The provider was aware of and complied with the requirements of the Duty of Candour.
- Patients were treated in line with best practice guidance and appropriate medical records were maintained.
- An induction programme was in place for all staff and staff, including clinicians had access to all policies.
- The service had a policy to share information about treatment with the patient's own GP, but were unable to evidence where this had been followed.

The areas where the provider must make improvement are:

- Ensure care and treatment is provided in a safe way to patients.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care

Professor Steve Field CBE FRCP FFPH FRCGP

Chief Inspector of General Practice

Summary of findings

The five questions we ask and what we found

We always ask the following five questions of services.

Are services safe?

At our comprehensive inspection on 6 February 2017, we found this service was not providing safe

services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that many of the requirements of the warning notice had been met. This included:

- Staff had received safeguarding training appropriate for their role and had access to local authority information if safeguarding referrals were necessary.
- Patient identity was checked on registration with the service and at every consultation or when prescriptions were issued.
- Systems had been implemented to ensure the completion of an assessment and clinical diagnoses including reasons for the proposed care and treatment
- There were enough clinicians/GPs to meet the demand of the service and appropriate recruitment checks for all staff were in place.
- In the event of a medical emergency occurring during a consultation, systems were in place to ensure emergency services were directed to the patient.
- The provider had registered with the Information Commissioner's Office and there were secure systems in place for managing and retaining personal data.
- The service had a business contingency plan addressing both disruption to their physical premises and staffing structure.
- There were systems in place to meet health and safety legislation and to respond to patient risk.
- There were systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. The provider was aware of and complied with the requirements of the Duty of Candour and encouraged a culture of openness and honesty.

However, the provider had only recently introduced systems to promote safe prescribing and we were unable to determine if they were effective.

Summary of findings

Are services effective?

At our comprehensive inspection on 6 February 2017, we found this service was not providing effective services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that many of the requirements of the warning notice had been met. This included:

- The GP assessed patients' needs and delivered care in line with relevant and current evidence based guidance and standards. For example, National Institute for Health and Care Excellence (NICE) evidence based practice.
- There were induction, training, monitoring and appraisal arrangements in place to ensure staff had the skills, knowledge and competence to deliver effective care and treatment.
- Consent to care and treatment was sought in line with the Mental Capacity Act 2005 and staff had received cascaded Mental Capacity Act training.
- The provider had revised their policy and guidelines to ensure systems were in place to follow up on sexually transmitted infection (STI) test results.
- The service's web site contained information to help support patients lead healthier lives, and information on healthy living was provided in consultations as appropriate.

However, Whilst we found the service had some arrangements in place to coordinate care and share information appropriately, for example, the provider had introduced a policy and procedure to share information with the patients' own GP. This was new and we were unable to find sufficient evidence to show it was being adhered to. The service also had no programme of on going quality improvement activity.

Are services caring?

At our comprehensive inspection on 6 February 2017, we found this service was not providing caring services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that this service was providing caring services in accordance with the relevant regulations and that the requirements of the warning notice had been met. This included:

- The provider had revised their information governance systems to ensure patient information was stored and kept confidential.

Summary of findings

Are services responsive to people's needs?

At our comprehensive inspection on 6 February 2017, we found this service was not providing responsive services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that this service was providing responsive services in accordance with the relevant regulations and that the requirements of the warning notice had been met. This included:

- The service gathered feedback from patients through an online review website. Where there was negative feedback received, we found that the provider had responded to these comments in a timely way.

The provider had revised their complaints policy and this provided staff with information about handling formal and informal complaints from patients. Information was available to patients about how to make a complaint.

Are services well-led?

At our comprehensive inspection on 6 February 2017, we found this service was not providing well-led services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that this service was providing well-led services in accordance with the relevant regulations and that the requirements of the warning notice had been met. This included:

- There was a clear staffing structure and staff were aware of their own roles and responsibilities. The provider had introduced governance systems but they were in their infancy and needed time to be embedded.
- The provider had revised and improved their 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.
- There was evidence of quality improvement activity from the pharmacy team who had conducted self-initiated audits on prescribing behaviours.
- Systems were in place to ensure that all patient information was stored securely and kept confidential. There were systems in place to protect all patient information and ensure records were stored securely. Both the service and the GP was registered with the Information Commissioner's Office.

Summary of findings

The service encouraged patient feedback via an online review process.	
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Summary of findings

Areas for improvement

Action the service **MUST** take to improve

- Ensure care and treatment is provided in a safe way to patients.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care

Nationwide Pharmacies Ltd

Detailed findings

Our inspection team

Our inspection team was led by:

Our inspection team was led by a CQC Lead Inspector accompanied by a second CQC Inspector, a GP specialist advisor and a CQC Regional Medicines Manager.

Background to Nationwide Pharmacies Ltd

Background

Nationwide Pharmacies LTD is based in High Wycombe in Buckinghamshire. Nationwide Pharmacies LTD set up an online service in October 2012 and includes 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 a superintendent pharmacist, pharmacy and administrative staff. The GP worked remotely from the provider. At the time of the inspection, the service had approximately 40,000 patients registered, not all of them had been prescribed medicines.

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. Patients can access the service by telephone from 9am 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, medicines are supplied by the affiliated pharmacy.

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.

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.

We undertook a follow up focused inspection of Nationwide Pharmacies LTD on 27 June 2017. This inspection was carried out to review in detail the actions taken by the provider to improve the quality of care in response to the service of the warning notices and to confirm that the provider was now meeting those legal requirements.

Detailed findings

How we carried out this inspection

Before visiting, we reviewed a range of information we hold about the service.

During our visit we:

- Spoke with a range of staff including the Managing Director, the superintendent pharmacist, a pharmacist 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.

Are services safe?

Summary of findings

At our comprehensive inspection on 6 February 2017, we found this service was not providing safe services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that many of the requirements of the warning notice had been met. This included:

- Staff had received safeguarding training appropriate for their role and had access to local authority information if safeguarding referrals were necessary.
- Patient identity was checked on registration with the service and at every consultation or when prescriptions were issued.
- Systems had been implemented to ensure the completion of an assessment and clinical diagnoses including reasons for the proposed care and treatment
- There were enough clinicians/GPs to meet the demand of the service and appropriate recruitment checks for all staff were in place.
- In the event of a medical emergency occurring during a consultation, systems were in place to ensure emergency services were directed to the patient.
- The provider had registered with the Information Commissioner's Office and there were secure systems in place for managing and retaining personal data.
- The service had a business contingency plan addressing both disruption to their physical premises and staffing structure.
- There were systems in place to meet health and safety legislation and to respond to patient risk.
- There were systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. The provider was aware of and complied with the requirements of the Duty of Candour and encouraged a culture of openness and honesty.

However, the provider had only recently introduced systems to promote safe prescribing and we were unable to determine if they were effective.

Are services safe?

Our findings

At our previous inspection on 6 February 2017. We found that this service was not providing safe services in accordance with the relevant regulations. We found;

- Patient accounts were not secure and amendments were not auditable.
- There were insufficient systems in place to confirm the patient's identity.
- Staff had not received appropriate safeguarding training.
- Recruitment checks had not been conducted prior to staff commencing their employment.
- The provider had been prescribing off prescription medicines.
- Contemporaneous records were not being maintained of patient consultations

These arrangements had improved when we undertook a follow up inspection on 27 June 2017.

Keeping people safe and safeguarded from abuse

Nationwide Pharmacies LTD provided an online doctor consultation and medicines ordering service. Patients registered for the service on the provider's website and in the process set up an individualised encrypted account. The service was not intended for use by patients with chronic conditions or as an emergency service. All patient information was stored on the provider's computer system. This IT system protected the storage of all patient information. 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. The provider explained that they had improved the management of patient accounts to ensure that patient records could not be altered except by a clinician and that all entries or amendments to the patient record could be audited. Documents examined confirmed this.

The service had registered with the Information Commissioner's Office in February 2017 on the day of our last inspection. They had a business contingency plan to minimise the risk of losing patient data.

The provider had revised their system for checking the identification of a patient when they registered for the service. Previously on registering with the service, patient identity (ID) was verified through their payment card

details. This had been improved to include a search of multiple data sources cross checking and verifying the name, age and address of the person. Where discrepancies were identified the patient was asked for further identification such as formal photographic identity in order to continue with their order. We saw evidence of declined requests for medicine based on lack of sufficient proof of identity.

Improvements had been made to the provider's system for confirming the identity and appropriate delivery address of the patient. The service operated a one patient, one address IT system to help prevent additional medicine orders being made in different names from a single address. The provider told us they had stopped prescribing for children under 18 years of age.

Staff had received training in safeguarding and knew the signs of abuse and to whom to report them. The registered manager was the appointed safeguarding lead and had not undertaken training. However, following our inspection the provider revised their policy and the GP and Superintendent Pharmacist were appointed responsibility for safeguarding. Both had completed appropriate training for children and vulnerable adults and were aware of escalation procedures. All staff had access to updated safeguarding policies.

Monitoring health & safety and responding to risks

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 carried out online consultations from a remote location. The service did not carry out telephone consultations.

The provider informed patients of the services available on their website. The service was not intended for use as an emergency service. 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. We reviewed the staff handbook dated February 2017. There was a policy outlining the management of a clinical emergency and the escalation to emergency services. All staff had signed to confirm they had read and understood the details of the handbook.

We reviewed the meeting minutes from the last management and clinical meeting. We found the service

Are services safe?

had reviewed the new patient messaging system. They had discussed and agreed the structure for automated medical reviews including the timescales; had discussed monthly dispensing qualities and had reviewed the complaints received in the last quarter.

Staffing and Recruitment

The service clinical team consisted of a GP and a Pharmacist Superintendent who was an independent prescriber. They were supported by a separate administration team. The practice relied on the GP who logged into the encrypted clinical system daily each morning, afternoon and evening. The GP managed all prescriptions. We previously had concerns relating to the provider's reliance on a sole GP to provide the service. However, they told us they had seen a decline in demand for their service of approximately 50% following the introduction of their enhanced screening and assessment processes. They also attributed this to the service no longer prescribing and distributing medicine outside of the UK. We saw documents that showed the provider had appointed the superintendent pharmacist to act in the GP's absence and the lead on aspects of medicine management.

We reviewed seven personnel files. We found that recruitment checks had been conducted for all staff including the most recently employed member of the team. We found that basic Disclosure and Barring Service (DBS) checks had been obtained for all staff and enhanced DBS were being sought for the pharmacy team. (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). The GP was on the national performers list. The provider had a system in place to identify training undertaken and that pending. Annual checks on the professional registration of clinicians were undertaken for the GP and pharmacist.

Prescribing safety

Following our inspection on 6 February 2017 the provider stopped prescribing medicines 'off label' (for use in a way that is different from that described in its licence). They showed us how they had revised their system. It no longer allowed patients to select and place an order for medicines independently of the screening questions and subsequent clinical consultation, including a contraindication form. Patients could only purchase medicines after the online

consultation process was seen and approved by the GP in accordance with their diagnosis. Once the patient selected the medicine and dosage recommended by the GP, relevant instructions were given to the patient regarding when and how to take the medicine. This included the purpose of the medicine and any likely side effects and what they should do if they became unwell.

We looked at patient consultation records and saw that there were accurate contemporaneous notes kept since April 2017. The system was new and time was needed for this to embed fully. All of the patient information was contained within this record, including their on-line consultation and any messages exchanged between the patient and the clinician. The records were held in an encrypted account that the patient could access using a password. No private email exchanges were used.

Diagnostic templates were examined and we found that most of these reflected current guidance. However, the malaria template was not sufficiently up to date and the asthma template did not sufficiently assess the severity of the patients' symptoms. The provider reviewed and updated both of the templates in line with national guidance. These were submitted to the Commission and reviewed by the inspection team.

We reviewed the processes for prescribing and dispensing opioids, medicines that act on the nervous system to relieve pain and may be highly addictive. We found that an audit had been conducted to identify high requestors of this medicine and that these patients were declined the medicine and flagged on the system. The new IT system automatically prompted a three month review for patients prescribed pain relief medicine and maximum quantities were established which were checked by the pharmacist. However, the system had only recently been introduced and we were unable to assess its effectiveness.

The provider told us that they had established a system to limit the amount of medicine prescribed for each patient and that patients could order one, two or six months' supply of medicine in advance. However, the system did not have an inbuilt automated check. The provider was reliant on the pharmacist or GP checking to see when the last medicine was prescribed and whether this was an appropriate timeframe for re-prescribing. This was discussed with the provider during the inspection.

Are services safe?

Following the inspection the provider introduced a flag system to alert the clinician if more than a month of medicine has been prescribed to help prevent over-prescribing.

The provider had stopped prescribing antibiotics except for where there was a confirmed diagnosis of a sexually transmitted infection (STI).

The provider had reviewed their systems for capturing their patient's preferences and the sharing of information with their GP. Since April 2017 their clinical system invited patients to agree for their GP to be contacted. The provider did not explain to patients when or how they would have their information shared. Checks of the patient record system showed the patient would be required to send an email to the provider independently of their order if they wished certain information not to be disclosed. We found no information had been shared with patients GPs. The provider introduced a policy and guidance for their patients and staff on the disclosure and sharing of relevant medical information to promote safe prescribing practices for all medicines prescribed.

For example, in documents seen after the inspection the provider demonstrated that an audit of patients prescribed asthma medicine had been carried out and a policy requiring the patients GP details and permission to share information had been established.

Management and learning from safety incidents and alerts

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). The provider had revised all of their systems for identifying, investigating and learning from incidents relating to the safety of patients and staff members. We saw minutes of management meetings which discussed incidents and significant events and a new policy had been implemented.

The provider had an awareness and understanding of The Medicines and Healthcare Products Regulatory Agency (MHRA) and National Patient Safety Alerts (NPSA) alerts. We were told by the superintendent pharmacist and the provider that all alerts (either MHRA or NPSA) went directly to the superintendent pharmacist who acted on them accordingly and shared them with the GP. We saw that a system had been introduced to ensure alerts were checked and where that when these were relevant to their patients, action was taken. For example, staff told us that an extra question was added to the diagnostic questionnaire regarding Mefloquine (brand name Lariam) as a treatment for Malaria, after an alert was received which detailed strengthened warnings for potential neuropsychiatric side effects. The provider also told us they had ceased to supply medicines to patients in Europe due to a March 2017 MHRA alert. We saw a recent alert had been actioned and shared appropriately.

Are services effective?

(for example, treatment is effective)

Summary of findings

At our comprehensive inspection on 6 February 2017, we found this service was not providing effective services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that many of the requirements of the warning notice had been met. This included:

- The GP assessed patients' needs and delivered care in line with relevant and current evidence based guidance and standards. For example, National Institute for Health and Care Excellence (NICE) evidence based practice.
- There were induction, training, monitoring and appraisal arrangements in place to ensure staff had the skills, knowledge and competence to deliver effective care and treatment.
- Consent to care and treatment was sought in line with the Mental Capacity Act 2005 and staff had received cascaded Mental Capacity Act training.
- The provider had revised their policy and guidelines to ensure systems were in place to follow up on sexually transmitted infection (STI) test results.
- The service's web site contained information to help support patients lead healthier lives, and information on healthy living was provided in consultations as appropriate.

However, Whilst we found the service had some arrangements in place to coordinate care and share information appropriately, for example, the provider had introduced a policy and procedure to share information with the patients' own GP. This was new and we were unable to find sufficient evidence to show it was being adhered to. The service also had no programme of on-going quality improvement activity.

Our findings

At our previous inspection on 6 February 2017. We found that this service was not providing effective services in accordance with the relevant regulations. We found:

- 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 system or process to routinely record who the service user's registered GP was at any stage during the purchase.
- There was no evidence of staff (both clinical and non-clinical) having received appropriate training.

These arrangements had improved when we undertook a follow up inspection on 27 June 2017.

Assessment and treatment

The provider had reviewed their procedures for capturing, assessing, diagnosing and dispensing medicines. The provider had introduced a three tier process for assessment, diagnosis and treatment. This included an auditable communication log to evidence questions, discussions and decisions. For example, a communication log was recorded on the system showing day, time and author of the question and responses.

We were told that the GP reviewed the online questionnaires 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 checked clinical templates to assist in diagnosis and review of long term medicine. We found most reflected current guidance. However, some were unclear using complex medical terms, failed to be sufficiently comprehensive and/or did not reflect national guidelines and standards 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). For example,

Are services effective?

(for example, treatment is effective)

- We reviewed the assessment template for Malaria, this relied on links to other systems that had not been updated to reflect recent guidance.
- The asthma template also failed to assess the severity of the patient's conditions and their control of their asthma prior to the reauthorisation of medicines.

Following our inspection the provider revised both templates with clinical input and amended the screening templates to reflect best practice and improve the safe assessment of patients. We received these amended documents within 24 hours of the inspection and they were reviewed and found to reflect national guidelines and standards.

The provider told us of other improvements they had made to their assessment and treatment processes. For example; the provider had introduced a standard operating procedure for the management of sexually transmitted infections (STI) specifically Chlamydia. We found there were insufficient clinical entries to enable us to assess if the policy was being adhered to as the system was newly introduced and therefore did not yet hold historical information.

Quality improvement

The provider and GP were unable to provide any evidence of quality improvement conducted in relation to the service.

Coordinating patient care and information sharing

The service had revised their systems regarding the confirmation of the patients' own GP practice. The IT system invited the patient to confirm the identity of their NHS GP as part of the consultation process. They provided them with a comprehensive list of surgeries in their area to aid the timely identification of their service. Patients were asked to confirm whether they were willing for their NHS GP to be contacted. Although this process was established, we found no evidence that this had been done or that information had been shared appropriately.

The provider had introduced a new 'Contacting a patient's GP' policy, which demonstrated that patients who did not provide their GP information and consent for the service to make contact if it was in their best interest would not be prescribed medicine.

Staff training

Staff told us they felt supported by the management team and that meetings were held on a three monthly basis. Minutes of meetings were seen.

An induction policy had been developed and detailed the process for new staff members for the first month of employment and outlined the review and appraisal periods for the staff team. All staff could access policies and procedures manually or via their IT system for reference. The provider informed us these were discussed during team meetings. We found that clinical and non-clinical were undertaking online information governance training. Most staff including members of the clinical team had completed their safeguarding training and those outstanding had been scheduled to undertake safeguarding adults and children training within the month. The staff handbook contained key policies and all policies had to be signed as read and understood by individual staff members.

Documents seen demonstrated that the GP had been appraised in 2017. The document showed that the GP had discussed their digital prescribing work during their appraisal and had reviewed the GMC guidelines on remote prescribing.

The provider explained that if the patient's test results were of concern they kept the patient record active. They would check to confirm the patient placed an order for the appropriate amount and type of medicine. The provider told us that they would contact the patient if an order had not been placed on the system and would advise them of the result of the test.

Are services caring?

Summary of findings

At our comprehensive inspection on 6 February 2017, we found this service was not providing caring services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that this service was providing caring services in accordance with the relevant regulations and that the requirements of the warning notice had been met. This included:

- The provider had revised their information governance systems to ensure patient information was stored and kept confidential.

Our findings

At our previous inspection on 6 February 2017. We found that this service was not providing caring services in accordance with the relevant regulations. We found insufficient systems were in place for the safe management and retention of personal data.

These arrangements had improved when we undertook a follow up inspection on 27 June 2017.

Compassion, dignity and respect

The practice had revised their information governance systems to ensure patient information was stored and kept confidential. The provider now encrypted emails to their patients to ensure only patients with the information may access the patient account. We found that the provider had stopped using personal email accounts and ensured all correspondence was initiated and managed through their patient system which was encrypted. Thereby ensuring sufficient protection for the storage and transmission of personally identifiable information, for example passport details. The revised policies had been shared with staff who were required to sign each to confirm receipt and understanding of the content.

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 had received. Patients were also able to provide confidential feedback directly to the registered manager.

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?)

Summary of findings

At our comprehensive inspection on 6 February 2017, we found this service was not providing responsive services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that this service was providing responsive services in accordance with the relevant regulations and that the requirements of the warning notice had been met. This included:

- The service gathered feedback from patients through an online review website. Where there was negative feedback received, we found that the provider had responded to these comments in a timely way.

The provider had revised their complaints policy and this provided staff with information about handling formal and informal complaints from patients. Information was available to patients about how to make a complaint.

Our findings

At our previous inspection on 6 February 2017. We found that this service was not providing responsive services in accordance with the relevant regulations. We found:

- There were no systems to assist patients in the rare event of a medical emergency occurring during consultation.
- 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.

These arrangements had improved when we undertook a follow up inspection on 27 June 2017.

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 9am 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. We revised the services staff handbook dated February 2017. There was a policy outlining the management of clinical emergency policy and their escalation to emergency services. All staff had signed to confirm they had read and understood the details of the handbook.

The service no longer provided international consultations and did not distribute medicines outside of the UK. This decision was taken in response to a Medicines Safety Alert published in March 2017.

Tackling inequity and promoting equality

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

The service provided brief details of their prescribing GP such as their registration details.

Are services responsive to people's needs?

(for example, to feedback?)

Managing complaints

Information about how to make a complaint was available on the service's web site. It included how to escalate concerns to The Parliamentary and Health Service Ombudsman if dissatisfied with the outcome. We asked to see complaints they had received since February 2017. The provider told us they had received no formal written complaints addressed to the registered manager since April 2017. We reviewed comments made on their online website Trust Pilot. There had been 146 of which 20 were negative. However, many of the negative comments related to the non-receipt of medicines from the affiliated pharmacy, extended screening questionnaires or requests being declined. We found the provider had acknowledged all of the negative comments and provided a response where possible without breaching confidentiality. For example, a patient had complained that they service no longer provided the service to Europe and the provider had explained this was due to a change in the law prohibiting the practice. We found evidence of the provider advising patients to speak directly with their NHS GP regarding their concerns and declining to provide a service.

We also reviewed a comment recorded in May 2017. The patient stated they were asked inappropriate questions not

relevant to their gender when being assessed. We asked the provider if they had taken any action in response, such as reviewing their clinical templates to identify the discrepancy and amending the template. The provider had not conducted any review or changes to their practise.

The service had not formally analysed trends, identified actions to improve the service or lessons learnt. The provider told us that people could complain directly to him and this was supported by information provided to people on the website.

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 make contact with any enquiries. Information about the cost of the consultation and prescription was known in advance and paid for before the consultation appointment commenced.

The provider had a Mental Capacity Act 2005 policy and summary and includes an assessment of capacity checklist.

Are services well-led?

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

Summary of findings

At our comprehensive inspection on 6 February 2017, we found this service was not providing well-led services in accordance with the relevant regulations and improvements were required.

At our focused inspection on 27 June 2017 we found that this service was providing well-led services in accordance with the relevant regulations and that the requirements of the warning notice had been met. This included:

- There was a clear staffing structure and staff were aware of their own roles and responsibilities. The provider had introduced governance systems but they were in their infancy and needed time to be embedded.
- The provider had revised and improved their 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.
- There was evidence of quality improvement activity from the pharmacy team who had conducted self-initiated audits on prescribing behaviours.
- Systems were in place to ensure that all patient information was stored securely and kept confidential. There were systems in place to protect all patient information and ensure records were stored securely. Both the service and the GP was registered with the Information Commissioner's Office.

The service encouraged patient feedback via an online review process.

Our findings

At our previous inspection on 6 February 2017. We found that this service was not providing well-led services in accordance with the relevant regulations. We found an absence of governance of systems to monitor and improve the quality for services. Some of the arrangements had improved when we undertook a follow up inspection on 27 June 2017.

Business Strategy and Governance arrangements

There was a 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. The provider had reviewed a number of policies and procedures to govern activity in response to our previous inspection findings. These included significant event and incident reporting, managing and monitoring complaints, data protection, recruitment checks, MHRA and patient safety alerts, managing and monitoring consent and the mental capacity act, responding to medical emergencies, staff training, supervision and appraisal. All policies were signed as read by the staff team, including the GP.

We found a number of systems had been introduced to support the provider to identify and respond to risks and undertake quality improvement activities. Many were in their infancy and therefore there was insufficient data available to track through the system and confirm policies and processes were being fully adhered to. However, we tracked through a number of patient records and found all assessments stages had been appropriately completed. These were then forwarded for clinical review and diagnosis and only appropriate medicines could be selected by the patient on completion of the process. Where further clarity was needed we saw a system was in place for messages to be exchanged in an encrypted area where contemporaneously recorded communications were stored which were auditable.

Leadership, values and culture

The provider had responsibility for any medical issues arising. We confirmed the provider held appropriate medical indemnity insurance and company insurance. The provider attended the service daily. They told us they felt it was important to be present and accessible to their staff. They were committed to the timely resolution of any concerns brought to their attention.

Are services well-led?

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

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.

Safety and Security of Patient Information

Systems were in place to ensure that all patient information was stored and kept confidential.

There were policies and IT systems in place to protect the storage and use of all patient information. The service could provide a clear audit trail of who had access to records and from where and when. Both the service and the GPs were registered with the Information Commissioner's Office. There were business contingency plans in place to minimise the risk of losing patient data.

Seeking and acting on feedback from patients and staff

Patients could rate the service they received via an online review website. This was constantly monitored and responded to the feedback. 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.

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.

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
Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>The provider was failing to provide care and treatment to service users in a safe way as they were failing to ensure they were doing all that was reasonably practicable to mitigate the risks to the health and safety of service users receiving care or treatment.</p> <p>In that: Medication reviews were planned as part of an automated system but had not yet been undertaken; the impact of alerts placed on patient notes to help ensure safe prescribing had not been seen.</p> <p>This was in breach of regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</p>

Regulated activity	Regulation
Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>The provider was failing to ensure that systems were established and operated effectively to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users who may be at risk from the carrying on of the regulated activity.</p> <p>In that: The new IT system, although introduced and in use had not been established for a long enough period to determine whether it would be effective in ensuring safe care and treatment.</p> <p>This was in breach of regulation 17 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</p>