

PrivateDoc Limited

PrivateDoc Limited

Inspection report

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Overall summary

Letter from the Chief Inspector of General Practice

We carried out an announced comprehensive inspection at PrivateDoc Limited on 10 May 2017. PrivateDoc Limited offers a digital service that allows patients to obtain a prescription and purchase medicines from an affiliated pharmacy which we do not regulate but is registered with the General Pharmaceutical Council.

We found this service did not provide a safe, effective and well led service but did provide a caring and responsive service in accordance with the relevant regulations.

Our key findings were:

- There were systems in place to protect patient information and ensure records were stored securely.
- On registering with the service, patient identity was only verified by credit/debit card checks. Electoral roll identity checks were in the process of being introduced, but were not yet live at the time of our inspection.
- The provider complied with the requirements of the Duty of Candour.
- Safety alerts, for example those from the Medicines and Healthcare products Regulatory Agency (MHRA), were considered but there were no records available to indicate that these had been actioned.
- There were enough doctors to meet the demand of the service and appropriate recruitment checks for all staff were in place.
- We found that assessments of patient needs and care was not consistently being delivered in line with relevant and current evidence based guidance and standards. Clinical questionnaires that patients had to complete required improvement and there were no clear dosage instructions highlighted to patients. The provider told us they amended their questionnaires to reflect NICE guidelines after our inspection.
- The service had arrangements in place to coordinate care and share information appropriately for example, when patients were referred to other services. But information sharing with other services did not take place consistently.
- Medicines prescribed to patients from online forms were monitored by the provider through ad-hoc reviews to ensure prescribing was evidence based, although we noted the process for following up these reviews was not fully embedded. There was a complaints policy which provided staff with information about handling formal and informal complaints from patients.
- The provider told us they had a clear vision to provide an accessible and responsive service.
- Practice policies were in place and available.

Summary of findings

- The provider was responsive to our findings and made immediate changes where possible. For example, on the day of the inspection the provider removed asthma treatment from their website and service provision while they reviewed the prescribing protocol.

We identified regulations that were not being met.

The areas where the provider must make improvements are:

- Ensure that effective age verification processes are in place.
- Ensure that care and treatment is delivered in line with evidence based guidelines. For example, ensure that dosage instructions for patients are clearly highlighted on prescriptions and that health questionnaires follow national guidance.
- Consent was electronically recorded and required to access further services from PrivateDoc. However there were no risk assessments in place on declining treatment if the patient didn't consent to informing their GP.

- Ensure effective safeguarding processes are in place, including appropriate training for lead individuals.
- Ensure there is an effective programme in place for monitoring and supporting quality improvement.

The areas where the provider should make improvements are:

- Implement an effective process in place for the recording of safety alerts, for example those from the Medicines and Healthcare products Regulatory Agency (MHRA).
- Improve the recording of incidents and significant events.
- Maintain evidence of training for clinicians.

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 that this service was not providing safe care in accordance with the relevant regulations.

- There were systems in place to protect patient information and ensure records were stored securely.
- On registering with the service, patient identity was only verified by credit/debit card checks. Electoral roll identity checks were in the process of being introduced, but were not yet live at the time of our inspection.
- The service had a business contingency plan, to consider how the service would continue if there were any adverse events, such as IT failure or building damage.
- There was a policy in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. However, there was no summary to demonstrate that incidents or significant events were recorded as such, analysed for trends or that learning was shared with staff. We did see evidence that the provider had considered certain incidents and made changes in accordance with them but these were logged under different processes.
- The provider complied with the requirements of the duty of candour and encouraged a culture of openness and honesty.
- There were enough doctors to meet the demand of the service and appropriate recruitment checks for all staff were in place.
- The safeguarding lead had not received safeguarding training appropriate for their role but did have access to local authority information for adults if safeguarding referrals were necessary.
- Improvements were needed for the safety on the provider's prescribing; questionnaires that patients had to undertake were not in-depth enough or consistently followed national guidance. The provider was responsive to our findings and made immediate changes where possible. For example, on the day of the inspection the provider removed asthma treatment from their website and service provision while they reviewed the prescribing protocol. The provider also reviewed all other template questionnaires immediately after the inspection and told us they had amended their questionnaires to reflect NICE guidelines after our inspection.

Are services effective?

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

- There was clear information on the service's website with regards to how the service worked and what costs applied, including 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.
 - Consent to care and treatment was sought in line with the provider policy. Consent was electronically recorded and required to access further services from PrivateDoc. There were no risk assessments in place on declining treatment if the patient didn't consent to informing their GP. As a result information was not consistently shared with patients' GPs when required. All of the clinicians had received training about the Mental Capacity Act.
 - We found that assessments of patient needs and care was not consistently delivered in line with relevant and current evidence based guidance and standards, for example, National Institute for Health and Care Excellence (NICE) evidence based practice. We reviewed a sample of anonymised consultation records and found that requests for asthma inhalers were on a few occasions dealt with inappropriately and not always communicated to the patient's own GP.
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Summary of findings

- There was a formal programme in place for clinical audits or quality improvement to assess the service provision but we found that this needed more effective implementation. Audits of patient records were done on an adhoc basis only.
- The service's website contained information to help support patients lead healthier lives, and information on healthy living was provided in consultations as appropriate.
- 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.

Are services caring?

We found that this service was providing a caring service in accordance with the relevant regulations.

- Systems were in place to ensure all patient information was stored securely and kept confidential
- We did not speak to patients directly as part of the inspection but we did review survey information that the provider had undertaken themselves in July 2016. Ten patients responded and information showed, amongst other elements, that: 90% of patients were confident in the care provided by PrivateDoc and 70% 'agreed' or 'strongly agreed' that PrivateDoc kept them up to date with the progress of their prescription.
- Out of 183 TrustPilot reviews 99.5% of patients had rated the service four (5.5%) or five (94%) out of five stars, with only one patient rating the service two out of five stars.
- In anticipation of our inspection the provider had contacted all their patients via email to inform them of our inspection and whether they were prepared to provide any feedback based on their experiences; feedback received was positive.
- Patient information guides about how to use the service were available. There was a dedicated manager to respond to any enquiries and patients had access to information about the terms and conditions via the website.

Are services responsive to people's needs?

We found that this service was providing a responsive service 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 or e-mail. The provider's website was available 24 hours a day and the service operated between 9am and 5pm, Monday to Friday.
- The provider offered consultations to anyone who requested and paid the appropriate fee, and did not discriminate against any client group.
- The provider 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 service gathered feedback from patients though an online review website.
- There was a complaints policy which provided staff with information about handling formal and informal complaints from patients.

Are services well-led?

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

- The provider told us they had a clear vision to be a safe and secure online service.

Summary of findings

- During the inspection the provider of the service could demonstrate they had the experience, capacity and capability to run the service and ensure high quality care but we found several improvements were required. Although there were systems in place to support the dispensing process and recording of information was generally well organised, there was a lack of recognition of the impact of some risks on the risk register, clinical questionnaire templates and prescribing for asthma medication.
 - We found the provider to be extremely responsive to our findings with the full intention to rectify any issues and act on our findings with urgency.
 - There were governance arrangements in place to support processes in the organisation but we found several of these required improvement. For example, dosage instructions on medicines required more in-depth information and audits of patient notes were done on an adhoc basis only.
 - There was a business continuity plan to consider how the service would continue if there were any adverse events, such as IT failure.
 - Staff told us that clinical meetings were happening and we saw minutes confirming this.
 - There was a quality improvement plan in place to monitor quality and to make improvements, for example, through risk registers.
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PrivateDoc Limited

Detailed findings

Background to this inspection

PrivateDoc Limited offers a digital service providing patients with prescriptions for medicines that they can obtain from the affiliated registered pharmacy. We inspected the digital service at the following address: Unit 7, Wharfside House, Prentice Road, Stowmarket, Suffolk, IP14 1RD.

PrivateDoc Limited was originally established in 2012 to provide an online service that allows patients to request prescriptions through a website. Patients are able to register with the website, select a condition they would like treatment for and complete a consultation form. This form is then reviewed by a clinician and a prescription is issued if appropriate. The clinicians were sub-contracted. Once the consultation form has been reviewed and approved, a private prescription for the appropriate medicine is issued. This is sent to the affiliated pharmacy (which we do not regulate) for the medicines to be supplied. During 2016-17 the service processed approximately 2000 prescriptions for the treatment of 13 different conditions.

The service can be accessed through their website, www.privatedoc.com, where patients can place orders for medicines seven days a week. The service is available for patients in the UK only. Patients can access the service by phone or e-mail from 9am to 5pm, Monday to Friday. This is not an emergency service. Subscribers to the service pay for their consultation and medicines when making their on-line application.

A registered manager is in place. A registered manager is a person who is registered with the Care Quality Commission 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.

How we inspected this service

Our inspection team was led by a CQC Lead Inspector accompanied by a GP Specialist Advisor, a CQC Pharmacist Specialist and a second CQC inspector.

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

During our visit we:

- Spoke with a range of staff
- Reviewed organisational documents.
- Reviewed 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.

Why we inspected this service

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 care in accordance with the relevant regulations.

Safety and Security of Patient Information

Systems were in place to ensure that all patient information was stored and kept confidential. There were procedures in place, for the IT systems, to protect the storage and use of all patient information and to instruct staff working off site how to access patient information safely. The service could provide a clear audit trail of who had access to records and from where and when.

The service was registered with the Information Commissioner's Office.

The provider made it clear to patients what the limitations of the service were. The service was not intended for use as an emergency service. Alternatively they would re-direct patients to other care pathways as required.

The service did not treat children; however, there were no effective safeguards in place to ensure that patients were over 18 years of age. The registered manager who was the safeguarding lead, was trained to safeguarding level two, clinicians were trained to level three.

On registering with the service, and at each consultation, patient identity was only verified through debit/credit card checks. However, the provider had commenced the implementation of additional electoral checks prior to our inspection. This process was due to go live shortly after our inspection.

The doctors had access to the patient's previous orders held by the service and we saw that verbal conversations with patients were recorded in the patient records.

Prescribing safety

If medicine was deemed necessary following a consultation, a doctor was able to issue a private prescription to patients. The doctor could only prescribe from a set list of medicines. There were no controlled drugs on this list. Medicines prescribed to patients from online forms were monitored by the provider through ad-hoc reviews to ensure prescribing was evidence based, although we noted the process for following up these reviews was not fully embedded.

The service's website advertised treatment for asthma. The provider had identified the need to restrict the number of inhalers prescribed, the frequency, and the importance of getting patient's consent for their GP to be informed, but had not implemented the restrictions consistently. We saw a small number of incidences where prescribing was in excess of current guidance by a small number of inhalers. On the day of the inspection the provider removed asthma treatment from their website and service provision while they reviewed the prescribing protocol. The service did not prescribe medicines for use in an emergency.

Once the doctor prescribed the medicine, information was given to patients on the purpose of the medicine and any likely side effects and what they should do if they became unwell. However most prescriptions included the general instruction "take as directed" and did not give specific dosage instructions for patients. The provider had already identified this as an area of risk and for improvement. We saw that they had amended this for one medicine and assured us they would review all instructions.

The service offered Avodart capsules as a treatment for hair loss. Avodart is not licensed for this use. There was clear information on the website to explain that this medicine was being prescribed outside of their licenced use. (Medicines are given licences after trials have shown that they are safe and effective for treating a particular condition. Use for a different medical condition is called unlicensed use and is a higher risk because less information is available about the benefits and potential risks).

The provider did not prescribe antibiotic medicines.

The patient record system allowed the prescriber to view the complete patient history with the provider, allowing them to monitor prescribing and identify patients who may be requesting excessive quantities of medicines. However, correspondence with the patient and notes made by the prescriber were not visible to the prescriber as part of the patient record. This was addressed and the issue resolved during our visit.

Certain medicines were allowed to be repeatedly prescribed based on an assessment of risk. If patients wished to receive repeat medicines they had to confirm whether anything had changed. They also had to complete a new questionnaire every six months.

Are services safe?

Management and learning from safety incidents and alerts

There was a policy in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. However, there was no summary to demonstrate that incidents or significant events were recorded as such, analysed for trends or that learning was shared with staff. We did see evidence that the provider had considered certain incidents and made changes in accordance with them but these were logged under different processes. This included feedback from patients and system changes. Due to the recording means we were unable to confirm whether any incident had been fully investigated. The provider informed us during the inspection they would immediately adopt a new means of recording their incidents, in line with their policy. There was some assurance that significant events would have been highlighted due to the systems in place to seek continuous improvement.

The provider told us they held meetings quarterly where incidents and complaints were communicated and discussed with all staff. We saw minutes to demonstrate that these had been discussed and changes implemented had been communicated with all staff.

We asked how patient safety alerts were dealt with such as those issued by the Medicines and Healthcare products Regulatory Agency (MHRA), and were told that these were reviewed by sub-contracted prescribers. Prior to our inspection there were no records available to indicate that these had been actioned and there was no process within the organisation to review patients who may have been prescribed medicines which were the subject of these alerts. The provider immediately started maintaining records after our inspection and a process was put in place.

Safeguarding

Arrangements for safeguarding adults reflected relevant legislation and local requirements. There were no arrangements in place for safeguarding children. The provider explained that they treated patients aged over 18 only. From the arrangements in place it could not be assured that the service was taking a wider family approach and considered the needs of children around adults. The adult safeguarding policy outlined who to contact for further guidance if staff had concerns about a

patient's welfare. There was a lead member of staff for safeguarding but they were trained to level two only. However, the lack of thorough identity checking did not ensure patients would be safeguarded from abuse or harm.

The provider told us that as they do not routinely have the patient's GP details it could be problematic if there were safeguarding concerns and further contact was required.

We saw minutes of meetings that contained information on prescriptions that had been issued, including the number of prescriptions and flags for concerns. Safeguarding concerns were also discussed.

Staffing and Recruitment

At the time of our inspection, there was enough staff, including clinicians, to meet the demands for the service.

The provider had a selection process in place for the recruitment of all staff. Required recruitment checks were carried out for all staff prior to commencing employment. There was a system to check on a monthly basis whether doctors, who were all sub-contracted, were registered with the General Medical Council (GMC). All candidates were on the GMC register and were up to date with their appraisal. Those clinical candidates that met the specifications of the service then had to provide documents including their medical indemnity insurance.

We reviewed two non-clinical recruitment files which showed the necessary documentation was available. The provider kept records for all staff including the doctors. However, the provider informed us they did not keep evidence of training for the clinicians but had reviewed it.

The providers had a process for Disclosure and Barring Service (DBS) checks. (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). This detailed that DBS checks were undertaken quarterly and we saw evidence of records being kept of these checks.

Monitoring health & safety and responding to risks

A reviewing clinician was able to see electronic and verbal correspondence with patients and there was a system for clinicians to carry out checks on approved consultations and prescriptions to ensure they were appropriate. This took place on an ad-hoc basis. However, we found that the consultation reviews which highlighted the need for action

Are services safe?

by the prescriber had not yet been reported and acted on. None of them required urgent action, however the provider explained that they would ensure a more thorough and regular review process.

Clinicians carried out the online consultations remotely. Staff on the premises had received in house induction in health and safety including fire safety.

The provider expected that all clinicians would conduct consultations in private and maintain the patient's confidentiality. Each clinician could log in remotely into the operating system, which was secure.

Are services effective?

(for example, treatment is effective)

Our findings

We found that this service was not providing effective care 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 what costs applied, including 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.

Staff understood and sought patients' consent to care and treatment in line with legislation and guidance. All staff had received training about the Mental Capacity Act 2005. The provider had a protocol in place to assist in assessing capacity and consent for the digital service but there were no means of highlighting vulnerable people on the system. Staff told us they could only assess mental capacity based on the information provided on the consultation forms.

Consent was electronically recorded and required to access further services from PrivateDoc. There were no risk assessments in place on declining treatment if the patient didn't consent to informing their GP. We saw a number of records of patient consultations where consent to sharing information was not recorded.

Assessment and treatment

We reviewed 24 examples of medical records and found that care was not always delivered in line with relevant and current evidence based guidance and standards, including National Institute for Health and Care Excellence (NICE) best practice guidelines. For example, requests for asthma inhalers were on a few occasions dealt with inappropriately and not always communicated to the patient's own GP.

Patients completed an online form about their general health and about the specific condition they were requesting treatment for. These did include their past medical history, symptoms and any medication they were currently taking. However, these were not detailed enough to provide us with assurances that a complete assessment could be undertaken. The service responded immediately on the day of the inspection by removing the option for patients to request asthma medicines. They assured us that all other questionnaires would be reviewed and amended within two weeks of the inspection. We have

since had sight of these and found some of the revised questionnaires to be of an improved standard but required further improvement to ensure they take effective account of national guidance. For example, in the indigestion questionnaire there was no attempt to exclude other important conditions that can present with indigestion symptoms (e.g. pancreatic cancer or angina) and the weight loss questionnaire didn't include a mechanism to verify the weight/BMI. The provider told us they amended their questionnaires further to reflect NICE guidelines after this inspection.

There was a set template to complete for the consultation that included the reasons for the consultation and the outcome to be manually recorded. We reviewed 24 medical records which were consistently completed and, other than on one occasion, had adequate notes recorded.

The doctors providing the service were aware of the strengths (speed, convenience, choice of time) and the limitations (inability to perform physical examination, lack of access to medical records, inability to ensure the patient is who they say they are) of working remotely from patients. However, when we spoke with one of the doctors providing the consultations we could not be reassured of their awareness in patients being dishonest or at risk of abuse of exploitation.

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.

Management, monitoring and improving outcomes for people

The service monitored consultations, and carried out prescribing audits and reviews of patient records to improve patient outcomes. This was done on an ad-hoc basis. There was a formal programme in place for clinical audits for quality improvement to assess the service provision but we found this to be on an ad-hoc basis only. The service explained that they would instigate regularity to this immediately after the inspection.

We saw minutes of meetings that contained information on prescriptions that had been issued, including the number of prescriptions and flags for concerns.

Coordinating patient care and information sharing

When a patient contacted the service they were asked if the details of their consultation could be shared with their

Are services effective?

(for example, treatment is effective)

registered GP. The provider requested information from the patient about their GP when they registered to join the service. Every contact with the patient recommended informing the GP. However, the provider would continue to issue prescriptions if a patient did not consent to GP contact. The provider did not risk assess when it would be appropriate to decline providing treatment in the absence of consent to share this information with the patient's GP. This is not in accordance with the GMC evidence based guidance in relation to remote prescribing.

Supporting patients to live healthier lives

The service identified patients who may be in need of extra support and had a range of information available on the website. For example, the provider had information and frequently asked questions on their website for a range of advice related to the range of conditions they prescribed for, such as smoking cessation, sexual health and weight management. The provider also had an advice system set

up on their website that enabled patients to obtain advice anonymously for sensitive issues. This included seeking advice from the affiliated pharmacist if the patients so wished.

The time taken for patients to complete a questionnaire was recorded and if this was undertaken in a time frame the provider considered too quick a box was shown querying "Are you sure you have read all the questions?".

Staff training

Staff had completed an induction process, which amongst others, included fire safety. Administration staff received annual performance reviews. All the clinicians had to have received their own appraisals and have up to date registrations with the General Medical Council (GMC) before being considered eligible at recruitment stage. There were systems in place to monitor when staff were due to have their appraisal. GMC status of clinicians was checked on a monthly basis and we saw records to evidence this.

Are services caring?

Our findings

We found that this service was providing a caring service in accordance with the relevant regulations.

Compassion, dignity and respect

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

The provider undertook random spot checks to ensure the GPs were complying with the expected service standards and communicating appropriately with patients. We saw that the manager of the service provided regular communication with patients and actively sought feedback on the service they provided.

We did not speak to patients directly as part of the inspection but we did review survey information that the provider had undertaken themselves in July 2016. Ten patients responded and information showed, amongst other elements, that: 90% of patients were confident in the care provided by PrivateDoc and 70% 'agreed' or 'strongly agreed' that PrivateDoc kept them up to date with the progress of their prescription.

We saw that patients had the opportunity to rate the service on an online system called "Trustpilot"; which is an open system provided by a third party supplier. Out of 183 reviews 99.5% of patients had rated the service four (5.5%) or five (94%) out of five stars, with only one patient rating the service two out of five stars.

In anticipation of our inspection the provider had contacted all their patients via email to inform them of our

inspection and whether they were prepared to provide any feedback based on their experiences. Some of the feedback produced as a result included the following comment: 'I have found the whole process from consultation to delivery very quick and the staff are always very courteous and helpful'.

Involvement in decisions about care and treatment

Patient information guides about how to use the service were available. There was a dedicated manager to respond to any enquiries and patients had access to information about the terms and conditions via the website.

Information on the provider's website informed patients about each medicine that was on offer and what it was intended for. Pricing for medicines was clearly displayed on the website.

Patients could not book a consultation with a doctor of their choice as there was only doctor sub-contracted to undertake consultations at the time of our inspection. Patients were informed which doctor had reviewed their information, with a GMC number available. After the inspection the provider informed us they had recruited two more doctors. At the time of inspection consultations were offered in English only, however, the provider told us that they were upgrading the system to allow other languages.

The provider's 2016 survey information indicated that 70% of patients 'agreed' or 'strongly agreed' that there was sufficient information on the website regarding conditions and treatment options.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was providing a responsive service in accordance with the relevant regulations.

Responding to and meeting patients' needs

The service can be accessed through the provider's website, www.private-doc.com, where patients can place orders for medicines seven days a week. The service is available for patients in the UK only. Patients can also access the service by phone or e-mail from 9am to 5pm, Monday to Friday. This service was not an emergency service. Patients who had a medical emergency were advised to ask for immediate medical help via 999 or if appropriate to contact their own GP or NHS 111.

Patients selected the condition they required treatment for, filled in a consultation form and paid for the cost of the medicines and the consultation. The consultation form was then reviewed by a clinician, and once approved, a prescription was issued to the affiliated pharmacy. We were informed that when required, the clinician would contact patients for further information before approving the consultation form. These contacts were recorded and stored separately from the patient's notes. The provider changed this on the day of the inspection to enable all practitioners to view the complete record patient communications.

Any prescriptions issued were delivered within the UK to an address of the patient's choice. During 2016-17 the service processed approximately 2000 prescriptions for the treatment of 13 different conditions.

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.

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.

Managing complaints

Information about how to make a complaint was available on the service's web site. The provider had developed a complaints policy and procedure. The policy contained appropriate timescales for dealing with the complaint. There was escalation guidance within the policy. A database for the recording of complaints had been developed and was in use.

We reviewed the complaint system and noted that complaints made to the service had been recorded. Where appropriate we saw evidence that complaints had driven a change in the service delivery. For example, changes in packaging and the ability for patients to track their prescription deliveries. The provider maintained records of the complaints to assess these for trends.

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 'be the safest, most secure, most trusted online clinic in the UK, renowned for putting the patient first and being a responsible stakeholder within the healthcare industry'.

The provider had a draft business plan in place that outlined the overview, strategic objectives and financial investment for 2017. They informed us that this would be updated and finalised after the inspection to incorporate any improvements they may need to make.

The provider also had a continuous improvement plan in place which highlighted intended improvements to the service. For example, improving the way patients were checked for identification and completing a full review of current clinical guidelines. The improvement plan was supported by risk registers for each condition that the provider prescribed for, however, we found that progress in addressing the risks in the registers was slow. For example, the lack of dosage directions had been raised in April 2017 and had a planned completion for October 2017. At our inspection we found this had not yet been addressed.

There was a business continuity plan to consider how the service would continue if there were any adverse events, such as IT failure. The provider had ensured arrangements were in place to store patient information for the appropriate timescale should the business cease to operate. In the case of patient data being compromised due to a business continuity related incident the provider had an effective system in place to ensure patient data would not be compromised longer than 15 minutes.

There was a clear organisational structure and staff were aware of their own roles and responsibilities. There was a range of service specific policies which were available to all staff. These were reviewed regularly and updated when necessary.

There were effective systems in place to monitor the performance of the service, including random spot checks for consultations. We saw minutes of meetings and

standing agenda items that indicated that various elements of business information were discussed at monthly meetings. This included risks and flags for concerns. Safeguarding concerns were also discussed.

Care and treatment records were complete, legible and accurate, and systems were in place to ensure they were securely kept.

Leadership, values and culture

During the inspection the provider of the service could demonstrate they had the experience, capacity and capability to run the service and ensure high quality care but we found several improvements were required. There was a lack of recognition of the impact of some risks on the risk register and the level of adherence to national guidance for care and treatment required improvement. We found the provider to be extremely responsive to our findings with the full intention to rectify any issues and act on our findings with urgency. For example, when we raised concerns about the prescribing processes for asthma medication the provider immediately withdrew the service from its provision and website until they could be confident that they were prescribing safely and in line with national guidance.

There were arrangements in place for a second doctor to cover absences and leave. The registered manager was on site during the service opening times to support staff should any issues arise.

The service told us they 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. This was supported by an operational policy. We saw evidence of correspondence with patients where the provider had made changes to processes based on their comments or complaints. For example, changes in packaging.

Safety and Security of Patient Information

There were policies, agreements and effective procedures in place, for the IT systems, to protect the storage and use of all patient information and to instruct staff working off site how to access patient information safely. The service could provide a clear audit trail of who had access to

Are services well-led?

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

records and from where and when. There were robust contingency plans in place to minimise the risk of losing patient data. The service was registered with the Information Commissioner's Office.

Seeking and acting on feedback from patients and staff

Patients had the opportunity to rate the service on an online system called "Trustpilot" which was an open system provided by a third party supplier. At the end of every consultation, patients were sent an email asking for their feedback.

Patients could also contact the service directly to ask questions or raise a concern and the contact details was clearly displayed on the website. Live chat was also available on the website.

In anticipation of our inspection the provider had contacted all their patients via email to inform them of our inspection and whether they were prepared to provide any feedback based on their experiences; a small amount of feedback was received and was positive.

The provider had a whistleblowing policy in place. A whistleblower is someone who can raise concerns about practice or staff within the organisation.

Continuous Improvement

The service was actively seeking ways to improve from complaints and day to day operations. All staff were involved in discussions about how to run and develop the service, and were encouraged to identify opportunities to improve the service delivered. Minutes were available to show improvements were discussed.

There was a quality improvement plan in place to monitor quality and to make improvements, for example, through risk registers. Although progress was slow on certain risks we saw that the provider took a proactive approach to wanting to develop their service. This was also reflected in the amendments the provider made during and shortly after the inspection, based on our findings.

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

Treatment of disease, disorder or injury

Regulation

Regulation 11 HSCA (RA) Regulations 2014 Need for consent

The provider did not consistently risk assess when it would be appropriate to decline providing treatment in the absence of consent to share this information with the patient's GP. The provider must ensure that consent is recorded consistently and information shared with patients' GPs if required.

Regulated activity

Treatment of disease, disorder or injury

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

Medicines prescribed to patients from online forms were monitored by the provider through ad-hoc reviews to ensure prescribing was evidence based, although we noted the process for following up these reviews was not fully embedded. The provider needs to ensure a consistent review and audit process is in place.

The safeguarding lead in the service was trained to level two. The provider needs to ensure training for safeguarding leads is in line with national guidance.

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
Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Age and identity checks were undertaken through credit/debit card checks only. This system of identity verification had not been risk assessed.</p> <p>Most prescriptions included the general instruction “take as directed” and did not give specific dosage instructions for patients.</p> <p>Care and treatment was not consistently delivered in line with relevant and current evidence based guidance and standards. Online consultation questionnaire templates that patients had to undertake in order to be prescribed medication based on the questionnaires’ answers, were not fully compliant with relevant and current evidence based guidance and standards.</p> <p>Safety alerts such as those issued by the Medicines and Healthcare products Regulatory Agency (MHRA) were reviewed by sub-contracted prescribers. There were no records available to indicate that these had been actioned and there was no process within the organisation to review patients who may have been prescribed medicines which were the subject of these alerts.</p>