

Pharmacy2U Limited

Pharmacy2U Limited

Inspection report

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Overall summary

Letter from the Chief Inspector of General Practice

We previously inspected Pharmacy2U Limited on 14 February 2017. At that time the service was found not to be meeting some areas of the regulations relating to safe, effective or well-led services. The full comprehensive report for that inspection can be found by selecting the 'all reports' link for location name on our website at www.cqc.org.uk.

On 18 December 2017, we carried out an announced comprehensive inspection at Pharmacy2U Limited, 1 Hawthorn Park, Coal Road, Leeds, West Yorkshire LS14 1PQ, to check that the service was now meeting all the regulations.

Pharmacy2U Limited provides online doctor consultation, treatment and prescribing services relating to a range of medical conditions. Details of the services provided can be accessed via their website www.pharmacy2u.co.uk/onlinedoctor. Pharmacy2U Limited also offers pharmacy and NHS prescription services which are not regulated by the Care Quality Commission.

Our findings in relation to the key questions were as follows:

Are services safe?

We found the service was providing a safe service in accordance with the regulations. Specifically:

- Arrangements were in place to safeguard people, including arrangements to check patient identity.
- Prescribing was in line with national guidance, and people were told about the potential risks associated with any medicines used off-label or outside of their licence.
- Suitable numbers of staff were employed and appropriately recruited.
- Risks were assessed and action taken to mitigate any risks identified.

Are services effective?

We found the service was providing an effective service in accordance with the regulations. Specifically:

- Following patient consultations information was appropriately shared with a patient's own GP in line with consent and GMC guidance.
- Quality improvement activity, including clinical audit, took place.
- Staff received the appropriate training to carry out their role.

Are services caring?

We found the service was providing a caring service in accordance with the regulations. Specifically:

Summary of findings

- The provider carried out checks to ensure consultations by GPs met the expected service standards.
- At the end of every consultation patients were asked for their feedback via email.
- The provider used an online external customer satisfaction service to monitor and react to patient feedback.

Are services responsive?

We found the service was providing a responsive service in accordance with the regulations. Specifically:

- Information about how to access the service was clear and the service was available seven days a week via the provider website.

- The provider did not discriminate against any client group.
- Information about how to complain was available and complaints were handled appropriately.

Are services well-led?

We found the service was providing a well-led service in accordance with the regulations. Specifically:

- The service had clear leadership and governance structures
- A range of information was used to monitor and improve the quality and performance of the service.
- Patient information was held securely.

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 the service was providing a safe service in accordance with the regulations.

Are services effective?

We found the service was providing an effective service in accordance with the regulations.

Are services caring?

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

Are services responsive to people's needs?

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

Are services well-led?

We found the service was providing a well-led service in accordance with the regulations.

Pharmacy2U Limited

Detailed findings

Background to this inspection

Pharmacy2U Limited is the provider of Pharmacy2U Limited online doctor service. The provider also has a pharmacy and NHS prescription services which are not regulated by the Care Quality Commission (CQC).

Online consultation, treatment and prescribing services for a range of medical conditions are available for patients who reside in the United Kingdom. All online patient consultations are with a General Medical Council (GMC) registered doctor. The service does not treat patients under the age of 18.

The online doctor service consists of two male GPs and a female GP, who are all registered with the General Medical Council (GMC). The doctors are contracted to undertake remote consultations by reviewing completed medical questionnaires and patients' request for treatment.

There is a small team of customer services/administration staff who support the Pharmacy2U Limited online doctor service.

We carried out an announced inspection of this service on 18 December 2017. We visited their head office based in Leeds and spoke with a range of staff employed by the

provider in relation to the online doctor service. We looked at policies, records and other documentation that was maintained in relation to the provision of the service. We also reviewed patient feedback which had been submitted to the Care Quality Commission.

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.

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

At the previous inspection on 14 February 2017, we found the service was not providing safe services in accordance with the relevant regulations. Specifically, the safeguarding policy did not include details of local authorities to escalate concerns to; there was no documented protocol in place for checking patients' identity; patients' NHS GP information was not always available should they need to be contacted in an emergency.

During this inspection we found the service had addressed the previously identified issues. We now found them to be providing safe services in accordance with the relevant regulations.

Keeping people safe and safeguarded from abuse

All staff had received training in safeguarding and whistleblowing and knew how to recognise and act on signs of abuse. They had access to organisational safeguarding policies which contained details of how to escalate concerns. Staff had access to a safeguarding app and website links for all relevant safeguarding authorities, appropriate to where the patient resided. The availability of the app ensured that information was up to date on a continuous basis.

All the GPs had received adult and level three child safeguarding training. It was a requirement for the GPs employed by the service to provide evidence of up to date safeguarding training certification. The service did not provide consultations or treatment to patients who were under the age of 18. Since the previous inspection the provider had reviewed their process of patient identity checks. They had procured the services of an external agency (whose primary function is to support person identification systems) and had put in place a comprehensive three tier identification process and a written protocol. We were informed that the provider was continually looking at what, if any, improvements could be made to the patient identity check system.

Monitoring health & safety and responding to risks

The provider headquarters were located within offices which housed the IT system and a range of administration

staff. Patients were not treated on the premises as GPs carried out the online consultations remotely; usually from their own home. All staff based in the premises had received training in health and safety including fire safety.

The provider expected that all GPs would conduct consultations in private and maintain the patient's confidentiality. Each GP used an encrypted, password secure laptop to log into the operating system, which was a secure programme. GPs were required to complete a home working risk assessment to ensure their working environment was safe.

All clinical consultations were rated by the GPs for risk. For example, if the GP assessed there may be serious mental or physical issues that required further attention. Consultation records could not be completed without a risk rating. Those rated at a higher risk or immediate risk were reviewed and discussed at clinical meetings. There were protocols in place to notify Public Health England of any patients who had a notifiable infectious disease.

There were processes in place to manage any emerging medical issues during a consultation and for managing test results and referrals. The service was not intended for use by patients with either long term conditions or as an emergency service. In the event an emergency did occur, the provider had systems in place to ensure that, at the beginning of the consultation, the telephone number and location details of the patient were known, so emergency services could be directed appropriately. The service's medical emergency protocol stipulated that any patient who needed emergency services was followed up and the incident identified as a significant event to be discussed at a clinical meeting.

A range of clinical and non-clinical meetings were held with staff, where standing agenda items covered topics such as significant events, adherence to expected standards and service issues and performance. Clinical meetings also included case reviews and clinical updates. We saw evidence of meeting minutes to show where some of these topics had been discussed, for example improvements to the consent policy, a significant incident and updating clinical pathways in line with national guidance.

Staffing and Recruitment

Are services safe?

There were enough staff, including GPs, to meet the demands for the service and there was a rota system in place for the GPs. There were support and IT teams available to the GPs during consultations.

The provider had a comprehensive recruitment and selection process in place for all staff. All doctors were required to be currently working in the NHS and be registered with the General Medical Council (GMC). Evidence of professional indemnity cover (to include cover for video consultations), an up to date appraisal and certificates relating to their qualifications and training in safeguarding and the Mental Capacity Act, were also mandatory requirements for employment with the provider.

There were a number of checks that were required to be undertaken prior to commencing employment, such as references and 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.) The GPs could not be registered to undertake any consultations until these checks and induction training had been completed.

Newly recruited GPs were supported during their induction period and an induction plan was in place to ensure all processes had been covered. We were told that GPs did not start consulting with patients until they had successfully completed several test scenario consultations.

We reviewed two recruitment files which showed the necessary documentation was available. The provider kept records for all staff including the GPs and there was a system in place that flagged up when any documentation was due for renewal such as their professional registration. The recruitment policy also included details of the process to be undertaken for any staff leaving employment. This included an exit interview to be conducted by a member of the Human Resources (HR) department.

Prescribing safety

There were protocols for each condition the service provided treated for; which clearly set out the inclusion and exclusion criteria and treatment options which could be prescribed. All medicines prescribed to patients from online questionnaire forms were monitored by the provider to ensure prescribing was evidence based.

If a medicine was deemed necessary following a consultation, the GPs were able to issue a private prescription to patients. The GPs could only prescribe from a set list of medicines which the provider had risk-assessed. Once the GP prescribed the medicine and dosage of choice, relevant instructions were given to the patient regarding when and how to take the medicine, the purpose of the medicine and any likely side effects and what they should do if they became unwell. Any requests for repeat prescriptions were reviewed and authorised, as appropriate, by a GP. Any changes from the initial consultation would also be reviewed before requests would be either approved or denied. There were control processes in place regarding those medicines that were at a higher risk of potential misuse or abuse, or which should not be used for anything other than the short term due to medical reasons.

Prescriptions for medicines relating to long term conditions such as diabetes, chronic obstructive pulmonary disease and heart failure were not available through the online doctor service. These patients were advised to see their own NHS GP. Prescriptions for antibiotics were only given for a narrow range of conditions and were provided in line with national guidance. We were informed that the service did not issue prescriptions for controlled drugs. The provider had introduced a policy where treatment for asthma would only be provided if the patient had disclosed their GP details and given consent for this information to be shared.

The GPs were able to prescribe some unlicensed medicines, and medicines for unlicensed indications, such as treatment for hair loss. (Medicines are given licences after trials have shown they are safe and effective for treating a particular condition. Use of a medicine for a different medical condition that is listed on their licence is called unlicensed use and is a higher risk because less information is available about the benefits and potential risks.) In addition to written information which was supplied with the medicine, patients were given clear information to explain that the medicines were being used outside of their licence, and the patient had to acknowledge that they understood this information. An email was also sent to the patient following their consultation, advising them of the specific nature of the unlicensed use.

Are services safe?

A pharmacist was employed who checked the suitability of each treatment and reviewed patients' prescription history to ensure excessive quantities of medicines were not being prescribed. We were informed that some medicines had been removed from their formulary due to a risk analysis. For example, hormone replacement therapy (HRT) and non-steroidal anti-inflammatory drugs (NSAIDS). Prescriptions were dispensed by the provider's pharmacy service.

Since the previous inspection, the provider had reviewed and changed their patient identification and verification protocols to ensure they were in line with General Medical Council guidance. A regular audit of records was undertaken to ensure that guidelines were being followed.

Information to deliver safe care and treatment

On registering with the service, and at each consultation patient identity was verified and the GPs had access to the patient's previous records held by the service.

At the previous inspection it had been noted that there were some deficits relating to the consent policy, particularly in relation to mental capacity. As a result, the policy had been revised to reflect national guidance and the British Medical Association's advice relating to capacity

and consent. Records we reviewed could evidence those revisions had been put into practice. Clinicians also had access to an online General Medical Council interactive tool to support decision making where there were possible concerns regarding a patient's capacity and consent.

Management and learning from safety incidents and alerts

There were systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. We were informed that there had been no significantly adverse incidents since the previous inspection. However, the provider was aware of the requirements of the Duty of Candour to explain to patients what went wrong, offer an apology and advise them of any action that had been taken.

There were systems in place to receive, record, discuss and take action regarding any safety alerts. We reviewed a sample of the most recent alerts and found that the processes had been followed. We saw evidence where alerts and any identified changes that had been made were discussed at meetings. The pharmacist had oversight of all safety alerts relating to medicines.

Are services effective?

(for example, treatment is effective)

Our findings

At the previous inspection on 14 February 2017, we found the service was not providing effective services in accordance with the relevant regulations. Specifically, medical questionnaires did not reflect current evidence based guidance and a low percentage of patients were having their NHS GP details recorded.

During this inspection we found the service had addressed the previously identified issues. We now found them to be providing effective services in accordance with the relevant regulations.

Assessment and treatment

Patients completed an online questionnaire which included their past medical history. There was a set template to complete for the consultation that included the reasons for the consultation and the outcome to be manually recorded, along with any notes about past medical history and diagnosis.

Since the previous inspection, the provider had reviewed all their medical questionnaires to ensure they were in line with national and evidence based guidance. The service provided treatment for 35 different conditions which ranged from cystitis to jet lag. We reviewed the majority of the questionnaires, which included those relating to asthma, migraine and hair loss, and found they reflected the appropriate guidance.

We reviewed a sample of 25 medical records that demonstrated each patient had been assessed appropriately. We saw that care and treatment had been delivered in line with relevant and current evidence based guidance and standards, including National Institute for Health and Care Excellence (NICE) evidence based practice. GPs had access to all notes held by the provider if a patient had previously used the service.

The GPs providing the service were aware of both the strengths (speed, convenience, choice of time) and the limitations (inability to perform physical examination) of working remotely from patients. If a patient needed further examination they were directed to an appropriate agency, for example their NHS GP. If the provider could not deal with the patient's request, this was explained to the patient and a record kept of the decision.

The service had adopted a process of external peer review of clinical decision making and record keeping. Medical questionnaires and treatment pathways were reviewed in line with updated guidance. We saw that consultation and prescribing audits were carried out to improve patient outcomes.

Quality improvement

The service collected and monitored information on people's care and treatment outcomes.

- We saw evidence where national guidance was discussed at clinical meetings.
- The service used information about patients' outcomes to make improvements.
- The service took part in quality improvement activity, which included a programme of clinical audit. We reviewed two audits; one related to the treatment of a specific sexually transmitted disease and the other audit related to the treatment of genital warts. Both of these audits evidenced patients were being treated in line with clinical guidance.

Staff training

All staff had to complete induction training which consisted of an overview of the service, the policies and procedures in place and where to access them. Training relating to information governance, data security, safeguarding and health and safety was also provided. An induction log was held in each staff file and signed off when completed.

Staff had to complete training on an ongoing basis, such as in safeguarding and mental capacity, in line with the requirements of the service. We saw evidence of a training matrix which identified when training was due. Administration staff received annual performance reviews and monthly one to ones with their supervisor. Staff informed us they felt well supported and were kept up to date with relevant issues within the service. We saw minutes from meetings to support what staff told us.

Supporting material was available, for example, a GPs' handbook, how the IT system worked and aims of the consultation process. The GPs told us they received excellent support if there were any technical issues or clinical queries and could access policies. When updates were made to the IT systems, the GPs received further

Are services effective?

(for example, treatment is effective)

online training. Since the previous inspection the service had introduced an internal appraisal system for the GPs. This was in addition to the external appraisal system the GPs accessed.

Coordinating patient care and information sharing

At the previous inspection it had been identified that only 9% of patients' NHS GP details had been recorded. As a result, the service had proactively discussed with patients the possibility of obtaining details and gaining consent to share information with their respective GPs. In addition, it had been identified their own electronic system had hindered patients inputting details of their GPs. This had now been rectified to allow the patient to either pick their GP from a list or to input details manually. At the time of this inspection we saw evidence to support they had increased the percentage to almost 50%.

With a patient's consent, a letter was sent to their GP advising them of treatment provided. This was in line with GMC guidance. We were informed that in some instances,

when a patient did not agree to provide their GP's details and consent to share information, prescribed treatment would not be provided. The provider had used a risk assessment tool to identify those conditions where it was imperative the GP was informed of the treatment prescribed, for example asthma.

The service monitored the appropriateness of referrals or follow-ups from test results to improve patient outcomes. Patients were contacted to discuss results and, with the patient's consent, their respective NHS GP was informed by letter.

Supporting patients to live healthier lives

The service identified patients who may be in need of extra support in maintaining a healthy lifestyle, disease prevention or those wanting general health advice. Information was available on a range of conditions, such as hay fever, eczema, travel health and smoking cessation. In their consultation records we found patients were given advice on healthy living as appropriate.

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

We were told that the GPs undertook consultations in a private room and were not to be disturbed at any time during their working time. The provider carried out random spot checks to ensure the GPs were complying with the expected service standards and communicating appropriately with patients. Feedback arising from these spot checks was relayed to the GP. Any areas for concern were followed up and the GP was again reviewed to monitor improvement.

We did not speak to patients directly on the days of the inspection. However, we reviewed the latest patient survey information. At the end of every consultation, patients were sent an email asking for their feedback. Prior to this inspection, the service had asked patients if they could feedback any comments to the CQC via the 'share your experience' form. There had been 40 which were overwhelmingly positive about how they were treated by staff at the service.

Patients were also recommended to rate the service via Trustpilot. We saw that out of 38,772 reviews, 93% were satisfied with the service and an overall score of four out of five stars was recorded.

Involvement in decisions about care and treatment

Patients did not book a consultation or have the option of choosing to have their questionnaire reviewed by a particular clinician. However, the patient was informed of the name and GMC number of the GP who had reviewed their questionnaire. There was also additional information about the qualifications and experience of the GPs, which patients could access via the provider's website.

Through discussion, a treatment path was agreed between the GP and patient. Patients were given the opportunity to indicate which treatment they would prefer. This allowed a treatment to continue which may have been initiated elsewhere; provided the treatment was authorised by the prescriber.

Patients had access to their records via a patient portal, using their own log in details and password they created when registering with the service. Patients' feedback through various sources, was generally positive with regard to being satisfied with information they received and their involvement in decisions about their care and treatment.

Patient information guides about how to use the service and technical issues were available via the provider's website. There was a dedicated team to respond to any enquiries. However, this team did not provide any clinical advice.

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

Patients were able to use the website and submit their online questionnaires 24 hours a day, seven days a week. However, the website made it clear the questionnaire would be reviewed by a GP "usually within 24 hours". The provider had employed an additional GP to ensure they could meet this target.

The digital application allowed people to contact the service from abroad but all medical practitioners were required to be based within the United Kingdom. Any prescriptions issued were checked by a pharmacist employed within the provider's pharmacy service. Medicines were sent to the patient's chosen delivery address within the UK and were not sent overseas.

The provider made it clear to patients what the limitations of the service were. For example, it was not an emergency service. Patients who had a medical emergency were advised to seek for immediate medical help via 999 or, if appropriate, to contact their own GP or NHS 111.

Tackling inequity and promoting equality

Patients could access the service through the provider's website. Consultations were available for anyone aged 18 and over who requested the service, paid the appropriate fee and had a UK postal address.

Managing complaints

Information about how to make a complaint was available on the provider's website. 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 specific form for the recording of complaints has been developed and introduced for use.

We reviewed the complaint system and noted that all comments and complaints made to the provider were recorded. We discussed the complaints the service had

received directly and saw that they had been identified and grouped into specific areas, such as what they related to, the channel they had been received through, what changes had been made and whether the complaint had been resolved. We also discussed the complaints that had been received by CQC in the preceding 12 months.

The provider was able to demonstrate that the complaints were handled correctly and in line with their policy. There was evidence of learning as a result of complaints, changes to the service had been made following complaints, and these had been communicated to staff. For example, a patient had complained the website was not clear on the information provided about delivery timescales. This had been discussed with the IT team and the website altered accordingly.

Consent to care and treatment

There was clear information on the service's website with regards to how the service worked, 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.

Patients could find the cost of the consultation and treatment in advance via the website. This was done by selecting the condition from a drop down menu and then selecting the name of the treatment being requested. The total pricing for the consultation and treatment combined was then displayed. There was also a link to start the consultation questionnaire.

Staff understood and sought patients' consent to care and treatment in line with legislation and taking into account guidance. The process for seeking consent was monitored through audits of patient records.

All GPs/staff had received training about the Mental Capacity Act 2005. Staff understood and sought patients' consent to care and treatment in line with legislation and guidance. Where a patient's mental capacity to consent to care or treatment was unclear the GP assessed the patient's capacity and, recorded the outcome of the assessment.

Are services well-led?

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

Our findings

At the previous inspection on 14 February 2017, we found the service was not providing well-led services in accordance with the relevant regulations. Since the previous inspection, the provider had reviewed the areas of concern raised. They had developed a clear action plan and could now evidence all the improvements they had made.

During this inspection we found the service had addressed all the previously identified issues. We now found them to be providing well-led services in accordance with the relevant regulations.

Business Strategy and Governance arrangements

The provider told us they had a clear vision to work together to provide a high quality responsive service that put caring and patient safety at its heart.

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 and updated when necessary, to reflect any service changes or new national guidance.

There were a variety of regular checks in place to monitor the performance of the service. These included an “all heads of service” monthly meeting where performance and quality were reviewed and discussed. The information from these checks was used to produce reports which were discussed at weekly team meetings. This ensured a comprehensive understanding of the performance of the service was maintained. We looked at minutes from recent meetings and saw there were regular agenda items, such as significant events, clinical updates and service issues.

There were arrangements for identifying, recording and managing risks, issues and implementing mitigating actions.

We saw that care and treatment records were complete, accurate, and securely kept.

Leadership, values and culture

There was a senior management team in place, which consisted of a Chief Pharmaceutical Officer, Clinical Pharmacist and Medical Director; who was also the

Registered Manager. There were also two GPs; one of whom had been recruited since the previous inspection. Staff told us they felt informed and included in the development of the service and valued by the management team.

The values of the service were articulated in a poster which was displayed in most areas of the provider’s operating centre. Staff were aware of these values and how they contributed to the overall performance of the organisation.

Staff informed us there was an open and transparent culture in the service. 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.

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. The service was registered with the Information Commissioner’s Office. There was a business contingency plan 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. This was constantly monitored and if it fell below the provider’s standards, this would trigger a review of the consultation to address any shortfalls.

Patients were emailed at the end of each consultation with a link to a survey they could complete. This included questions such as how easy they found the website to use; satisfaction with the time it took for the doctor to review a consultation; did they have confidence and trust in the doctor treating them. Patients were also emailed two weeks after their initial consultation to check on their progress and any issues they may have encountered.

Patient comments and feedback were available on the service’s website, including a link to Trustpilot where patients could also provide comments. The provider used these comments and patient feedback to drive

Are services well-led?

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

improvements in service delivery. For example, some patients had commented on the length of time it took to upload any test results. As a result this had been identified as an action for the IT team; which they had completed.

The provider had a staff suggestion scheme and staff were encouraged to use this or to suggest agenda items for team meetings. Staff we spoke with said they felt comfortable raising issues with any of the management team. The GPs were able to provide feedback about the quality of the operating system and any change requests were logged, discussed and decisions made for the improvements to be implemented

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 management team had an ethos of continuous improvement. They told us they were beginning to establish networks with organisations, such as the National Association of Patient Participation (NAPP).