

White Pharmacy Ltd

# White Pharmacy Ltd

## Inspection report

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### Overall summary

#### Letter from the Chief Inspector of General Practice

We carried out an announced comprehensive inspection at White Pharmacy Ltd on 12 and 16 January 2017.

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

Our key findings across all the areas we inspected were as follows:

- Whilst the provider recorded dispensing near misses, there were no effective systems in place for recording, reporting and learning from significant events.
- Risks to patients were not appropriately assessed or managed.
- One clinician working for White Pharmacy Ltd was not registered with the General Medical Council (GMC). The GMC is the statutory body responsible for licensing and regulating medical practitioners.
- There was no evidence of clinical training for clinicians available at the time of our inspection; since our inspection the provider has provided some evidence of staff training.
- The medical questionnaires used to assess a patient's condition were not all evidence based or risk assessed, did not enable clinicians to make an informed decision and did not ensure safe prescribing.
- There was a system in place for checking a patient's identification; however this system was not failsafe and we saw evidence of several orders being dispatched without an identification check.
- There was no evidence of sharing information with a patient's own GP. Patients were given the option of providing GP details; this was not compulsory. Patients were not asked for consent in order information could be shared with their GP.
- Medicines and safety alerts were received by the provider, checked for relevance and actioned if appropriate. At the time of our inspection this system was not recorded; however since our inspection the provider has taken action address this.
- There was a selection of policies available; however these were not readily available to clinicians working remotely.
- There was no safeguarding lead, the safeguarding policy did not include guidance on who to contact if there was concerns about a patient.

# Summary of findings

- There had only been one formal complaint since 2013. This had been responded to in a timely manner. Informal complaints were recorded in brief. There was no evidence of thematic reviews of complaints or of sharing learning outcomes.
- There was no continuous programme of audits or quality improvement.
- Whilst there was a leadership structure, there was no clear clinical leadership.
- There was no business continuity plan in place at the time of our inspection.

We identified regulations that were not being met and the provider must:

- Ensure the safety of patients by having appropriate systems to manage incidents, consultation forms, prescribing, patient consent and identity verification, safeguarding, recruitment and business continuity.
- Ensure the quality of the service by having appropriate clinical leadership and governance strategies including policies and protocols available for all staff, training, quality assurance monitoring and learning from complaints.
- Ensure patient identification verification is carried out for every patient.
- Take into account the 'Good practice in prescribing and managing medicines and devices' Guidance

produced by the General Medical Council when deciding how to protect patients from the risk of unsafe prescribing of medicines (including opioid based medicines) at White Pharmacy Ltd.

- Ensure that its clinical members of staff do not prescribe medicines (including opioid based medicines) to patients unless the clinician has sufficient, reliable information to enable them to prescribe safely.
- Ensure that where patients are registered with a general practitioner, in order to ensure safe care and treatment is provided to the patient overall, the provider must decide whether they are able to treat patients who refuse to give consent to White Pharmacy Ltd for their general practitioner to be contacted and informed of the medicines (including opioid based medicines) that have been prescribed.
- Carry out a comprehensive review of all medical questionnaires used to ensure they are evidence based. A GMC registered General Practitioner must sign off each of the final questionnaires to confirm they are satisfied that the revised versions meet the standard required for safe prescribing.

We have taken urgent action in response to the concerns identified at White Pharmacy Ltd; we have imposed conditions on the provider's registration.

**Professor Steve Field** CBE FRCP FFPH FRCGP Chief Inspector of General Practice

# Summary of findings

## The five questions we ask about services and what we found

We always ask the following five questions of services.

### **Are services safe?**

We found this service was not operating in accordance with the relevant regulations.

- Patients were at risk of harm because systems and processes were not in place to keep them safe. For example, there was no system in place to confirm patients' medical history and previous prescribing decisions before prescribing medicines. This included the prescribing of opioid based medicines.
- The medical questionnaires completed by patients when placing an order were not evidence based or risk assessed and did not rule out red flag symptoms to ensure prescribing was safe or appropriate, for example the questionnaire relating to indigestion did not ask questions to flag any concerns relating to conditions such as cardiac or gastrointestinal problems.
- Clinicians working for White Pharmacy Ltd had not provided any evidence of continued clinical professional development to ensure they were up to date with current clinical guidance or that they were clinically competent to carry out the role of remote prescribing. White Pharmacy Ltd have provided some evidence of clinical professional development for staff since our inspection.
- There was no significant event policy or recording form. Dispensing near misses were recorded in a near miss book.
- Staff were not aware of who was the safeguarding lead. There was a safeguarding policy; however it did not detail external stakeholders who should be contacted if staff had immediate concerns regarding a patient.

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### **Are services effective?**

We found this service was not operating in accordance with the relevant regulations.

- Patient outcomes were hard to identify as little reference was made to audits or quality improvement. There was evidence that the assessment of patients' conditions was not comprehensive and there was no evidence of any communication with patients' GPs to ensure patients were appropriately reviewed or followed up.
- Consent to care and treatment was not sought in line with the Mental Capacity Act 2005.
- At the time of our inspection, patients (with the exception of the family and friends of White Pharmacy Ltd) were not asked for specific consent regarding sharing information with a patient's GP. Since our inspection, this question about consent has been added to the initial patient questionnaire.

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### **Are services caring?**

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

- The provider was rated as excellent on an online review website by patients. The provider also sent feedback forms to patients.
- Information on the provider's website informed patients about the usage, side effects and costs of each medicine that was on offer.

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### **Are services responsive to people's needs?**

We found this service was not operating in accordance with the relevant regulations.

- There were systems and processes for gathering patient feedback although we did not find evidence to demonstrate this feedback was always acted on.

# Summary of findings

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- Complaints were responded to in a timely manner. Informal complaints were recorded in brief. There was no evidence of a thematic review or cascading of learning from these complaints.
  - There was no information on the provider's website to advise anyone with an emergency to contact the appropriate service.
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## **Are services well-led?**

We found this service was not operating in accordance with the relevant regulations.

- The provider had a vision and a set of values.
  - Whilst there was organisational structure and some non-clinical leadership demonstrated, we were not assured of sufficient clinical leadership.
  - The provider did not have a business continuity plan in place at the time of our inspection.
  - The provider had a number of policies and procedures; these were not readily available to clinical staff who worked remotely.
  - Systems and processes in place did not ensure prescribing was always safe or appropriate.
  - We saw minutes of a clinical meeting which had been held in the last 12 months.
  - The provider received feedback from patients via an online review website.
  - Office based staff had received annual appraisals.
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# White Pharmacy Ltd

## Detailed findings

### Background to this inspection

White Pharmacy Ltd is based in an industrial unit in Farnham, Surrey. White Pharmacy Ltd employ staff who work on site which includes IT staff, pharmacy and dispensing staff and office staff. They also have contracted clinicians who work remotely to process the prescriptions requested by patients.

The service is accessed through a website, <https://www.whitepharmacy.co.uk> and orders can be placed seven days a week and is available to patients in the UK and the EU. Orders are processed onsite by staff during normal working hours; Monday to Friday 9am to 5pm. This is not an emergency service. Subscribers to the service pay for their medicines when their on-line application has been assessed and approved. Once approved by the prescriber, medicines are dispensed, packed and posted; they are delivered by a third party courier service.

White Pharmacy Ltd was registered with the CQC on 12 June 2015 and they have a registered manager in place. (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).

We carried out our inspection on 12 and 16 January 2017. During our inspection, we spoke with the registered manager, the superintendent pharmacist, office based staff, the medical director and a clinician who worked remotely. We looked at policies, medical questionnaires, other documentation and patient records.

To get to the heart of people's experiences of care, we always ask the following five questions of every service and provider:

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

Our inspection team was led by a CQC Lead Inspector. The team included a GP specialist adviser, a second CQC inspector, a member of the CQC medicines team, and a further specialist advisor.

We inspected this service as part of our comprehensive inspection programme. We carried out a comprehensive inspection of this service under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. The inspection was planned to check whether the provider is meeting the legal requirements and regulations associated with the Health and Social Care Act 2008, to look at the overall quality of the service.

# Are services safe?

## Our findings

We found this service was not operating in accordance with the relevant regulations.

### Safety and Security of Patient Information

- 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.
- We were told by the provider that a patient's identity would be verified by comparing details submitted by a patient during the online registration with a data management website which can confirm identity when provided with details such as name, address, date of birth and credit card details. If this security check failed, the patient was asked for additional proof of identification. We saw evidence that this process was not always followed and that orders had been sent out without proof of an identity check. Since our inspection the provider implemented an additional security measure on their computer system which prevented an order being dispatched without an identity check.

### Prescribing safety

- We asked the provider about systems that were in place to identify and analyse any incidents, near misses and clinical errors. We were given three different books, which detailed incidents that overlapped with each other. There wasn't a unified system for recording incidents. Any issues that arose between the prescriber and the affiliated pharmacy, or the prescriber and the patients requesting prescriptions were dealt with as they happened. Whilst some actions had been taken in response to near misses, we did not see evidence of learning from incidents which commonly occurred. For example, we saw five instances in the last six months where patient's repeat prescriptions had been withheld in error due to a miscalculation of dates.
- We asked how the list of medicines which could be prescribed had been developed. There was no documented strategy for considering the range of

medicines to make available, and there had been no risk assessment undertaken when developing the list. Since our inspection the provider has taken some action in response to this finding.

- We noted that unlicensed medicines were prescribed (for example a medicine used for migraine) and that patients were informed that these medicines were unlicensed. However, no records were kept of the rationale for prescribing those medicines. We found that the pharmacist did provide additional information as part of the online prescribing service to guide the patient about when and how to take these medicines. We did not see evidence of consent by the patient to acknowledge and accept that they were receiving a medicine for use outside of its licence. This posed a risk to the patients and was not in accordance with GMC guidance. The provider has taken some action in response to this finding since our inspection.
- We were told that a patient's identity was checked before medicines were prescribed, and there was a policy which supported this. Patient's identity was checked using a system called "Lexis-Nexis" which cross referenced an applicant's details with several credit reference agency details. Once approved by a clinician, any prescribed medicines were dispensed and packed by the affiliated pharmacy. They were then posted and delivered by an external courier service. We were told that the courier's systems for delivery were high quality and that they checked medicines were delivered to the correct address.

### Management and learning from safety incidents and alerts

- We saw a system of recording and monitoring safety alerts, such as those provided by the Medicines and Healthcare products Regulatory Agency (MHRA). This was done by pharmacy staff. However, there was no process to distribute patient safety alerts to clinical staff within the organisation and therefore, the provider could not assure themselves that their clinicians knew about any safety information contained in the alerts. Since the inspection the provider has told us that they have reviewed their process.
- There was no policy in place for reporting and recording significant events and there was a lack of understanding of what a significant event was. Since the inspection the provider has told us that they have reviewed their process for recording significant events.

# Are services safe?

- As no significant events had been recorded, the provider was unable to carry out an analysis of significant events to identify trends and patterns.

## Safeguarding

- A safeguarding policy was available but this was not available to staff who worked remotely. Staff we spoke with were unable to identify a safeguarding lead. The safeguarding policy did not include contact details for external agencies who should be contacted if staff had immediate concerns relating to a patient. Staff had received training on safeguarding vulnerable adults relevant to their role. The provider has told us they have appointed a safeguarding lead since our inspection.

## Staffing and Recruitment

- The provider kept employment personnel files for staff members. These files confirmed personal details and registration details for clinical staff. There were no records of clinical professional development for clinical staff; the provider was able to provide some evidence of clinical professional development following the inspection. With the exception of one clinician who was based outside the UK, staff had Disclosure and Barring Service (DBS) checks on file. Despite the provider's website stating that their doctors were all UK qualified and registered with the UK General Medical Council (GMC), we found records of a doctor based and registered outside of the UK and we received conflicting reports regarding this doctor's role within White Pharmacy Ltd. The provider has taken some action in response to these findings since our inspection.
- Not all clinicians employed by the service were qualified GPs, but were qualified doctors and registered with the GMC (with the exception of the doctor based outside the UK). Some of these doctors were A&E consultants and

White Pharmacy Ltd assumed this demonstrated clinical competence to carry out the role of remote prescribing. The provider has taken some action in response to these findings since our inspection.

## Monitoring health & safety and responding to risks

Risks to office based staff were assessed and managed.

- There were risk assessments relating to health and safety and fire available. Portable electrical appliances had been tested.
- The provider headquarters was located within modern purpose built offices, housing the IT system, management and administration staff. Patients were not treated on the premises and GPs carried out the online consultations remotely usually from their home. Administration staff had received training in health and safety including fire safety.
- There was a protocol in place to deal with medical emergencies should one take place during an online consultation.
- There was a data security policy and arrangements for a backup system in the event of a hardware failure.
- The provider expected that all GPs would conduct consultations in private and maintain the patient's confidentiality. Each GP used their 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.
- Due to the nature of the service provided, no medical equipment was required to carry out the consultations.
- The service did not have a business continuity plan in place for major incident such as power failure or building damage; the provider was writing a plan at the time of our inspection.

# Are services effective?

(for example, treatment is effective)

## Our findings

We found this service was not operating in accordance with the relevant regulations.

### Consent to care and treatment

Staff did not seek patients' consent to care and treatment in line with legislation and guidance.

- Staff did not fully understand the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005. The provider has taken some action in response to this finding since our inspection and carried out some staff training.
- Staff we spoke with believed that the fact a patient was able to navigate through the process required to register and order medication was sufficient evidence of their capacity to make decisions about their care.

### Assessment and treatment

- The service had no overall strategy for assessing the needs of patients who were requesting prescriptions. Clinical staff, working outside of the provider's headquarters, reviewed orders placed by patients. There was no system in place to gain sufficient details of a patient's medical history in order to make a clinical diagnosis. We saw evidence of patients' diagnosing themselves and requesting a medicine in order to treat this self-diagnosis.
- There was a lack of communication with patients' own GPs to ensure patients were requesting medicines that were safe and appropriate or that patients had received medicines reviews. This included a high volume of orders for opioid based medicines. We spoke with one clinician who told us they had never communicated with a patient or a patient's GP by telephone or video communication in order to gain further insight. We asked for evidence where any clinician had communicated with a patient's own GP to discuss a patient's needs, the provider was unable to demonstrate this had ever occurred.
- When patients placed an order for a medicine, they completed a medical questionnaire. We were informed these questionnaires had been based on the medical director's experience as an A&E consultant but were not evidence based and the provider had not ensured they complied with current evidence based guidance and

standards, including National Institute for Health and Care Excellence (NICE) evidence based guidelines. These questionnaires did not enable a clinician to rule out red flag symptoms or a differential diagnosis.

- The way in which orders were reviewed by clinicians did not ensure that these questionnaires had been updated with each new order. For example, we saw evidence of patient submitting an exact copy of a previous medical questionnaire for several repeat orders even though the information supplied was out of date. This had not been identified as a concern by clinical staff.
- We asked to see examples of clinical audits and we were provided with an audit carried out to check the steps completed by a clinician when prescribing; this did not fulfil the criteria of a clinical audit and did not demonstrate quality improvement.
- The provider has taken some action in response to these findings regarding the assessment and treatment of patients. The provider has informed us they have appointed a new medical director responsible for clinical governance since our inspection.

### Coordinating patient care and information sharing

- Relevant staff had access to the patient's medical notes from interactions with the service. We were not assured that clinicians were able to gain sufficient information to manage the conditions they were treating.
- As this was not an NHS provider, there was no access to 'special notes'/summary care record which detailed information provided by the person's GP.
- The provider told us that they did not share information with the patient's primary physician or GP with whom they were registered, and we saw that there was no option on the registration or order forms for patients to consent to the information being shared. Since our inspection the provider added a question asking for consent to share information with the patient's own GP and has taken action to inform a patient's GP of their prescribing decision when consent is gained.

### Supporting patients to live healthier lives

- The provider has a range of information available on their website including a blog which discussed topics such as weight management, medicine side effects, pain management and insomnia.

### Staff training

# Are services effective?

(for example, treatment is effective)

We were shown limited evidence that staff had the skills, knowledge and competence to deliver effective care and treatment.

- All UK based doctors working for White Pharmacy Ltd were General Medical Council registered. One doctor who was not based in the UK was not registered with the GMC.
- The provider felt they were satisfied with the doctors' experience as either a GP or an A&E consultant; however we were not shown evidence of the clinicians knowledge and skills to carry out the role.
- The clinicians working outside of the headquarters were unable to access the service policies.
- The service could not demonstrate how they ensured role-specific training and updating for clinical staff.
- The provider had no oversight of continuous professional development of clinical staff.
- Since our inspection the provider has provided some evidence of staff training.

# Are services caring?

## Our findings

We found this service was operating 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.
- We were told that the clinicians undertook consultations in private. The provider carried out random spot checks to ensure the clinicians were complying with the expected service standards and communicating appropriately with patients.
- The provider engaged with an online review website on which they are rated by customers as excellent and had an overall rating of 9.8 out of 10 from over 900 reviews. Positive feedback included comments regarding access to services and being responded to in a timely manner.

- The provider also sent out customer review surveys and we were provided with several examples of these which showed positive feedback.

### Involvement in decisions about care and treatment

- 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. The website also detailed how to combine medicines for certain conditions.
- Staff told us that translation services were not available for patients who did not have English as a first language. The provider's website only had information and application forms in English.
- Patient information guides about how to use the service were available. There was a dedicated team to respond to any enquiries.

# Are services responsive to people's needs?

(for example, to feedback?)

## Our findings

We found this service was not operating in accordance with the relevant regulations.

### Responding to and meeting patients' needs

- All patients using the service referred themselves for medicine prescriptions. None were referred from NHS services.
- The website was available 24 hours a day, seven days a week. Patients registered on the provider's website and completed a general medical questionnaire. They would then request a medicine and complete a questionnaire relevant to the chosen medicine or condition. This request was then passed to a remote clinician who reviewed the order and either approved the order, requested additional information or rejected the order. If approved, the order was passed to the pharmacy where the medicine was dispensed and dispatched via a third party courier. If an order was rejected, the patient was informed of the reason why. The third party courier company were responsible for delivery to the patient's address which would require a signature for receipt.
- Patients accessed the service via the website from their computer or other portable device with internet access.
- This was not an emergency service. There was no information on the provider's website to advise anyone with an emergency to contact the appropriate service (999, their own GP or NHS 111). The provider has taken action in response to this finding since our inspection.

### Tackling inequity and promoting equality

- The provider had a policy to treat adults aged 18 years and over who had a postal address in the UK or the EU however based on the identify checking system in place we could not be assured that this was the case. The provider did not discriminate against any client group.
- No translation services were provided either on the website or in any correspondence with the patient.

### Managing complaints

- The service published their complaints procedure on their website which detailed how to make a complaint in writing, by email or by telephone.
- The one formal complaint, made in 2013, we reviewed had been responded to in a timely manner. Informal complaints were recorded in brief; however there was no evidence of a thematic review, sharing of lessons learned through complaints or an action plan to drive improvement.
- We were told that patients had the opportunity to rate the service from one to five stars on a web-based system. The system was called Trust Pilot and is an open system provided by a third party supplier. Any information that patients put onto the system could be seen by anyone.

# Are services well-led?

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

## Our findings

We found this service was not operating in accordance with the relevant regulations.

### **Business Strategy and Governance arrangements**

- The provider demonstrated to us that they had a vision and a set of values of which staff were aware.
- The service had a statement of purpose and a business plan that reflected the vision and values.
- There was a clear organisational structure and the executive team demonstrated non-clinical leadership, however we were not assured of sufficient clinical leadership.
- There were arrangements for identifying, recording and managing risks, issues and implementing mitigating actions.
- Care and treatment records were legible and securely kept.
- There were a number of policies but these were not available to clinicians who worked remotely. There was no significant event policy, the safeguarding policy lacked details on who to contact in an emergency and there was no business continuity plan. The provider has taken some action in response to these findings since our inspection.
- There was no system of quality improvement including continuous clinical and internal audit to monitor quality and to make improvements. The only audits we were shown did not constitute a clinical audit and did not demonstrate actions taken to drive improvement.

- There was no system in place to ensure medical questionnaires were routinely reviewed and revised based on current evidence based guidance. The provider has taken some actions in response to this finding since our inspection.
- There was no system in place to ensure prescribing was always safe and appropriate.

### **Leadership, values and culture**

- During the inspection the registered manager told us of how White Pharmacy Ltd was proud of the culture in the company and that they had been awarded an Investors in People Silver Award. There was an organisational structure and evidence of non-clinical leadership for office based staff. We were not assured of sufficient clinical leadership and not all staff knew who was responsible for lead roles such as safeguarding.

### **Seeking and acting on feedback from patients and staff**

- Patient feedback was available and the provider did document patient complaints and comments. Most complaints related to delivery issues and although individual complaints were resolved there was no evidence of any actions taken in response to trends in complaints such as deliver issues.