White Pharmacy Ltd

White Pharmacy Ltd

Inspection report

7 Riverside Park Industrial Estate, Dogflud Way,
Farnham, Surrey, GU9 7UG Way
Tel:01252 299 044
Website: www.whitepharmacy.co.uk

Date of inspection visit: 22 May 2017
Date of publication: 02/08/2017

Overall summary

Letter from the Chief Inspector of General Practice

We carried out an announced focused inspection at White Pharmacy Ltd on 22 May 2017.

We carried out our initial inspection on 12 and 16 January 2017. Following this inspection conditions were placed on the provider's registration. A second inspection was undertaken on 28 March 2017. At this inspection we found the provider had not met all of the requirements of the conditions and further improvements were still required.

This report covers the findings from the 22 May 2017 inspection. This inspection was carried out to check whether the provider had made the improvements required following the inspection in March 2017 and to review the provider's compliance with the conditions imposed on their registration following our inspection in January. During the inspection we found there had not been sufficient improvement to meet the conditions imposed. The report of our comprehensive inspection in January 2017 can be found by selecting the 'all reports' link for White Pharmacy Ltd on our website at www.cqc.org.uk.

We found this service did not provide safe and well led services in accordance with the relevant regulations.

Our key findings were:

- Patients were at risk of harm because effective governance systems and processes were not in place to keep them safe
- We identified continued significant risks to the safety of patients' health and welfare, which related to insufficient or ineffective systems in place in relation to remote prescribing of medicines having regard to the General Medical Council (GMC) 'Remote patient consultations and prescribing' guidance.
- Where letters had been sent to the GP, they did not always contain sufficient clinical information to facilitate effective continuity of care.
- Since the last inspection in March 2017 the provider's medical director had undertaken a review of patient questionnaires. However, we found the review had not ensured that full and comprehensive information was ascertained or recorded on the patient's condition prior to prescribing.
- There were systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. However, we saw that the learning and actions were not always recognised or acted upon.
- There was no system of quality improvement. For example there was no continuous clinical and internal audit to monitor quality and to make improvements.
- The care and treatment records of patients were not always complete or contemporaneous and the rationale around the decisions about prescribing were not recorded. We noted records were legible and securely kept.

Summary of findings

- We found changes to clinical process and governance systems continued to be made with minimal clinical oversight. This included a lack of clinical awareness and acknowledgement of the risks of opioid analgesics and neuropathic pain medicine prescribing.

We identified regulations that were not being met (please see the enforcement notices at the end of this report). The areas where the provider must make improvements are:

- Implement effective governance systems and processes to enable the provider to assess, monitor and improve the quality of the service and identify, assess and monitor risks relating to the health, safety and well being of patients and staff.
- Maintain accurate, complete and contemporaneous records in respect of all patients.
- Respond and act on feedback from the Care Quality Commission for the purposes of evaluating and improving the services to patients.
- Ensure care and treatment is provided in a safe way for all patients. Including the proper and safe supply and management of medicines.
- Ensure policies are in place to ensure children are safeguarded from harm and all staff have completed children's safeguarding training to the level required for their role.

Summary of any enforcement action

We are now taking further action in relation to this provider and will report on this when it is completed.

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.

- We identified continued significant risks to the safety of patients' health and welfare, which related to insufficient or ineffective systems in place in relation to the remote prescribing of medicines and not having regard to the General Medical Council (GMC) 'Remote patient consultations and prescribing' guidance. Medicines prescribed to patients during a consultation were not always monitored by the provider to ensure prescribing was evidence based.
- Patients were at risk of harm because systems and processes were not in place to keep them safe. For example, where a patient had either told the provider that they did not have a registered GP or that they did not consent for their GP being informed about the medicines they were being prescribed (especially opioid based medicines), there was no clinical rationale for the decision to prescribe recorded in the patient's records that we reviewed on the day of inspection.
- Where letters had been sent to the GP, they did not always contain sufficient clinical information to facilitate effective continuity of care and lacked the duration of the medicine supply and the dosage of medicine prescribed.
- Since the last inspection in March 2017, a review of patient questionnaires had been undertaken by the medical director. The medical questionnaires had been reviewed but did not ensure that full and comprehensive information was ascertained or the patient's condition identified and recorded prior to prescribing.
- There were systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. However, we saw the learning and actions were not always recognised or acted upon.

Are services well-led?

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

- There were no systems or policies in place to ensure safe prescribing guidelines.
- There was a lack of arrangements for identifying, recording, managing risks to ensure the implementation of mitigating actions. Opportunities to learn from particular risks and significant events were not always recognised. Therefore effective action was not always undertaken to mitigate these risks. The lack of governance arrangement for monitoring prescribing resulted in patients being at risk of harm.
- There was an insufficient system of quality improvement. For example there was no continuous clinical and internal audit to monitor quality and to make improvements.
- Care and treatment records were not always complete, although they were legible and securely kept
- We found changes to clinical process and governance systems continued to be made with minimal clinical oversight. This included a lack of provider awareness and acknowledgement of the risks of opioid analgesics and neuropathic pain medicine prescribing.

White Pharmacy Ltd

Detailed findings

Background to this inspection

White Pharmacy Ltd is based in an industrial unit in Farnham, Surrey. White Pharmacy Ltd employs information technology (IT), pharmacy, dispensing and office staff at this site. They also have contracted clinicians who work remotely to authorise the prescriptions requested by patients.

The service is accessed through a website www.whitepharmacy.co.uk. Orders can be placed seven days a week and the service is available to patients in the UK and the European Union. Orders are processed onsite by staff working during normal working hours; Monday to Friday 9am to 5pm. Patients are able to register with the website, select a condition they would like treatment for and complete a consultation form which is then reviewed by a clinician and a prescription is issued if appropriate. When certain medicines are ordered for new patients for the first time, such as opioid analgesics and neuropathic pain relief medicines, a pharmacist speaks with the patient to discuss their treatment and social situation. The prescription is sent to the affiliated pharmacy before being supplied to the patient. (The affiliated pharmacy is regulated by General Pharmaceutical Council). Patients to the service pay for their medicines when their on-line application has been assessed and approved.

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 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.

We carried out our initial inspection on 12 and 16 January 2017. Following this inspection conditions were placed on the provider's registration requiring changes to be made to how the provider operated. A second inspection was undertaken on 28 March 2017. At that inspection we found the provider had not met all of the requirements of the conditions and further improvements were still required.

This report covers the findings from the 22 May 2017 inspection. This inspection was carried out to check whether the provider had made the improvements required and to review the provider's compliance with the conditions. During the inspection we found there had not been sufficient improvements to meet the conditions imposed.

During our inspection, we spoke with the registered manager, the medical director, an acting medical director and prescribing GP, a superintendent pharmacist and the head of IT services. We looked at policies, medical questionnaires, other documentation and patient records.

Our inspection team was led by a CQC Lead Inspector who was accompanied by an inspection manager, a GP specialist adviser and a CQC clinician.

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 our two previous inspections in January 2017 and March 2017, we found the provider was not providing safe services in accordance with the relevant regulations. Adequate systems were not in place to enable clinicians to review previous decision making effectively. Patient questionnaires were not adequately risk assessed or evidence based. Patients were at risk of harm because systems for prescribing high risk medicines were not in place to keep them safe.

At this follow up inspection on 22 May 2017 we specifically looked at the conditions imposed and whether the provider had implemented changes to meet these conditions.

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

Safety and Security of Patient Information

On registering with the service, and at each consultation a patient's identity was verified and the White Pharmacy Ltd GPs had access to the patient's previous records held by the service. The provider had a policy not to provide care or treatment to persons under the age of 18 years, and identity checks were completed to ensure this.

Prescribing safety

We identified continued significant risks to the safety of patients' health and welfare, in relation to the remote prescribing of medicines and not having regard to the General Medical Council (GMC) 'Remote patient consultations and prescribing' guidance. Medicines prescribed to patients during a consultation were not always monitored by the provider to ensure prescribing was evidence based and informed by sufficient and reliable information.

We reviewed thirteen patient records and found eleven cases of long term opioid analgesics and neuropathic pain relief prescribing with no contact made with the patient's GP and no access to the patient's full medical history. There was inconsistent documentation of rationale for decisions to prescribe medicines where consent was not given to contact a registered GP.

We saw from significant events reported within the service, two examples of patients being prescribed opioid and neuropathic pain relief medicines with no consent from the patient to contact and discuss the relevant medical history with their regular GP. The patients were later found to have an addiction to this medicine. Following notification from a GP and a patient's family that the patients had an addiction, White Pharmacy Ltd stopped the patients from being able to order further prescriptions.

Where letters had been sent to the GP, they did not always contain sufficient clinical information to facilitate effective continuity of care. We reviewed 51 letters sent to GPs and found that all 51 letters did not contain the quantity of medicine prescribed and issued or the duration of treatment.

Since the last inspection in March 2017 a review of patient questionnaires had been undertaken. The medical questionnaires had been reviewed by the medical director but did not ensure full and comprehensive information was ascertained or the patient's condition identified and recorded prior to prescribing new or additional medicines. The reviewed templates did not ensure essential, appropriate information was obtained. They did not consistently rule out differential diagnoses or identify potential red flag symptoms for clinicians to consider in their prescribing decisions.

For example: a full assessment of symptoms was not undertaken for medicines relating to irritable bowel syndrome to ensure that the diagnosis was correct; for patients requesting medicines for reflux there was insufficient assessment questions to rule out cardiac concerns and the questionnaire for assessment of haemorrhoids presumed that this was the correct diagnosis and did not rule out other conditions, such as anal cancer.

Management and learning from safety incidents and alerts

Since previous inspections the provider had implemented a process for recording and discussing significant events. Meetings took place on a monthly basis with the provider and clinical team members and learning and action points from these meetings were emailed to all staff.

There were systems in place for identifying, investigating and learning from incidents relating to the safety of

patients and staff members. We reviewed eight incidents and found that these had been fully investigated, discussed and as a result some action taken in the form of a change in processes.

However, we saw that the learning and actions from some incidents were not recognised and acted upon. We saw an example of a significant event where a patient's regular GP had received notification from White Pharmacy Ltd that they had supplied one of their patients with an opioid medicine. The GP had sent White Pharmacy Ltd a complaint regarding the provider's prescribing of opioid medicines to their patient, with whom they were monitoring and treating for an addiction to this medicine. The GP was concerned that the provider had been prescribing large quantities of this medicine to this patient with no contact or communication with the patient's registered GP on 39 occasions prior to this notification. We were told by the provider that they had not made contact with the registered GP because the patient had not given consent for their GP to be contacted.

Following the significant event analysis the patient was prevented from ordering from the provider again. However, the provider had failed to consider the risks of prescribing medicines that can be addictive and have potential for abuse without consent to communicate prescribing to a patient's registered GP. They had failed to seek urgent consent from their existing and new patients ordering these medicines.

There were systems in place to deal with medicine safety alerts. We saw that the alerts were dealt with and actioned by pharmacy staff. We saw evidence that the alerts were emailed, including read receipts, to the clinical staff to ensure they were aware of the information.

Safeguarding

Staff employed at the White Pharmacy Ltd had received training in adult safeguarding and the one member we spoke with knew the signs of abuse and to whom to report them. There was a lead member of staff for safeguarding. The safeguarding lead and other staff had training in adult safeguarding; however, they did not have children safeguarding training to ensure they knew the appropriate action to take if there were any concerns with children they may come into contact with during the provision of the service. All the GPs had received adult safeguarding training. None of the staff had received safeguarding children training, including the safeguarding lead. All staff had access to a safeguarding policy and could access information about who to report a safeguarding concern to by searching for the local contact details online. There was an adult safeguarding policy; however, there was no child safeguarding policy.

Monitoring health & safety and responding to risks

The service had implemented a business continuity plan for major incidents such as power failure or building damage. The plan was stored off site and was emailed to the clinical staff to ensure they had a copy if they could not access the building.

Are services well-led?

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

Our findings

At our two previous inspections in January 2017 and March 2017, we found the provider was not providing well-led services in accordance with the relevant regulations for providing safe services. Adequate systems were not in place to ensure prescribing for high risk medicines kept patients safe.

At this follow up inspection on 22 May 2017 we specifically looked at the conditions imposed and whether the provider had implemented changes to meet these conditions.

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

Business Strategy and Governance arrangements

There were no systems or policies in place to ensure safe prescribing guidelines such as having regard to the General Medical Council (GMC) 'Remote patient consultations and prescribing' guidance. The provider told us that there was no policy or framework to ensure the effective management of medicines and support clinicians with their prescribing decisions. The provider told us such a policy was not required as they believed it was the individual prescriber's decision to make in line with their professional and registered body requirements.

There was an adult safeguarding policy in place. However, the provider did not have a children's safeguarding policy to ensure that any children that clinicians may come into contact with or have concerns about (such as the child of a parent receiving treatment from White Pharmacy Ltd) would be safeguarded from harm.

There were no regular checks in place to monitor the performance of the service. This included no random spot checks for consultations and to ensure accurate, complete and contemporaneous records were kept in regards of all patients. Although two audits had recently been undertaken there was no ongoing system of quality improvement. For example, there was a lack of continuous clinical and internal audit to monitor quality and to make improvements.

There were insufficient arrangements for identifying, recording and managing risks, issues and implementing mitigating actions. Opportunities to learn from risks within significant events were not always recognised and therefore actions were not undertaken to mitigate these risks.

The lack of governance arrangements for monitoring prescribing resulted in patients being at risk of harm. We saw an example of a patient that had a documented action plan in place, to register with a GP and provide evidence of this, before any further medicines would be provided. Despite this action plan, we saw that further prescriptions had been issued, despite no evidence that registration with a GP had taken place as required by the plan.

Care and treatment records were not always complete, although they were legible and securely kept. We saw evidence to confirm that patient records were not always accurate, complete and contemporaneous. Telephone communications with patients were recorded but we found that the written records did not always fully detail these conversations. We found there was a lack of documented prescribing rationale when patients had refused consent to contact their GP, mental capacity assessments were not always documented in the records and letters sent to patients' GPs did not include all the relevant clinical information.

Leadership, values and culture

The significant levels of risk found at this inspection was a direct result of the provider not ensuring appropriate systems had been implemented to effectively identify, manage and mitigate risk, particularly when prescribing opioid analgesics and neuropathic pain medicines. This issue had been highlighted to the provider previously and they had failed to sufficiently mitigate this risk. During the inspection we found changes to clinical process and governance systems continued to be made with minimal clinical oversight and a lack of provider and clinical awareness and acknowledgement of the risks of opioid analgesics and neuropathic pain medicine prescribing.

During a meeting with the provider following the inspection the registered manager told us they did not have sufficient expertise in clinical governance and audit to formulate and execute an action plan in response to the issues raised. We were told that following the inspection the medical director had resigned from their post and that although there was

Are services well-led?

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

an interim medical director in post there were plans to recruit a clinician with appropriate governance experience to support the improvements. A permanent medical director was also to be appointed.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider were failing to establish a process or system to assess, monitor and improve the quality of service or to assess, monitor and mitigate risks relating to the health, safety and welfare of service users and others who may be at risk arising from the carrying on of the regulated activity. Governance systems in place to assess, monitor and mitigate risks to the health and welfare of patients were ineffective. Governance systems failed to identify risks relating to clinical activity and monitoring of clinicians actions. There was a lack of policies and procedures to govern clinical activity. Changes to clinical process and governance systems were made with minimal clinical oversight and a lack of awareness and acknowledgement of clinical risks. There was no formal process in place for clinical audits or quality improvement to assess the service provision and ensure services were effective. We found learning from significant events was not always identified and actioned appropriately. The provider had not considered and mitigated the risk for children who may be at risk of abuse and whom they may come into contact with during consultations with patients. The safeguarding lead had not completed level three child safeguarding training and there was no safeguarding children's policy in place. These omissions have not been picked up as part of a process or system established to assess, monitor and improve the quality of service or to assess monitor and mitigate risks relating to the health, safety and welfare of service users and others who may be at risk arising from the carrying on of the regulated activity.

This section is primarily information for the provider

Enforcement actions

There was a lack of maintaining accurate, complete and contemporaneous records in respect of each service user. We reviewed and have evidence of 13 patient records. These records did not contain a rationale of the decisions taken in relation to the care and treatment provided by White Pharmacy Ltd. We found that conversations noted in significant event records were not documented in the complete medical record.