Medical Prescription Services Ltd

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Inspection report

28 The Square
Clifford Chambers
Stratford-upon-Avon
CV37 8HT
Tel: 08450941692
Website: www.medicalprescriptionservices.co.uk

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Overall summary

We carried out an announced comprehensive inspection on 10 October 2018 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

We found that this service was not providing safe care in accordance with the relevant regulations. The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of this occurring in the future is low.

Are services effective?

We found that this service was not providing effective care in accordance with the relevant regulations. The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of this occurring in the future is low.

Are services caring?

We were unable to assess this question as the service did not provide direct patient care.

Are services responsive?

We were unable to assess this question as the service did not provide direct patient care.

Are services well-led?

We found that this service was providing well-led care in accordance with the relevant regulations

Medical Prescription Services Ltd. develops patient group directions (PGDs), written instructions which allow healthcare professionals to supply and administer specified medicines to pre-defined groups of patients without a prescription. The service does not provide services directly to patients, but supplies a range of PGDs for use in community pharmacies. It does this via two community pharmacy trade associations which make them available to their members. Individual pharmacists who have completed the appropriate training can use the PGDs to extend the range of services available to their patients.

The medical director is the registered manager. 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.

Summary of findings

Our key findings were:

- The provider risk assessed the treatments offered and did not develop patient group directions for medicines which were not suitable for supply by this route
- There was an effective system for recording and acting on significant events
- The provider carried out audits which led to quality improvement
- Patient group directions were only made available to pharmacists who were suitably trained
- There was a process for obtaining patient consent, and for informing the patient's usual GP of treatment
- Staff provided information and support to the pharmacists who used the patient group directions
- The provider worked closely with partners to develop the range of services available
- There was a range of policies which were reviewed regularly and available to staff
- The service did not need access to patient information and ensured that it was redacted before information was shared with them

There were areas where the provider could make improvements and should:

- Review the monitoring of patient safety alerts to ensure the new process is fully implemented
- Review the systems for ensuring that they have staff with the current knowledge and experience to support the full range of patient group directions they produce.
- Review the process for ensuring that staff have the appropriate indemnity arrangements

Professor Steve Field CBE FRCP FFPH FRCGP

Chief Inspector of General Practice

Medical Prescription Services Limited

Detailed findings

Background to this inspection

Medical Prescription Services Ltd. develops patient group directions (PGDs), written instructions which allow healthcare professionals to supply and administer specified medicines to pre-defined groups of patients, without a prescription. The PGDs are made available for use in community pharmacies through two community pharmacy trade associations, and allow pharmacists to offer an extended range of services such as travel vaccines to their customers. The service works closely with the trade associations to ensure that the PGDs are accessed only by pharmacists who are suitably trained, and they provide templates for recording the consultations. The service does not provide direct patient care, and medicines are supplied and administered under the governance arrangements of the community pharmacies.

Our inspection team was led by a member of the CQC medicines optimisation team**.** The team included a second member of the medicines optimisation team.

Before the inspection we reviewed information from the service. During the inspection we spoke to the Registered Manager who was the medical director, a member of the management team and a pharmacist who developed the PGDs. We also spoke to two pharmacists about their experience of using PGDs developed by Medical Prescription Services Ltd., but we did not inspect the provision of patient services as they are separately regulated.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

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

These questions therefore formed the framework for the areas we looked at during the inspection.

Are services safe?

Our findings

Safety systems and processes

The service had clear systems to keep people safe and safeguarded from abuse.

- The provider conducted safety risk assessments. It had appropriate safety policies, which were regularly reviewed and communicated to staff who signed to confirm they had seen them. Staff received safety information from the service as part of their induction and refresher training.
- The service did not provide direct patient care, and systems to safeguard children and vulnerable adults from abuse were part of the regulated activity of the community pharmacies where the PGDs were used. The two pharmacists we spoke to were aware of their responsibilities.
- The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. There was a risk assessment process to determine which staff should have Disclosure and Barring Service (DBS) checks and these were undertaken when required.
- Infection prevention and control arrangements were the responsibility of the community pharmacists who operated the PGDs and this was set out in the terms and conditions.

Risks to patients

There were systems to assess, monitor and manage risks to patient safety.

- There was an appropriate number and mix of staff to manage the service and develop PGDs for travel health.
- The provider ensured that the pharmacists using the PGDs understood their responsibilities to manage emergencies and to recognise patients in need of urgent medical attention.
- There were appropriate indemnity arrangements in place for the organisation and the consultant pharmacist. The medical director told us they were in the process of confirming their cover with their indemnity provider. The terms and conditions for use of the PGDs required the community pharmacists to have the appropriate indemnity cover in place.
- The provider had risk assessed the treatments they offered. They had identified medicines that were not suitable for supply under PGD, for example they had declined requests from the pharmacy agencies they worked with to develop PGDs for antibiotic treatments for acne and urinary tract infections. The PGD for an inhaler for patients with asthma included restrictions on the frequency of supply, and encouraged pharmacists to obtain consent to share the information with the patient's GP.

Information to deliver safe care and treatment

The service did not deliver direct patient care or treatment.

- Individual care records were written by the community pharmacists who used the service and it was their responsibility to maintain them safely.
- The service provided template letters for community pharmacists to use to support the sharing of information with the patient's usual GP.

Safe and appropriate use of medicines

The service had systems for developing and authorising PGDs.

- There was a policy in place for the process of authorising and reviewing PGDs
- There was a system for ensuring that users had access to the current version of the PGDs
- Community pharmacists were required under the terms and conditions of the service to ensure that medicines were supplied and labelled in accordance with the relevant regulations.

Track record on safety

The service had a good safety record.

- Regular discussions with the pharmacy agencies which managed the PGDs helped the service to understand risks and gave a clear, accurate and current picture that led to safety improvements.
- Risks associated with the online service in development were recorded and assessed.

Lessons learned and improvements made

The service learned and made improvements when things went wrong, however they did not have an effective process in place to manage safety alerts.

Are services safe?

- There was a system for recording and acting on significant events. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- There were effective systems for reviewing and investigating when things went wrong. The service learned and shared lessons identified themes and took action to improve safety in the service. Patient care was provided under the governance arrangements of the community pharmacies which used the PGDs, but the provider collected information on significant events and reviewed them to identify whether they could make any changes to the PGD service to reduce the risk of further incidents.
- The provider was aware of the Duty of Candour but did not provide services directly to patients so there were no examples. The provider encouraged a culture of openness and honesty. The service had systems in place for knowing about notifiable safety incidents
- The service received safety alerts, but had not acted on all relevant alerts. We saw a PGD which had not been updated in line with an alert from 2017. After the inspection the provider sent us a copy of a revised policy to improve the management of patient safety alerts, and told us that they had implemented an alert spreadsheet to monitor the process.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

The provider did not have effective systems to keep clinicians up to date with current evidence in some areas of their practice. We saw evidence that clinicians did not always develop the clinical content of PGDs in line with current standards and guidance.

- We saw a PGD for a medicine linked to depression and risk of suicidal thoughts which had not been revised in line with current guidance. Following the inspection the provider told us they had updated this PGD and put in place an annual review of all their PGDs by an independent third party to improve compliance with current evidence based guidance.
- The templates developed by the provider for use by community pharmacists ensured that patients were screened to make sure they met the criteria for treatment under PGD.
- We saw no evidence of discrimination in making care and treatment decisions.

Monitoring care and treatment

- The service was actively involved in quality improvement activity. They met regularly with the pharmacy agencies which managed the provision of PGDs to individual pharmacies.
- The service made improvements through the use of completed audits. They had carried out an audit of the consent forms which acted as the consultation record, and made changes to the consent template to make it clearer for the pharmacists to use.

Effective staffing

Staff did not always have the skills, knowledge and experience to carry out their roles.

- The provider ensured that staff had expertise in the development of immunisation and travel health PGDs, which was their main business. They did not demonstrate that they had staff with the expertise to develop and review some of the other PGDs, however following the inspection they confirmed that they had made arrangements for an independent clinical review.
- All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff.
- Relevant professionals were registered with the General Medical Council (GMC), Nursing and Midwifery Council and General Pharmaceutical Council and were up to date with revalidation
- The service required pharmacists who used the PGDs to have undertaken specific training on vaccination, including regular refresher training. There was a process to ensure that they could only access PGDs which they were trained to use.

Coordinating patient care and information sharing

Staff worked with their partner organisations, the community pharmacy agencies, to support pharmacists to deliver effective care and treatment.

- The service provided a consent form which allowed pharmacists to collect relevant information about the patient's health and their medicines history before supplying or administering medicines.
- The service required pharmacists to ask patients for consent to share details of their consultation and any medicines supplied or administered with their registered GP on each occasion they used the service. The service provided a template letter, and the pharmacists we spoke to told us they routinely informed the patient's GP where the patients agreed to share their information.

Supporting patients to live healthier lives

The service did not provide direct patient care or treatment.

Consent to care and treatment

The service supported pharmacists to obtain consent to care and treatment in line with legislation and guidance.

- The service provided a consent form for use by the pharmacists who used the PGDs, and monitored the process by auditing completed forms.
- The pharmacists we spoke to told us that a consent form was provided and they used it routinely during the consultation.

Are services caring?

Our findings

Kindness, respect and compassion

The service did not provide direct patient care or treatment.

- During a pilot of the online PGD service in 2014 they collected patient feedback, and they told us they will do so again when the online service is relaunched.
- The service provided timely support and information to the pharmacists using the PGDs.
- Although not directly involved in patient care, when a patient experienced an anaphylactic reaction following vaccination staff contacted the pharmacy to check that the patient was safe.

Involvement in decisions about care and treatment

The service did not provide direct patient care or treatment.

Privacy and Dignity

- The terms and conditions of use required the community pharmacies to provide the PGD service in a consulting room which met the standards of the pharmacy regulator.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The service did not have any direct patient contact but they took account of the views of their partners in delivering services.

- The provider understood the needs of the pharmacists who used the PGDs. The pharmacists that we spoke to said the PGDs were comprehensive and clearly written.
- The pharmacists told us the practical training they were required to complete before carrying out vaccinations left them confident to provide the service.
- Pharmacies who provided the service were expected to have facilities which met the standards of the pharmacy regulator.

Timely access to the service

- Clinical staff were part time but worked flexibly and covered for each other, so there was someone available to answer queries from pharmacists in a timely way. We saw that emails from pharmacists had been responded to promptly, and both pharmacists we spoke to confirmed that they were able to contact the provider if needed.
- A member of staff was available to answer the telephone during office hours.

Listening and learning from concerns and complaints

The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.

- PGD services were provided to patients under the governance arrangements of the individual community pharmacy, and any patient complaints were handled by the pharmacy in line with their own policy.
- The provider had a policy for managing concerns or complaints raised by the trade associations or individual pharmacists, and for supporting them to manage complaints made by their patients. For example when a pharmacist received a complaint about the provision of a travel vaccine, they provided initial advice to the pharmacist and were considering whether they needed to make any changes to the PGD or other documentation.

Are services well-led?

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

Our findings

Leadership capacity and capability;

- As a small organisation staff worked together to develop and deliver the service.

Vision and strategy

The service had a clear vision and credible strategy to deliver high quality care and promote good outcomes for patients.

- The aim of the service in its statement of purpose was "to continue to develop and utilise cutting edge technology to ensure applicants are rigorously screened, and when medically appropriate, supplied with a range of Prescription Only Medicines (POMs) by a community pharmacist or nurse, using Patient Group Direction (PGD) services for which they have received specific training"
- At the time of our inspection PGDs were provided using a paper based recording system, but the provider was working towards an online system for use by patients and pharmacists. The intention was to improve safety and record keeping and maintain a full audit trail.

Culture

The service had a culture of high-quality sustainable care.

- Staff working for the service did not have direct patient contact but worked with the community pharmacy trade associations to develop the range of PGDs that they provided. Individual pharmacists who used the PGDs told us that they felt able to contact the provider with feedback or queries.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. Although medicines were supplied or administered to patients under the governance arrangements of the community pharmacies who used the PGDs, the provider collected and reviewed all incidents and complaints. A patient had recently experienced an anaphylactic reaction to a vaccination, and the provider had contacted the pharmacist to check the patient was safe. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- Staff we spoke with told us they were able to raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- The medical director and pharmacist worked for the organisation on a consultancy basis. They had an annual appraisal to discuss the administrative aspects of their work with the organisation. As the manager was not a clinician their clinical work was appraised through their professional revalidation process. All staff were up to date with this. The provider did not have a process to ensure that their clinical supervision and revalidation covered all aspects of their role in developing and authorising PGDs.
- Clinical staff worked remotely but it was clear that they were in regular contact and worked closely together.

Governance arrangements

There were clear responsibilities, roles and systems of accountability to support good governance and management.

- Structures, processes and systems to support good governance and management were clearly set out, and meeting minutes showed that relevant items were reviewed regularly.
- Staff had defined roles and accountabilities
- There was a range of policies which were available to all staff. They were reviewed and updated regularly and there were records to show that staff had read the policies.

Managing risks, issues and performance

There were processes for managing risks, issues and performance but they were not always effective.

- The provider did not have an effective process to monitor patient safety alerts. Minutes showed that they were discussed in meetings, but there was no check on whether all alerts had been reviewed and acted on when relevant to the service.
- The service carried out an annual review of incidents and complaints to identify trends and consider whether they needed to take action.
- Clinical audit had a positive impact on quality of care and outcomes for patients. There was clear evidence of action to change services to improve quality.

Are services well-led?

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

- As the service was not providing direct patient care they did not have access to data on how often each PGD was used but they did monitor the number of pharmacists signed up to offer each PGD.

Appropriate and accurate information

The service acted on appropriate and accurate information.

- The service used information from the trade associations it worked with to review the range of PGDs provided.
- The service submitted data or notifications to external organisations as required.
- The service did not have direct patient contact and did not maintain patient records. Information collected from community pharmacists for audit purposes did not contain patient identifiable data.

Engagement with patients, the public, staff and external partners

The service involved staff and external partners to support high-quality sustainable services.

- Staff and external partners' views and concerns were encouraged, heard and acted on to shape services and culture. We spoke to two pharmacists who used the PGDs provided by the service. They both said they had contacted the provider, either directly or through their trade association, to share their views. The service had changed some of their documentation to make it clearer, based on feedback from pharmacists.
- Staff said that the ethos of the organisation encouraged them to contribute ideas and we saw that there was regular communication between staff.
- The service was transparent, collaborative and open with stakeholders about performance.

Continuous improvement and innovation

There was evidence of systems and processes for learning, continuous improvement and innovation.

- The service made use of internal and external reviews of incidents and complaints. Learning was shared and used to make improvements.
- There were systems to support improvement and innovation work. Staff met regularly with their partner organisations to review the range of PGDs offered.
- The provider was developing an online system to support pharmacists to determine patient eligibility for medicines supply or administration, and to improve record keeping. They had carried out a pilot to test the system and obtain feedback.