

Freedomhealth Ltd

Freedomhealth Limited

Inspection report

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Date of inspection visit: 23 August 2017

Date of publication: 05/10/2017

Overall summary

Letter from the Chief Inspector of General Practice

We carried out an announced follow up inspection at Freedomhealth Ltd on 23 August 2017. We found this service had made significant improvement however there were some areas where the service was not able to demonstrate it could provide safe and well led services in accordance with the relevant regulations.

Prior to our inspection on 3 May 2017, Freedomhealth Limited offered a digital service that allows patients to obtain a prescription and obtain medicines from an affiliated pharmacy. Freedomhealth Limited also provides private general practice, specialist sexual health services and cosmetic treatments, however, this inspection focused on the digital service.

Following our inspection of the service on 3 May 2017 we imposed a condition on the provider's registration to prevent the provider from providing any Digital and Online Services to patients which fall within the scope of the regulated activity: Treatment of disease, disorder or injury.

This follow up visit was carried out to determine if the provider had taken action to address the non-compliance. We found the provider had put systems and processes into place which indicated that in most areas it could provide safe, effective responsive and well led services in accordance with the relevant regulations.

Our key findings were:

- There were improved systems in place to protect patient information and ensure records were stored securely.
- New software was being put into place to improve patient identity checks, however this was not yet operational.
- Patient questionnaires had been expanded and the request for consent to contact the patient's own GP to inform them of the treatment they were receiving had been strengthened and had been brought into line with GMC guidance.
- There was a complaints policy which provided staff with information about handling formal and informal complaints from patients. Staff told us that all verbal complaints would now be logged in accordance with that policy.
- Systems and processes to govern activity had been reviewed and improved.
- Measures were being put into place to improve the quality of patient records and to deliver care and treatment in accordance with evidenced based national guidelines and standards however these systems were not yet complete.
- A programme of clinical audits was planned.
- Prescribing processes and systems had been reviewed and revised however there remained some discrepancy between the list of medicines sent to us by the provider and those included on the patient questionnaires.

Summary of findings

- There was now a business continuity plan in place which considered how the service would continue if there were any adverse events, such as IT failure or building damage.

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

- Introduce appropriate measures to ensure patient records are complete and accurate and that care and treatment is delivered in accordance with evidence based guidelines.

In addition, the provider should:

- Ensure the new software will provide adequate patient identity checks, and is in line with current guidance.

- Ensure the list of medicines that can be prescribed is in accordance with medicines detailed in the patient questionnaires.

You can see full details of the regulations not being met at the end of this report.

Following the significant improvements the provider has made, we have now removed the condition which we imposed on the provider's registration following our inspection of the service in May 2017.

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 provider had put systems and processes into place which indicated that it could provide safe services in accordance with the relevant regulations.

- Processes had been put into place which would entail all staff data was regularly checked and updated where appropriate, including DBS checks, GMC registration and indemnity cover.
- The provider was in the process of re-building its website and updating its software so as to enable clinicians to access all parts of a patient's record so that they could see what advice and treatment had been given.
- The provider had reviewed their data protection policy to improve security.
- The provider had engaged the services of a pharmacist to consult and advise on processes, medicines offered and patient assessments. The medicines offered by the provider had been revised. Those for the treatment of high blood pressure and high cholesterol would no longer be available. We noted, however, that there remained some discrepancy between the list of medicines sent to us by the provider and those included on the patient questionnaires.
- Patient questionnaires had been revised and now required patients to provide additional information.
- The request for consent to contact the patient's own GP to inform them of the treatment they were receiving had been strengthened and had been brought into line with GMC guidance.
- Staff had reviewed the significant event policy. New reporting forms had been put into place and steps taken to enable staff to share learning with the associate pharmacy through a cloud based incident management system.

Are services effective?

We found the provider had put systems and processes into place which indicated that it could provide effective services in accordance with the relevant regulations.

- As the provider had not been offering an online service since that May inspection, there were no new patients' records the inspection team could review to determine if the provider could demonstrate appropriate record keeping and patient treatment. This will be re-visited at future inspections. In the interim, the provider had put a system in place to share NICE guidance and any patient safety alerts with staff. Incoming information would be logged, disseminated and a 'read receipt' obtained. The provider was also reviewing how it assessed patients needs and recorded patient treatment.
- The provider had not been in a position to carry out audits, but we saw, for example, written plans for quarterly medicine audits which they intended to share with their affiliated pharmacy.
- The provider had specifically reviewed treatment for asthma, and strengthened their policy in this regard.

Are services caring?

Not inspected on this visit.

Are services responsive to people's needs?

We found the provider had put systems and processes into place which indicated that it could provide responsive services in accordance with the relevant regulations.

- There had not been any complaints since the last inspection; however, we were given assurances that all verbal complaints would now be logged. A new log had been devised to assist staff with this process.

Summary of findings

Are services well-led?

We found the provider had put systems and processes into place which indicated that it could provide well-led services in accordance with the relevant regulations.

- The provider had put a business continuity plan into place.
- The provider's risk assessment policy had been updated and they were in the process of developing a plan to address data retention in the event they ceased trading.
- Quarterly clinical meetings were planned and we saw the standing agenda that had been put into place for these meetings.
- The provider had put into place a remote working policy to instruct staff who worked off site.
- The provider was in the process of implementing new software to improve the quality of identity checks of people using the service. As the software was not operational we could not assess if it would provide adequate patient identity checks, or if it was in line with current guidance.
- Security of patient information had been reviewed and increased password protection added.

Freedomhealth Limited

Detailed findings

Background to this inspection

Background

When in operation, Freedomhealth Limited offers a digital service providing patients with prescriptions for medicines that they can obtain from the affiliated registered pharmacy. We inspected the digital service at the following address: 60 Harley Street, London, W1G 7HA, which was located within an independent GP practice. The GPs working for the digital service also worked in the practice.

Freedomhealth Limited was originally established in 1997, and has evolved to provide an online service (since 2011) which, when operational, allows patients to request prescriptions through a website (this is the service we inspected). 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 GP and a prescription is issued if appropriate. Once the consultation form has been reviewed and approved, a private prescription for the appropriate medicine is issued. This is sent to the affiliated pharmacy before being dispensed, packed and sent to the patient by secure post (we did not consider the actions of the pharmacy as they are regulated by General Pharmaceutical Council).

When operational, the service can be accessed through their website, www.freedomhealthonline.co.uk where patients can place orders for medicines seven days a week. The service is available for patients in the UK only aged

over 18 years. Patients can access the service by e-mail from 9am to 5pm, Monday to Friday. This is not an emergency service. Subscribers to the service pay for their medicines when making their on-line application.

A registered manager is in place. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

How we inspected this service

Our inspection team was led by a CQC Lead Inspector accompanied by a GP Specialist Advisor and a member of the CQC medicines team.

During our visits we:

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

Why we inspected this service

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service had taken action to comply with the breaches in regulation identified at the inspection of this service in May 2017.

Are services safe?

Our findings

At our inspection in May 2017 we found that this service was not providing safe care in accordance with the relevant regulations due to ineffective systems relating to staff recruitment; data protection and access to patient records; prescribing and significant events.

On our visit on 23 August 2017 we found that the provider had taken steps to address these issues.

Staffing and Recruitment

At our May 2017 inspection we had found that staff were not following the in-house policy and procedure regarding Disclosure and Barring Service (DBS) checks (DBS checks identify whether a person had a criminal record or was 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 policy detailed that DBS checks would be undertaken every three years for all staff, but this was not being done. We also found that the indemnity cover for one clinician had not appeared to cover them for all the hours they worked at Freedomhealth; and that there was no system for checking that GPs were currently registered with the General Medical Council (GMC).

At the inspection on 23 August 2017 we were told that a review process had been put into place which would ensure all staff data was regularly checked and updated where appropriate. We reviewed the recruitment process for the newly appointed pharmacist consultant. We found that the provider had confirmed the individual's professional registration but had not requested any other documentation. The provider commented that as the individual was engaged on a consultancy basis and following recommendation they had felt additional checks were unnecessary. However, following our discussion the provider immediately started the process to obtain copies of relevant documents. The provider confirmed they had reviewed the indemnity cover in question and were confident it provided appropriate cover.

Monitoring health & safety and responding to risks

At our May 2017 inspection we had found that as the GPs were unable to see each other's electronic correspondence with patients, and verbal communication was not recorded, there was no system for them to carry out checks on approved consultations and prescriptions to ensure

they were appropriate. We also found that there was no policy detailing the requirements for data protection. Each GP used their laptop to log into the operating system, which was a secure

programme. However, we were told that the provider stored their password on the computer which may have made it accessible.

At the inspection on 23 August 2017 we found that the provider was in the process of re-building its website and updating its software so as to enable clinicians to access all parts of a patient's record so that they could see what advice and treatment they had been given. The updated system would provide an audit trail, which recorded all contact between clinicians and between clinicians and patients. All incoming and outgoing messages would be date and time stamped. The provider had also reviewed their data protection policy to improve security.

Prescribing safety

At our inspection in May 2017 we found that medicines prescribed to patients during a digital consultation were not monitored by the provider to ensure prescribing was evidence based. There was no formal review programme in place to ensure they followed best practice guidelines. We found, for example, that the provider prescribed numerous asthma medicines, on repeated occasions without any further communication with the patient's GP. There was no documented evidence of the rationale for this in the patient's notes. We saw that the medical questionnaires/templates used to gather information on the patient's condition prior to prescribing did not ensure essential, appropriate information was obtained.

At the inspection on 23 August 2017 we found the provider had revised the list of medicines on offer as a result of the findings of the previous inspection. Medicines for the treatment of high blood pressure and cholesterol lowering were no longer available. It was deemed unsafe to prescribe these medicines whilst solely relying on patients to provide blood monitoring data. The provider had engaged the services of a pharmacist to consult and advise on processes, medicines offered and patient assessments. Quarterly meetings were planned with the pharmacist to review prescribing and measure it against current good practice guidelines.

We looked at a variety of FreedomHealth Ltd - Online Doctor Questionnaire templates. We identified examples

Are services safe?

where contraindications or drug interactions listed in the British National Formulary (BNF – the BNF is a pharmaceutical reference book) had not been included. We discussed this and as a result, the provider agreed to review the templates immediately. The revised templates were received later the same day. The newly revised questionnaires required more information from patients and would also require more interactive doctor time to assess the request. The request for consent to contact the patient's own GP to inform them of the treatment they were receiving had been strengthened and had been brought into line with GMC guidance. Going forward, staff planned to review the templates on a quarterly basis to provide assurance that they appropriately minimise risks to patients using the service. We noted, however, that there remained some discrepancy between the list of medicines sent to us by the provider and those included on the patient questionnaires.

Patients could only request medicines for the conditions listed on the provider's website. In addition, there was no facility for the doctors to prescribe outside of this selection as the prescribing software did not allow for any formulary deviation. At the time of this inspection, there were no controlled drugs on the formulary. Sharing of information

with a patient's GP was going to be mandatory for certain conditions such as asthma. If a patient refused to provide this information, the provider told us that they would not prescribe the medicine. This decision was taken to ensure that patients were kept safe from potential harm.

Management and learning from safety incidents and alerts

At our May 2017 inspection we had not been assured that significant events would have been highlighted due to the ineffective systems in place to identify, report and mitigate risks to patients.

At the inspection on 23 August 2017 the provider informed us that while that had not been any significant events in the period between the two inspections, nevertheless identification and reporting of significant events had been reviewed with staff. We saw that the provider had designed a new significant event reporting form. Incidents would be logged on this form and discussed at meetings with clinical staff present. The provider was also enabling staff to have access to a cloud based incident management system which would allow shared learning between the provider as the prescriber and their associated pharmacy as the dispensers.

Are services effective?

(for example, treatment is effective)

Our findings

At our inspection in May 2017 we found that this service was not providing effective care in accordance with the relevant regulations as national clinical guidance was not always being followed and patient records were not always complete or accurate. There was a lack of clinical audit.

On our visit on 23 August 2017 we found that the provider had taken steps to address these issues.

Assessment and treatment

At the inspection in May 2017 we reviewed a number of patient electronic records and found examples of unsafe care. It was evident that national clinical guidance was not being followed in all cases.

As the provider had not been offering an online service since that May inspection, there were no new patients' records the inspection team could review to determine if the provider could demonstrate appropriate record keeping and patient treatment. This will be re-visited at

future inspections. In the interim, the provider had put a system in place to share NICE guidance and any patient safety alerts with staff. Incoming information would be logged, disseminated and a 'read receipt' obtained. The provider was also reviewing how it assessed patients needs and recorded patient treatment.

Quality improvement

At the inspection in May 2017 we found the service did not monitor consultations, or carry out prescribing audits to improve patient outcomes. There was no formal programme in place for clinical audits or quality improvement to assess the service provision.

As the provider had not been operating an online service since the May 2017 inspection, they had not been in a position to carry out audits but gave us reassurances that this was something that would be addressed. For example, we saw written plans for quarterly medicine audits which they planned to share with their affiliated pharmacy. The provider had, however, specifically reviewed treatment for asthma, and strengthened their policy in this regard.

Are services caring?

Our findings

Not reviewed on this inspection.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

At our inspection in May 2017 we found that this service was not providing responsive care in accordance with the relevant regulations, as not all complaints were being appropriately logged, and the provider was not following its own policy in this regard.

On our visit on 23 August 2017 we found that the provider had taken steps to address these issues.

Managing complaints

At the inspection on 23 August 2017 we discussed the provider's complaints policy and were given assurances that going forward, complaints would be recorded in accordance with that policy. A log has been devised for staff to use particularly for verbal complaints or concerns.

Are services well-led?

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

Our findings

At our inspection in May 2017 we found that this service was not providing well-led care in accordance with the relevant regulations as not all the systems to manage and govern risk were effective, including patient identification.

On our visit on 23 August 2017 we found that the provider had taken steps to address these issues.

Business Strategy and Governance arrangements

At the inspection in May 2017 we found that there was no business continuity plan to consider how the service would continue if there were any adverse events, such as IT failure or building damage. The provider had not ensured arrangements were in place to store patient information for the appropriate timescale should the business cease to operate or there was a disruption to service.

At the inspection on 23 August 2017 we found the provider had put a business continuity plan into place. They had also reviewed and updated their risk assessment policy and were in the process of developing a plan to address data retention in the event they ceased trading.

Quarterly clinical meetings were planned. They would have a standing agenda which we were told would include system reviews; audits, significant events, complaints, reviews of important alerts and case discussions.

Safety and Security of Patient Information

At the inspection in May 2017 we found that provider had not considered the risks relating to information governance and keeping patient information secure. There were ineffective systems to ensure that all patient information was stored and kept confidential. There were no policies in place, for the IT systems, to protect the storage and use of all patient information and to instruct staff working off site how to access patient information safely. The service could not provide a clear audit trail of who had access to records.

On registering with the service, patient identity checks were limited; other than via a credit/debit card check. The provider could not be sure they were consulting with the person who owned the card.

At the inspection on 23 August we found the provider had put into place a remote working policy. They were also in the process of implementing new software to improve the quality of identity checks of people using the service. As the software was not operational we could not assess if it would provide adequate patient identity checks, or if it was in line with current guidance.

Security of patient information had been reviewed and increased password protection added.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.: Safe care and treatment:</p> <p>How the regulation was not being met:</p> <p>The provider had not done all that was reasonably practicable to mitigate the risks to the health and safety of patients receiving care and treatment. In particular:</p> <ul style="list-style-type: none">• The provider had not ensured that care and treatment was delivered in accordance of evidence based guidelines. <p>This was in breach of regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</p>
Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>Regulation 17 HSCA (RA) Regulations 2014 Good governance:</p> <p>How the regulation was not being met:</p> <p>The registered person did not do all that was reasonably practicable to assess, monitor, manage and mitigate risks to the health and safety of service users. In particular:</p> <ul style="list-style-type: none">• The provider had not ensured that patient records were complete and accurate. <p>This was in breach of Regulation 17 of the Health and Social Care Act 2008 Regulated Activities) Regulations 2014.</p>