

New Leaf Healthcare Limited

New Leaf Health Care Limited – Leeds Clinic

Inspection report

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Overall summary

We carried out an announced comprehensive inspection of this service on 26 January 2016. Breaches of legal requirements were found. After the comprehensive inspection, the service wrote to us to say what they would do to meet legal requirements in relation to a breach of regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. We undertook this comprehensive inspection to confirm that they now met legal requirements. You can read the report from our last comprehensive inspection, by selecting the 'all reports' link for New Leaf Health Care -Leeds Clinic on our website at www.cqc.org.uk.

We carried out an announced comprehensive inspection on 25 July 2017 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

Are services effective?

We found that this service was providing effective care in accordance with the relevant regulations

Are services caring?

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

Are services responsive?

We found that this service was providing responsive care in accordance with the relevant regulations

Are services well-led?

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

Background

New Leaf Healthcare Limited is located in Leeds City Centre and offers a private weight reduction service for adults over the age of 18. The clinic comprises of reception and office areas and one clinic room. It has disabled access and a toilet facility. The clinic is open for both pre-booked and walk-in consultations 9:30am to 1:30pm Monday, Wednesday and Friday, and appointments can be booked by request every other Saturday. The clinic employs two doctors, one

Summary of findings

receptionist and a manager, who 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.

Our key findings were:

- We identified some examples of unsafe prescribing
- Staff had the appropriate skills and experience
- Appropriate arrangements were in place to safeguard patients from abuse
- The clinic had a comprehensive set of policies and procedures governing all activities
- Patients told us staff were polite and helpful and the doctor was knowledgeable

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

- Ensure care and treatment is provided in a safe way for service users

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

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

- Carry out a risk assessment for the provision of medicines and equipment for use in a medical emergency
- Review the necessity for chaperoning at the service, and staff training requirements if necessary
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available

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.

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 once it has been put right. We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

The service had appropriate arrangements in place to safeguard patients from abuse. Employment checks had been performed for staff, including Disclosure and Barring Service checks. Premises and equipment were properly maintained and fit for use. However, we found examples of unsafe prescribing, which were not in accordance with the service's prescribing policy or national guidance.

We also found areas where improvements should be made relating to the safe provision of treatment. This was because the provider had not carried out a risk assessment for the provision of medicines and equipment for use in a medical emergency.

Are services effective?

We found that this service was providing effective care in accordance with the relevant regulations.

Staff had the appropriate skills and experience. Consent was obtained before treatment was provided and patients were routinely asked for consent to share details of their treatment with their usual GP. Before prescribing medicines, the doctor discussed appetite suppressants, and explained how they should be used and what the side effects could be.

Are services caring?

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

We obtained feedback about the service from 42 patients through completed CQC comment cards. All of the comments were positive; patients said staff were polite and helpful, the doctor was knowledgeable and they felt supported to lose weight.

Are services responsive to people's needs?

We found that this service was providing responsive care in accordance with the relevant regulations.

The facilities were appropriate to meet people's needs. The premises were accessible to patients with mobility difficulties. The provider had a policy and procedure in place for handling concerns and complaints. Information was not available in large print or in other languages. There was no induction loop available for patients who experienced hearing difficulties; however the provider had surveyed their patients to ask if one was needed and found that it was not.

Are services well-led?

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

The clinic had a comprehensive set of policies and procedures governing all activities and staff knew about the requirements of the duty of candour. The provider carried out regular audits of prescribing and clinical record keeping, however these did not always detect poor practice. A patient feedback form and comment cards were available and staff told us they were able to share ideas with the registered manager to improve the service.

New Leaf Health Care Limited – Leeds Clinic

Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection at New Leaf Healthcare –Leeds Clinic on 25 July 2017. The team was led by a CQC pharmacist specialist and included a member of the CQC medicines team.

Before visiting, we reviewed a range of information that we hold about the service which included information from the provider.

The methods we used were talking to patients using the service, interviewing staff, observation, and review of documents.

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 patient'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

Reporting, learning and improvement from incidents

Although the registered manager was not familiar with the term Duty of Candour, they were able to describe the process following an incident, which was in accordance with the requirements of the Duty of Candour. The service had systems in place for knowing about notifiable safety incidents. There had been one significant event in the last 12 months, which we reviewed:

- The service had carried out a thorough investigation
- They kept written records of verbal interactions as well as written correspondence
- Learning was shared with all staff to reduce the chance of re-occurrence

Reliable safety systems and processes (including safeguarding)

There was a safeguarding policy in place which included contact details for local safeguarding teams. The registered manager was the safeguarding lead, and all members of staff had received safeguarding training. Staff were able to describe the process to follow if they had any concerns. Although the service only treated adults the doctor demonstrated an understanding of safeguarding responsibilities for children who may accompany adults to appointments. Individual patient records were stored securely at the clinic.

Medical emergencies

This is a service where the risk of needing to deal with a medical emergency is low, however no risk assessment had been carried out with regards to what may be needed in the event of a medical emergency. The provider did not hold stocks of emergency medicines or equipment. We were told that staff would call the emergency services if necessary. There was an accident book and a first aid kit was available, although some of the contents needed replenishing.

Staffing

We checked employment records for all of the staff at the clinic and found appropriate checks had been carried out, for example proof of identity, full employment history, and confirmation of registration with the appropriate professional body. In addition, all staff had been checked

through the Disclosure and Barring Service (these checks identify whether a person has a criminal record or is on an official list of persons barred from working in roles where they may have contact with children or adults who may be vulnerable).

The service displayed a chaperone poster in the waiting room; however staff told us they had never been asked to provide a chaperone. Staff had not received chaperone training. Some patients chose to see the doctor with a friend or partner but the consultations did not involve an examination.

Monitoring health & safety and responding to risks

Health and safety risk assessments had been carried out and these were regularly reviewed. We saw evidence that the doctors working at the clinic had appropriate professional indemnity insurance relevant to their role. There was a rota in place to ensure a doctor was always present when the clinic was open. There was a system in place to respond to national patient safety alerts such as those issued by the Medicines and Healthcare products Regulatory Agency (MHRA), and records were kept of the action taken in response to these.

Infection control

We observed the premises to be clean and tidy. Handwashing facilities were available in the clinic, as well as gloves and alcohol gel. Patients had access to toilets on the floor below, which was accessible by either stairs or a lift. The service employed a cleaner, however they did not have a cleaning schedule or keep records when cleaning had been completed. The service had not carried out any infection control audits. The manager told us Legionella testing was not due until October 2017 because the sink had been recently installed (Legionella is a term for a particular bacterium which can contaminate water systems in buildings), however they had not carried out a Legionella risk assessment.

Premises and equipment

The premises were rented by the provider who was responsible for maintaining the décor. We observed the premises were in a good state of repair and the facilities were appropriate to meet the needs of patients using the service. Consulting rooms were private and confidential and staff offices and consulting rooms were secured to prevent unauthorised access. We saw evidence that

Are services safe?

electrical equipment was checked to ensure it was safe to use. Fire safety equipment had been serviced in accordance with manufacturer's recommendations. A fire risk assessment had been undertaken and a fire evacuation procedure was in place, which was displayed in the waiting area. There was a record of equipment calibration and a process was in place to ensure this was carried out at the right time.

Safe and effective use of medicines

The doctors at this service prescribed Diethylpropion Hydrochloride and Phentermine. The approved indication for these products are "for use as an anorectic agent for short term use as an adjunct to the treatment of patients with moderate to severe obesity who have not responded to an appropriate weight-reducing regimen alone and for whom close support and supervision are also provided." For both products short-term efficacy only has been demonstrated with regard to weight reduction.

Medicines can also be made under a manufacturers specials licence. Medicines made in this way are referred to as 'specials' and are unlicensed. MHRA guidance states that unlicensed medicines may only be supplied against valid special clinical needs of an individual patient. The General Medical Council's prescribing guidance specifies that unlicensed medicines may be necessary where there is no suitable licensed medicine.

At New Leaf Healthcare – Leeds Clinic we found patients were treated with unlicensed medicines. Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy. Doctors at the clinic explained this to each patient during their consultations.

The British National Formulary states that Diethylpropion and Phentermine are centrally acting stimulants that are not recommended for the treatment of obesity. The use of these medicines is also not currently recommended by the

National Institute for Health and Care Excellence (NICE) or the Royal College of Physicians. This means that there is not enough clinical evidence to advise using these treatments to aid weight reduction.

We checked how medicines were stored, packaged and supplied. Medicines were stored securely in the possession of the prescribing doctor. We saw orders, receipts and prescribing records for medicines supplied by the clinic. Medicines were checked after each clinic session to confirm that records reflected what stock had been supplied. Medicines were dispensed into appropriately labelled containers and records were kept of medicines supplied to patients.

There was a prescribing protocol in place which set out when medicines could safely be prescribed, however this was not in line with national guidance on the management of obesity. For example, the clinic policy stated treatment could be prescribed if a patient had a BMI of greater than or equal to 30Kg/m² or 27Kg/m² with co-morbid factors. National Institute for Health and Care Excellence (NICE) guidance states that in the presence of associated risk factors, it may be appropriate to prescribe an anti-obesity drug to individuals with a BMI of 28kg/m² or greater. We reviewed 17 patient records and found five patients had been prescribed appetite suppressants who had a BMI which was lower than that recommended in the guidance. This meant there was a risk people had been given inappropriate treatment which may have placed them at unnecessary risk. In addition, we found three patients had been prescribed appetite suppressants who had high blood pressure, which was above the safe thresholds set out in the clinic policy and in national guidance. In each case, the prescriber had not documented in the medical notes the reason(s) for these prescribing decisions. This meant patients had been put at risk because they had been prescribed a medicine known to raise the blood pressure when their blood pressure readings had been recorded as high.

Are services effective?

(for example, treatment is effective)

Our findings

Assessment and treatment

We saw evidence that a brief assessment of each patient took place before medicines were prescribed. This included a medical history, blood pressure, and measurement of body-mass index (BMI). During the initial consultation, the doctor discussed the treatment available. Written information was provided on eating healthily, and we saw examples of this. The doctor also checked for contraindications to treatment such as heart disease, high blood pressure, mental ill health, thyroid disorders and pregnancy. Before prescribing medicines, the doctor discussed appetite suppressants, and explained how they should be used and what the side effects could be. Patients were also provided with written information about medicines in the form of a patient information leaflet. We did not see evidence that the service undertook any clinical effectiveness audits to demonstrate effective weight loss over a period of time. The provider sent us evidence of weight loss audits following the inspection, however we were not provided with outcomes or action plans to drive forward improvement where audits had identified problems.

Staff training and experience

There were two doctors who worked at the clinic, both of whom had undertaken specialist training in obesity and weight management. We reviewed records showing staff

had undertaken continuing professional development (CPD), including mental health awareness training. The clinic policy stated clinicians should have an annual appraisal, however the manager was unable to provide us with appraisal records relevant to their role at New Leaf Healthcare on the day of our inspection. We received evidence that appraisals had been completed following the inspection. The service was a member of the Obesity Management Association.

Working with other services

People were asked before treatment commenced if they would like their GP informed of their treatment. The service routinely requested patient's GP details at the first consultation. We saw an example of a letter which could be sent to a patient's GP which was in accordance with GMC standards on information sharing. The manager told us copies of such letters were kept in the patient's medical record.

Consent to care and treatment

Consent was obtained from each patient before treatment was commenced. The doctor we spoke with explained how they would ensure a patient had the capacity to consent to treatment in accordance with the Mental Capacity Act. Where unlicensed medicines were prescribed, the implications of this were explained by the doctor and a record of the discussion made in the patient's medical notes.

Are services caring?

Our findings

Respect, dignity, compassion & empathy

Patients completed CQC comment cards to tell us what they thought about the service. We received 42 completed cards and all were positive. Patients said they felt the clinic offered an excellent service and staff were friendly, caring, and treated them with dignity and respect.

Involvement in decisions about care and treatment

The doctor explained how patients were given information about their treatment which included a range of information on healthy eating and regular exercise. Information on the costs of treatment was provided to patients at their first appointment and the doctor worked with each individual to set treatment goals and targets for weight loss.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting patients' needs

The facilities were appropriate to meet people's needs. We were told that doctors usually worked on the same days of the week which meant patients could usually plan appointments to see their doctor of choice.

Tackling inequity and promoting equality

The premises were accessible to patients with mobility difficulties; there was a lift and doorways and corridors were wheelchair friendly. Information and medicine labels were not available in large print. Written information was not available in any other languages; staff had access to a list of translator services they could use if patients did not

speak English. There was no induction loop available for patients who experienced hearing difficulties; however the provider had surveyed their patients to ask if one was needed and found that it was not.

Access to the service

The clinic ran from 9:30am to 1:30pm on Tuesday, Thursday and Friday, and from 9:30am until 1:00pm every other Saturday. Staff were available for enquiries and booking appointments from 9:00am to 3:00pm Monday to Friday. Patients could also attend the clinic without an appointment as a walk-in service.

Concerns & complaints

The provider had a policy and procedure in place for handling concerns and complaints, and there was information available about the steps people could take if they were not satisfied. We were told there had been no complaints received in the last 12 months.

Are services well-led?

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

Our findings

Governance arrangements

The clinic had a comprehensive set of policies and procedures governing all activities, including infection control, fire safety, recruitment, complaints handling and confidentiality, and these were available to all staff.

Leadership, openness and transparency

The doctor was aware of the need for openness and honesty with patients if things went wrong and would comply with the requirements of the Duty of Candour. Observing the Duty of Candour means that patients who use the service are told when they are affected by something that goes

wrong, given an apology and informed of any actions taken as a result. We saw the manager encouraged an open and honest culture, and all staff were given the opportunity to contribute when changes or improvements to the service were needed.

Learning and improvement

The provider carried out regular audits of prescribing and clinical record keeping to ensure doctors were operating within clinic policies. However, none of these audits had detected the problems we identified with unsafe prescribing during this inspection because the prescribing policy being audited against did not set out safe thresholds for prescribing in accordance with national guidance. We reviewed one significant event relating to a patient who had not divulged their full medical history. We saw this had been properly investigated and changes had been made to clinical documentation to improve medical history taking. In addition, learning from the incident had been shared with all staff at the clinic to reduce the chance of re-occurrence.

Provider seeks and acts on feedback from its patients, the public and staff

A patient feedback form and comment cards were available should patients wish to use them, however the provider did not encourage or routinely seek patient feedback. There were no formal staff meetings, however the staff we spoke with told us they were able to share ideas with the registered manager to improve the service.

This section is primarily information for the provider

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
Services in slimming clinics	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>The registered person had not ensured that care and treatment was provided in a safe way for service users. In particular, there were unsafe prescribing practices.</p>