Medical Slimming Clinic Ltd

Medical Slimming Clinic - Rotherham

Inspection report

94 Wellgate
Rotherham
South Yorkshire
S60 2LP
Tel: 01709 837462
Website:

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Overall summary

We carried out an announced comprehensive inspection on 19 January 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 because safety systems and processes were not reliable, proper recruitment checks had not been carried out, infection prevention and control arrangements were inadequate, medicines were not managed safely, and equipment was not maintained appropriately.

Are services effective?

We found that this service was not providing effective care in accordance with the relevant regulations because decisions about treatment were not always clearly recorded in patient's records and medicines were not prescribed in line with manufacturer's recommendations.

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations as staff were friendly and helpful however, the environment was not conducive to support people's privacy.

Are services responsive?

We found that this service was not providing responsive care in accordance with the relevant regulations as the service was inaccessible to patients with mobility difficulties, there was no hearing loop and information was not available in other languages. The clinic did not have access to an interpreter service.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations because the provider did not have adequate systems and processes in place to monitor and improve the quality of the service being provided.

Our key findings were:

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

- Ensure adequate infection control measures are in place at the service.

Summary of findings

- Ensure proper recruitment checks are carried out prior to employment.
- Ensure robust systems and processes are in place to prevent abuse of service users.
- Ensure all electrical appliances on the premises have been PAT tested, and medical equipment is regularly calibrated.
- Ensure there are safe systems in place for the management of medicines.
- Ensure there are systems and processes in place to monitor and improve the quality of services being provided.
- Introduce an up to date record of appraisals and system to confirm revalidation of medical staff.
- Ensure risk assessments are completed for emergency medicines and equipment.
- Ensure treatment protocols clearly set out when it is appropriate to prescribe medicines, and that unlicensed medicines are only supplied against valid special clinical needs of an individual patient where there is no suitable licensed medicine available

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:

- Review methods to encourage feedback from patients and show how patient feedback is driving improvements within the service
- Review interpretation services offered to clients who speak another language
- Review adjustments for disabled patients to ensure they are not disadvantaged compared to non-disabled patients.
- Review facilities to maintain dignity and privacy of service users.
- Review the process for sharing details of consultations for patients who do not opt out of information being shared with their GP.

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 have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

The provider did not have robust arrangements in place to keep people protected and safeguarded from abuse. Appropriate recruitment checks had not been carried our prior to staff being employed. The premises were clean and tidy however there was no infection control policy in place and there were no supplies of examination gloves or a sink in the clinic room. Medical equipment had not been calibrated. Medicines were stored safely in accordance with legal requirements however, there were no facilities or procedures for the safe destruction of out of date medicines.

Are services effective?

We found that this service was not providing effective care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

A brief assessment of each patient took place before medicines were prescribed. However, in some cases medical histories were not fully completed, clinical assessments were not fully documented and decisions relating to treatment were not clearly recorded in patient's notes. Patients were provided with written information about medicines in the form of a patient information leaflet.

Are services caring?

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

Staff were friendly and helpful. However, the environment was not conducive to support people's privacy when arriving at the clinic and during the consultation.

Are services responsive to people's needs?

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

We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

The premises were inaccessible to patients with mobility difficulties and there was no hearing loop for patients with hearing difficulties. Written information was not available in any other languages; the clinic did not have access to interpreter services.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

The clinic had a number of policies and procedures in place to govern activity although some of these were not fit for purpose. The provider had no comprehensive assurance systems and there was no systematic programme of clinical or internal audit to monitor the quality of the service. There were no systems in place for knowing about notifiable safety incidents, and the views of patients were not routinely sought or encouraged.

Medical Slimming Clinic - Rotherham

Detailed findings

Background to this inspection

Background

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.

Medical Slimming Clinic Limited has two sites; one in Doncaster and one in Rotherham. We inspected the Rotherham location which is located near Rotherham city centre. The service comprises of a reception, office areas and one clinic room. A toilet facility is available on the clinic premises. There are clinicians, a manager, receptionist and cleaner who work at the service. The service is open Tuesday 4pm to 6pm Thursday 11am to 1pm and Saturday 10am to 12 noon. Slimming and obesity management services are provided for adults from 18 to 65 years of age either by appointment or on a 'walk –in' basis.

Are services safe?

Our findings

Reporting, learning and improvement from incidents

We were told that there had been no incidents in the previous 12 months. The provider could tell us what they would do in the event of an unintended or unexpected safety incident. There was no system in place for knowing about notifiable safety incidents.

Reliable safety systems and processes (including safeguarding)

There was a safeguarding policy in place which had been recently updated to include the contact details for the safeguarding contacts at the local authorities. The policy itself did not describe how staff should report concerns. The registered manager told us the doctors working at the clinic had received safeguarding training but was unable to provide us with training records during the inspection (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 a legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run). There was no named safeguarding lead, but the registered manager and clinician told us what action they would take in the event of a safeguarding concern. Individual patient records were stored securely in the clinic. The registered manager told us that a chaperone was not available and that none of the staff had received training for this role.

Medical emergencies

Emergency medicines and equipment were not available at the service and the provider had not carried out a risk assessment of what medicines or equipment may be needed in the event of an emergency.

Staffing

We looked at employment records for three clinical staff and found appropriate recruitment checks had not been undertaken prior to them being employed which was not in line with the service's recruitment policy. For example, proof of identity, full employment history, confirmation of registration with the appropriate professional body, and appropriate checks through the Disclosure and Barring Service (These checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable). We checked that the doctors working at the service were registered with the General Medical Council (GMC). There was also a receptionist and cleaner who worked at the service. The registered manager could not provide us with any documentation relating to their employment.

Monitoring health & safety and responding to risks

A risk assessment had taken place for monitoring and managing risks to patient and staff safety, however this was limited in scope and focused primarily on environmental risks for example accidental damage to the aquarium may cause injury and low windows and glass doors may cause injury if broken. The actions required to mitigate risks were basic, for example, the action for the identified risk to the aquarium stated 'No member of the public to approach the aqaurium'. No records were available to show staff had completed health and safety awareness training.

We saw evidence that most electrical equipment was checked to ensure it was safe to use, and fire safety equipment had been serviced. However, on the day of our visit we found two items of electrical equipment in the reception area had not been tested.

The provider had no risk assessments in place for control of substances hazardous to health, infection control or Legionella (Legionella is a term for a particular bacterium which can contaminate water systems in buildings).

The registered manager did not have evidence of clinical staff's professional indemnity arrangements.

Infection control

The premises were clean and tidy. There was no infection control policy in place. The registered manager told us they employed a cleaner who came to the service weekly. Not all areas had been cleaned in December 2016 as ticks were missing from the cleaning schedule.There were no supplies of examination gloves, or a sink in the clinic room. Staff had access to a sink, liquid soap, alcohol gel and paper towels in the kitchen area, which was situated next to the consultation room. Staff and service users had access to a toilet on the second floor however there were no paper towels available in the toilet area. No infection control audits had been completed and new employees had no record of infection control training as part of their induction.

Are services safe?

Premises and equipment

The premises were generally in a good state of repair. There was a fire evacuation policy displayed in the waiting area. Fire equipment had recently been serviced. There was no fire alarm at the premises. We found that weighing scales in the clinic room had not been calibrated and there was no calibration schedule in place. This meant that we could not be sure that the measurements being recorded during consultations were accurate.

Safe and effective use of medicines

Medical Slimming Rotherham prescribes Diethylpropion Hydrochloride and Phentermine.

Diethylpropion Hydrochloride tablets 25mg and Phentermine modified release capsules 15mg and 30mg have product licences and the Medicine and Healthcare products Regulatory Agency (MHRA) have granted them marketing authorisations. The approved indications for these licensed 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 Medical Slimming Clinic Rotherham we found that 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.

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 are 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.'

Medical Slimming Clinic Rotherham had a policy for the dispensing and control of medicines. The policy was limited in detail. Medicines were stored securely in accordance with legal requirements and under the personal control of the doctor. We saw records of the ordering, receipt and prescribing of medicines. The policy detailed that balance checks of medicines were to be carried out each month however we saw no evidence of regular balance checks. The last full check had been carried out in August 2016. Medicines were dispensed by the doctor according to the clinic policy, however the labels used did not comply with professional guidance for example one set of labels did not have a space for the patients name a second label did not specify 'Keep out of reach of children'. Appropriate records of supplies were made in patient's notes at the time of supply. However, the entries in the controlled drug register did not always match to the entry made in the service user's notes.

We found a number of medicines, which had expired in October 2016, and were no longer used at the clinic as the provider had stopped offering these services. The medicines were not stored securely and there was no process in place for their safe disposal.

Are services effective?

(for example, treatment is effective)

Our findings

Assessment and treatment

We saw evidence that prior to prescribing, a brief medical assessment took place. This included a medical history, blood pressure and calculation of body-mass index (BMI). During the initial consultation the doctor discussed the treatments available. Information was recorded on the medical history and consent form and this identified if the person had any contra indications such as heart disease, high blood pressure, glaucoma, thyroid disorders and pregnancy. We saw that in some cases medical histories were not fully completed and allergy status was not always recorded.

The policy for the dispensing and control of all medicines set out the prescribing thresholds, and the doctor we spoke to confirmed the thresholds which were set out in the policy. Before prescribing, the doctor discussed the treatment options and explained how they should be used and what side effects could be experienced. Patients were also provided with written information about medicines in the form of a patient information leaflet.

We checked 20 sets of patient records and saw that regular reviews of weight, BMI and blood pressure were not always recorded. We saw that most patients were given limited supplies of medicines however we saw for two patients two weeks supply of medicines had been given within five days of the last supply. No record was made to explain why a second two week supply had been given five days after the initial two week supply. We also saw for one patient who had their first appointment during the inspection that four weeks of medicines had been given. The provider did not have a policy on the quantity of medicines to be supplied or the review period.

We saw that seven of the 20 patients we reviewed had received medicines even though their BMI was less than 30Kg/m2. This was not in line with the provider's policy, product license, or national guidance and no co-morbidities were recorded.

Staff training and experience

There were four doctors who worked at the clinic; none of the doctors had undertaken any specialist training in obesity or weight management. There were no records showing clinicians had undertaken any continuous professional development (CPD) in this area of practice. The provider did not have a record of appraisals or confirmation of doctors' revalidation.

Working with other services

As part of the consent form people were asked if they would like their GP to be informed of their treatment. If they did not agree they could opt out by ticking a box on the consent form. In two cases we saw patients had not opted out, however the letter to their GP remained in their patient file and there was no record of any communication being sent to their GP.

Consent to care and treatment

Consent was obtained from each patient before treatment was commenced. However the consent document did not refer to unlicensed medicines. Clinical staff showed a lack of understanding of what unlicensed medicines were. Information was not provided to inform patients what unlicensed medicines were. The doctor we spoke with explained how they would ensure a patient had capacity to consent to treatment in accordance with the mental capacity act. Patients had to sign to confirm they would inform clinic staff of any change in their health or circumstances and take reasonable precautions not to become pregnant during treatment with appetite suppressants.

Are services caring?

Our findings

Respect, dignity, compassion & empathy

We were shown four customer questionnaires. The customer questionnaire referred to services, which were no longer provided at the location and did not cover areas such as helpfulness, caring, dignity and respect. All four patient's stated that they were very satisfied with the customer services provided by the clinic and that staff were friendly and helpful.

Consultations took place in a consultation room located at the rear of the waiting area. Privacy was not maintained during the consultation as the door to the room was clear glass and no screen was available.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Tackling inequity and promoting equality

The premises were inaccessible to patients with mobility difficulties; the entrance to the building was via two steps and the toilet was on the first floor. There was no lift in the building. The provider did not have a hearing loop for patients with hearing difficulties and written information was not available in any other language. The clinic did not have access to an interpreter and patients were encouraged to bring a relative or friend who could translate for them.

Access to the service

The clinic ran from 4pm to 6pm on Tuesday, 11am to 1pm on Thursday and 10am to 12noon on Saturday. Staff were available for enquiries and booking appointments by telephone during normal business hours. Patients could also attend the clinic without an appointment as a walk in patient. One of the customer questionnaires mentioned that the clinic could open more hours/days.

Concerns & complaints

The provider had a procedure in place for handling concerns and complaints; this was displayed in the waiting area but was not dated or version controlled. 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

Medical Slimming Clinic Rotherham had a registered manager in post (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 a legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run).

The clinic had a number of policies and procedures in place to govern activity although some of these were not fit for purpose as they were limited in scope and detail. In addition, they were not version controlled or dated and there was no record of staff having read the policies as part of their induction.

Leadership, openness and transparency

The provider could describe what they would do if there were unintended or unexpected safety incidents. The service had no systems in place for knowing about notifiable safety incidents. The service had no robust systems or processes in place to provide safe care. Available procedures were not being followed and there was no process in place to assess compliance with policies or procedures.

Learning and improvement

The provider had no comprehensive assurance systems or performance measures in place and there was no programme of clinical or internal audit to monitor the quality of the service.

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

The views of patients were not routinely sought or encouraged, on the day of our visit three patient feedback forms were completed and we were shown a fourth form dated 6 September 2016. We were told there had been no suggestions for service improvement made in the last 12 months.

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
Services in slimming clinics	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment How the regulation was not being met: The provider failed to monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity. Specifically equipment had not been tested or calibrated, systems were not in place to safely manage medicines and there were inadequate infection control measures in place at the service This was in breach of regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Services in slimming clinics	Regulation 17 HSCA (RA) Regulations 2014 Good governance How the regulation was not being met; The provider failed to assess, monitor and improve the quality and safety of the services provided or to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity. Specifically the provider did not thoroughly, monitor and mitigate all potential health and safety risks. Employment checks had not been performed. Service users were not protected from abuse. This was in breach of regulation 17 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.