

Medical Slimming Clinic Ltd

Medical Slimming Clinic - Doncaster

Inspection report

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Overall summary

We carried out an announced comprehensive inspection of this service on 03 February 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 breaches of regulations 12, 13, 17, 18 and 19 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

We undertook this focused inspection to check that they had followed their plan and to confirm that they now met legal requirements. This report only covers our findings in relation to those requirements. You can read the report from our last comprehensive inspection, by selecting the 'all reports' link for Medical Slimming Clinic -Doncaster on our website at www.cqc.org.uk.

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 and a fire risk assessment had not been carried out.

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 prescribed against manufacturer's recommendations.

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.

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

- Ensure there are adequate systems and processes in place to monitor and improve the quality of the service being provided
- Ensure there is an adequate fire risk assessment in place
- Ensure there are safe systems in place for the management of medicines
- 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 that robust systems and processes are in place to prevent abuse of service users
- Maintain an up to date record of appraisals
- Only supply unlicensed medicines 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:

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. They had not carried out appropriate recruitment checks prior to staff being employed. There were ineffective infection prevention and control measures in place. Firefighting equipment had not been serviced in accordance with the manufacturer's recommendations. Medicines were not managed safely.

Are services effective?

We found that this service was not providing effective services 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 and decisions relating to treatment had not been clearly recorded in the patient's notes. There was no protocol in place to set out clear thresholds for treatment and medicines were prescribed against manufacturer's recommendations.

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 or performance measures in place, and there was no systematic programme of clinical or internal audit to monitor the quality of the service. The views of patients were not routinely sought or encouraged.

Medical Slimming Clinic – Doncaster

Detailed findings

Background to this inspection

We undertook an unannounced focused inspection of Medical Slimming Clinic -Doncaster on 17 December 2016. This inspection was carried out to check that improvements to meet legal requirements planned by the

service after our comprehensive inspection on 03 February 2016 had been made. We inspected the service against three of the five questions we ask about services: is the service safe, effective, and well-led. This is because the service was not meeting some legal requirements.

Are services safe?

Our findings

During our previous inspection we found the provider did not have appropriate arrangements in place to keep people protected and safeguarded from abuse and they had not carried out appropriate recruitment checks 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 sterile gloves, alcohol gel, or a sink in the clinic room. Fire fighting and medical equipment had not been serviced or calibrated in accordance with the manufacturer's recommendations. During this inspection, we checked to see what improvements had been made.

Reliable safety systems and processes (including safeguarding)

At our previous inspection we found the safeguarding policy had not been updated since 2011 and was not fit for purpose. During this inspection we found the safeguarding policy had been updated in June 2016. However, the policy was still not fit for purpose and did not describe when or how staff should report concerns. The registered manager told us they were the safeguarding lead, however they had not received any training for this role (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 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.

Staffing

We looked at employment records for three doctors and found appropriate recruitment checks had not been undertaken prior to two of them being employed. For example, proof of identity, satisfactory references and confirmation of registration with the appropriate professional body. In addition, the registered manager could not provide us with evidence that any of the three doctors had appropriate medical indemnity insurance. There was a fourth doctor who had been working at the clinic since October 2016; the registered manager could not provide us with any documentation relating to their

employment or proof of indemnity insurance. We checked with the general medical council (GMC) and found all of the doctors working at the service were registered with a licence to practise.

Infection control

The premises were clean and tidy. There was an infection control policy in place; the registered manager told us they performed cleaning duties twice weekly as set out in the cleaning schedule. We reviewed cleaning records and found this had only been carried out once-weekly. There were no hand-washing facilities in the clinic room. Alcohol gel was available in both the clinic room and reception area, and examination gloves were also available. Staff had access to a sink with liquid soap which was situated upstairs in the toilet above the clinic room, although there were no supplies of paper towels available. The registered manager told us no infection control audits had been carried out in the last 12 months.

Premises and equipment

The premises were generally in a good state of repair. There was information displayed in the reception area about what to do in the event of a fire and there was a fire evacuation procedure in place. Firefighting equipment had been serviced in February 2016, however the registered manager had never carried out a fire risk assessment and could not confirm fire alarms were in working order. We found weighing scales and blood pressure monitoring equipment in the clinic room had been calibrated within the last 12 months. Portable electrical appliances had been tested for safety in accordance with legislation.

Safe and effective use of medicines

Doctors at the service prescribed the appetite suppressants 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 market authorisations. The approved indications are "for use as an anorectic agent for short term use for the adjunct 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.

Are services safe?

Diethylpropion and Phentermine are not currently recommended for the treatment and management of obesity by the National Institute for Health and Care Excellence (NICE) or the Royal College of Physicians (RCP). The British National Formulary (BNF) states that these medicines are centrally acting stimulants that are not recommended for the treatment of obesity.

Medicines can also be made under a manufacturers special 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 -Doncaster 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.

Are services effective?

(for example, treatment is effective)

Our findings

During our previous inspection we found a brief assessment of each patient took place before medicines were prescribed. However, in some cases medical histories were not fully completed and decisions relating to treatment had not been clearly recorded in the patient's notes. There was no protocol in place to set out clear thresholds for treatment. During this inspection, we checked to see what improvements had been made. We reviewed patient records and found problems with six out of seven of them.

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). The doctor also checked for contraindications to treatment such as heart disease, high blood pressure, glaucoma, thyroid disorders and pregnancy. However, we saw examples of poor practice:

- In two cases medical histories were not fully completed and in one case medicines had been prescribed when they were contra-indicated
- Decisions relating to treatment had not been clearly recorded in the patient's notes. For example, we saw two patients with high blood pressure had been prescribed treatment with appetite suppressants, which is against the manufacturer's recommendations. The doctor had not recorded the rationale for prescribing

the treatment taking into account the raised blood pressure. This meant patients were at risk of harm because they were being prescribed medicines known to raise the blood pressure when their blood pressure readings had been recorded as high.

- Two patients had been prescribed appetite suppressants when their BMI had been recorded as less than 27Kg/m². Initiating treatment in this way is contrary to national guidance on the management of obesity. In addition, the appetite suppressant is only licensed for use in patients having a BMI greater than or equal to 30Kg/m². We asked the registered manager about treatment thresholds; they told us appetite suppressants should not be prescribed to people who had a BMI less than 30Kg/m² or 27Kg/m² with co-morbidities.
- We found regular monitoring of height, weight, BMI and blood pressure had not always been recorded for two patients. This meant patients were at risk of harm because they were not being properly monitored for the adverse effects of the treatment they had been supplied.
- When patients were prescribed unlicensed medicines, records did not show informed consent had been obtained. This meant patients were not fully informed about the risks of their treatment.
- Patients were asked for their consent to share information about their treatment with their usual GP. We saw that where patients had consented to this information being shared, there were no records of any communication with their GP.

Are services well-led?

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

Our findings

During our previous inspection, we found 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 or performance measures in place, 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. During this inspection, we checked to see what improvements had been made.

Governance arrangements

The clinic had a number of policies and procedures in place to govern activity although some of these were not fit for purpose. For example, the recruitment and selection policy had no date of implementation or review, and contained information that was not specific or relevant to the service. The policy referred to the chief executive (the service does not employ a chief executive) and included optional paragraphs which stated “delete as appropriate”.

We asked the registered manager if there was a written policy in place which specified the thresholds for the safe treatment of patients with appetite suppressants. The registered manager told us there was no policy or guidance, however they stated treatment should not be

prescribed if the blood pressure was high or if the BMI was less than 30Kg/m² or 27Kg/m² with co-morbidities. During the inspection, we found evidence that treatment had been prescribed to patients outside of these parameters.

The provider had no comprehensive assurance systems or performance measures in place, and there was no systematic programme of clinical or internal audit. This meant the provider could not assess or monitor the quality and safety of the service they provided, meaning they were not able to identify and mitigate risks posed to patients who used the service.

During the inspection, the registered manager provided us with a risk assessment form which had been completed in April 2012. This risk assessment identified four low risk items, for example the heating system not working properly. The document had been signed to say it had been reviewed in April 2013, June 2013, June 2014, June 2015 and April 2016. There had been no change in the risks identified or any mitigating actions put in place over this four year period. This meant the provider had repeatedly not acted to mitigate known risks to staff and patients using 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; we were provided with a blank patient feedback pro-forma but no completed feedback forms were available. 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	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>The provider did not have robust systems and processes in place to prevent abuse of service users.</p> <p>The provider did not have safe systems in place for the management of medicines.</p> <p>There were inadequate infection control measures in place at the service.</p> <p>The provider had not carried out an adequate fire risk assessment</p>
Regulated activity	Regulation
Services in slimming clinics	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>The provider did not have adequate systems and processes in place to monitor and improve the quality of the service being provided.</p> <p>The provider had not maintained up to date records relating to appraisal and revalidation.</p> <p>The provider had not undertaken the proper employment checks as set out in Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and had not performed checks with the relevant professional body to confirm registration.</p>