

Medical Slimming Clinic Ltd

# Medical Slimming Clinic - Rotherham

## Inspection report

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### Overall summary

We carried out an announced comprehensive inspection of this service on 19 January 2017. Breaches of legal requirements were found in relation to breaches of regulations 12 and 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

We undertook this focused inspection to confirm the provider 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 –Rotherham on our website at [www.cqc.org.uk](http://www.cqc.org.uk). We carried out a focused inspection on 13 July 2017 to ask the service the following key questions: Are services safe, effective 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 medicines were not managed safely, and appropriate checks or risk assessments had not been carried out as part of the recruitment processes for clinical staff.

##### **Are services effective?**

We found that this service was not providing effective care in accordance with the relevant regulations because medicines were not prescribed safely in line with the Medical Slimming Clinic policy and the process in place for sharing information with GPs when patient's have complex medical conditions was not robust.

##### **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 systems and processes in place to monitor and improve the quality of the service being provided.

##### **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.

At the last inspection on the 19 January 2017 we found a breach of legal requirements Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment because the

# Summary of findings

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. We checked this as part of this focussed inspection and found that some areas had not been resolved.

Also at the last inspection on the 19 January 2017 we found a breach of legal requirements Regulation 17 HSCA (RA) Regulations 2014 Good governance because 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.

We checked this as part of this focussed inspection and found that some areas had not been resolved.

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.

## Our key findings were:

- The Provider had improved the recruitment documentation in the service.
- Consent was obtained before treatment commenced.

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

- Ensure there are safe systems in place for the management of medicines.
- Ensure there are effective systems and processes in place to assess, monitor and improve the quality of services being provided.
- Ensure that doctors working at the service have the appropriate medical indemnity insurance.
- Review the process for starting medicines in people with a body mass index less than 30 kg/m<sup>2</sup> to ensure that national guidance and the clinic policy is followed.

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:

- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.
- Review the need for a risk assessment for chaperoning at the service and staff training requirements as necessary.

# 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).

Medicines were not managed safely. People were not protected from the risk of harm from abuse.

### **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).

An assessment of each patient took place before medicines were prescribed. However, medicines were not always safely prescribed in line with the Medical Slimming Clinic policy and national guidance on obesity management.

### **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).

There were governance arrangements in place to monitor the quality of the service however these were not effective and had not picked up the issues we found.

# Medical Slimming Clinic - Rotherham

## Detailed findings

### Background to this inspection

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.

We carried out an announced focussed inspection at Medical Slimming Clinic Rotherham on 13 July 2017. The inspection was led by a CQC Pharmacist Specialist accompanied by a CQC Regional Medicines Manager.

Before visiting, we looked at a range of information that we hold about the clinic including the previous inspection report and notifications.

The methods that were used during our visit included, interviewing staff, observations and review of documents.

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 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.

During this inspection, we checked to see what improvements had been made.

### **Reliable safety systems and processes (including safeguarding)**

There was a safeguarding policy in place which included the contact details for the safeguarding contacts at the local authorities. The acting Manager told us the doctors working at the clinic had received safeguarding training in their work with other organisations but was unable to provide us with training records during the inspection to confirm this. The safeguarding lead named in the policy was the registered manager, however we were told they were no longer working at the service. The acting manager had not completed safeguarding training. The doctor confirmed they had completed safeguarding training and told us what action they would take in the event of a safeguarding concern.

Individual patient records were stored securely in the clinic. The service did not have a chaperoning policy. This service was not provided and no assessment had taken place to identify its need. Staff told us that they had not been asked to chaperone.

### **Staffing**

We looked at employment records for five doctors and found appropriate recruitment checks were now in place. For example, proof of identity, full employment history, and confirmation of registration with the appropriate professional body. All doctors had been checked through the Disclosure and Barring Service (DBS). We checked that the doctors working at the service were registered with the General Medical Council (GMC). The acting manager could not provide us with evidence that one of the five doctors had appropriate medical indemnity insurance. There were also recruitment files for the receptionist and cleaner who worked at the service.

### **Monitoring health & safety and responding to risks**

No records were available to show staff had completed health and safety awareness training. However the acting Manager told us the doctors working at the clinic would receive health and safety training in their work with other organisations the service had not sought confirmation of this.

We saw evidence that electrical equipment was checked to ensure it was safe to use. We checked nine pieces of electrical equipment and all had been tested in March 2017. We also saw an invoice showing on that in March 2017 a total of 38 pieces of equipment had been checked and all had passed. Fire safety equipment had been serviced in accordance with manufacturer's recommendations.

### **Infection control**

The premises were clean and tidy. Since our last visit the provider had introduced an infection control policy dated June 2017. The acting manager told us they employed a cleaner who came to the service weekly. There was a cleaning record in place which had been ticked weekly listing the areas cleaned. The clinic room now had supplies of examination gloves and a sink in place.

Infection control audits had been completed monthly however it was not clear what action was taken where issues were identified. In addition, when we checked the audit dated June / July 2017 one issue had been identified that the audit stated required immediate action however it was not clear whether any action had been taken.

There was no evidence that staff had undertaken infection control training although the risk of infection was low.

### **Premises and equipment**

The service was located on the ground floor and consisted of a reception area and a private clinic room. The clinic also had access to a toilet. The premises were generally in a good state of repair.

There was a fire evacuation policy displayed in the waiting area. Staff knew where the assembly point was in the event of a fire but no fire evacuation drill had taken place. Fire equipment had recently been serviced. The fire service had visited since our last inspection and made a number of recommendations which the provider had implemented. There was no fire alarm at the premises and

## Are services safe?

the fire policy had now been updated to show that no fire alarm was present and smoke detectors were fitted. We were told that these were checked weekly on a Saturday however no records were kept.

We found two sets of weighing scales in the clinic; one was new and we were sent a receipt five days after the inspection to show the other set was calibrated in February 2017. We tested them on the day of the inspection and they weighed differently by 1.8kg. The doctor we spoke with at the inspection told us they were aware of this and encouraged patients to be weighed on the same scales at each visit though it was not documented in their treatment record which scales had been used.

### **Safe and effective use of medicines**

Medical Slimming Rotherham prescribes Diethylpropion Hydrochloride and Phentermine tablets. The approved indications for the 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. The products used by the Medical Slimming Clinic Rotherham are made under a manufacturer’s 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 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 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.’

Medical Slimming Clinic Rotherham had updated their medicines handling policies since our last visit and these were now version controlled, however there was no policy or procedure in place to cover the dispensing process. Medicines were stored securely in accordance with legal requirements and were under the personal control of the doctors working at the clinic. We saw records for the ordering, receipt and prescribing of medicines. We asked the clinic Doctor to check the stock levels of the medicines during our visit and they found for the three medicines that were kept by the clinic all stocks were incorrect. Five days after the inspection we received a letter from the provider stating that there had been a mistake in the dispensing process and that the strengths of the medicines had been mixed up and dispensed into the wrong bottles. This letter stated that the stock levels were now correct. This letter also stated that the doctors at the clinic had been reminded about checking medicines carefully whilst dispensing and supplying medicines to patients. This meant that there was a risk that the dispensing process was not safe. Labels on the medicines seen during our inspection contained all the required information. Appropriate records of medicines dispensed and given to patients were made in patient’s notes during the consultations. Entries were made at the end of clinic in the controlled drug register.

# Are services effective?

(for example, treatment is effective)

## Our findings

During our previous inspection we found that 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. During this inspection, we checked to see what improvements had been made. We reviewed patient records and found concerns with 5 out of the 16 records we checked.

### Assessment and treatment

We saw records that showed a medical assessment took place before medicines were prescribed and dispensed to patients. This included a medical history, a blood pressure measurement, a calculation of body-mass index (BMI) and setting a target weight loss. During the first visit to the clinic the patient completed the assessment form and the Doctor discussed any issues that arose from this and then prescribed medicines if appropriate.

The policy for the dispensing and control of all medicines described prescribing thresholds, and the doctor we spoke with confirmed they were following these the thresholds. However these were not in line with current guidance (NICE(National Institute for Health and Care Excellence) guidelines: Obesity: identification, assessment and management of overweight and obesity in children, young people and adults) which states that an anti-obesity drug should only be considered for those with a BMI of 30 or greater "In whom at least three months of managed care involving supervised diet, exercise, and behaviour modification fails to achieve a realistic reduction in weight. In the presence of associated risk factors, it may be appropriate to prescribe an anti-obesity drug to individuals with a BMI of 28kg/m<sup>2</sup> or greater." The clinic policy stated people with co-morbidities could be treated with a BMI of 27kg/m<sup>2</sup> or greater so this did not match current guidelines. This meant there was a risk people would be given inappropriate treatment and placed them at unnecessary risk.

We saw information available to patients about the risks of taking the medicines prescribed by the clinic. A medicines information sheet was available and this described risks for

both medicines used by clinic. However this was not specific to the particular medicine supplied to patients and so did not comply with dispensing laws. The Doctor told us that they explained the risks and side effects during the consultation and that they gave the medicines information sheet to each patient.

We checked 16 sets of patient records. Weight, BMI and blood pressure were routinely recorded but we found a number of records which raised concerns that treatment was not being prescribed safely following national guidelines and clinic policy. Two people were given four weeks' supply of medicine on their first visit and three people were given two weeks, another was given four weeks' supply on their second visit. Clinic policy stated on the first visit one week only should be supplied so their health can be monitored after one week before the next supply, it also stated 28 days could be supplied if the patient has been for at least three weeks and there is a need such as holiday or work commitments. Another person could not have their blood pressure measured as the blood pressure cuff was too small, records showed they were given two supplies of medicine but the doctor had not taken their blood pressure so there was a risk the treatment might not be safe.

### Staff training and experience

There were five 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 had a record of appraisals for two of the doctors working in the clinic.

### 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 for the GP to be informed they could opt out by ticking a box on the consent form. We saw letters in patient's notes that stated the treatment they were having. Clinic staff told us a copy of this was given to the patient to take to their Doctors if they so wished. Clinic staff told us they could not recall contacting a GP directly as normally they would ask the patient to pass on the information

# Are services effective?

(for example, treatment is effective)

themselves. One patient was supplied with medication without their GP being informed even though they had a complex long term medical condition which required regular monitoring.

## **Consent to care and treatment**

Consent was obtained from each patient before treatment was commenced. A new form about the use of the unlicensed medicines had been developed since our last inspection and this was seen in a number of patient records. The medicines information leaflet provided to patients also contained information about the use of unlicensed medicines.



# Are services well-led?

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

## Our findings

At our last inspection we found that this service was not providing well-led care in accordance with the relevant regulations. We found that 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. At this inspection we found that some assurance systems were now in place but these had not identified the issues we found.

### Governance arrangements

Medical Slimming Clinic Rotherham had a registered manager in post, however we were told that they were not currently involved in the running of the service (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).

A statement of purpose was in place. The clinic had a number of policies and procedures to govern activity and

these were available to the doctors and staff. We were told by the acting manager that a new form had been introduced for staff to sign to indicate they had read and understood the policies, however we found that it had not been completed by any of the staff working in the clinic. The doctor in the clinic on the day of our visit confirmed that they had read the policies but had not been asked to sign the new form.

### Learning and improvement

There were a limited number of audits in place to monitor the quality of the service. Monthly audits included infection control audit, patient medical record audit and new patient audit.

However these were not effective and had not identified the issues we found, for example the controlled drugs policy stated that balance checks of medicines were to be carried out each month. When we checked the register we saw a record of monthly checks had been made, however, we found these checks were inadequate as the actual stocks of medicines were not counted. The patient medical record audit had not been scored for the quality of the information as directed in the guidance for this audit. We also found that the infection control audit for June /July 2017 identified one issue which required immediated action but there was no action plan in place to show how it was being addressed.

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.

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><b>The provider did not have robust systems and processes in place to prevent abuse of service users.</b></p> <p><b>The provider did not have safe systems in place for the safe management of medicines</b></p>
Services in slimming clinics	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p><b>The provider did not have adequate systems and processes in place to monitor and improve the quality of the service being provided.</b></p>