

Slimfactor Limited

Slimmingmedics High Wycombe

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 28 March 2018 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 not providing well-led care in accordance with the relevant regulations

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.

The Slimmingmedics High Wycombe clinic provides weight loss services, including prescribed medicines and dietary advice to support weight reduction. The clinic is located on the first floor of a shared building in the town centre, and includes a reception area, a waiting room and one consulting room. The clinic is open for half a day twice week, on Wednesdays and Saturdays.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of the provision of advice or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of weight reduction. At Slimmingmedics High Wycombe the aesthetic cosmetic treatments that are also provided are exempt by law from CQC regulation. Therefore we were only able to inspect the treatment for weight reduction but not the aesthetic cosmetic services.

Staff include a clinic manager, two doctors (one available at each session), and one receptionist. The clinic

Summary of findings

manager is also 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.

We collected feedback about the service from twenty patients through comment cards and speaking to patients during the inspection. The observations made were all positive, and patients told us they found staff to be friendly, professional and respectful. Patients said they felt supported to lose weight and were given lots of encouragement, guidance and advice.

Our key findings were:

- There were no effective systems and processes in place to prevent abuse of service users
- The provider did not have systems and processes in place to monitor and improve the quality of services being provided. This included a lack of incident reporting systems, risk assessments, safety alerts and clinical audit
- Patients were assessed and monitored before and during treatment, and were provided with support and information
- We found feedback from patients was positive about the friendliness of staff and the care they received at the clinic

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

- Ensure patients are protected from abuse and improper treatment
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care

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 the need for chaperoning at the service and staff training requirements if necessary
- Improve the process for disposing of medicines so that it complies with the Misuse of Drugs Act 1971 and its associated regulations
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available
- Improve the training and appraisal requirements for all staff
- Review the arrangements necessary to meet the needs of patients with a disability, impairment or sensory loss and those needing translation

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 Requirement Notices at the end of this report).

The provider did not have suitable arrangements in place to keep people protected and safeguarded from abuse. The provider had no system in place to receive and action patient safety alerts, or for recording and learning from safety incidents. The clinic should only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available, and should introduce procedures for the safe and legal disposal of unwanted medicines.

Are services effective?

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

Doctors at the service screened and assessed patients prior to treatment, and ensured that individual consent was obtained before beginning treatment. Patients' on-going care and treatment was monitored, and patients were provided with support and information.

However, we found areas where improvements should be made relating to the effective provision of treatment. This was because the provider did not have a system for training and appraisal of staff to meet the needs for them to fulfil their roles.

Are services caring?

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

Patients were positive about the service provided at the clinic and told us that staff were friendly, professional and respectful. Patients felt they were treated with dignity and respect and were supported to make decisions about their care and treatment.

Are services responsive to people's needs?

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

However, we found areas where improvements should be made relating to the responsive provision of treatment. This was because the provider had not reviewed the needs of patients with protected characteristics such as a disability, impairment or sensory loss, or those needing translation, and there was no process for patients to raise concerns or complaints.

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 Requirement Notices at the end of this report).

The service lacked good governance arrangements and did not have systems to review, monitor and improve the quality of the service being provided. There were no systems for assessing and mitigating the risks relating to the health, safety and welfare of staff, patients or others, which arise from the carrying out of the regulated activity.

Slimmingmedics High Wycombe

Detailed findings

Background to this inspection

We carried out this inspection on 28 March 2018. The inspection was led and supported by two members of the CQC medicines team.

Before visiting, we looked at a range of information that we hold about the clinic. We reviewed the last inspection report from April 2016 and the information submitted by the service in response to our provider information request. The methods that were used during our visit included talking to people who used the service, interviewing staff, observations, and reviewing 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 people'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

Safety systems and processes

There was no adequate safeguarding policy or procedure in place that informed staff of what to do or who to contact if they had a safeguarding concern. Some staff working at the clinic had received some training in the safeguarding of adults or children, but this was not always appropriate for their role. There was no safeguarding lead in the clinic.

We saw evidence of suitable recruitment processes by the provider prior to the employment of doctors at the clinic. Appropriate checks, including full employment history and evidence of conduct in previous employment through references, were completed, as well as checks 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). Doctors were registered, and had up to date revalidation, with the General Medical Council.

The service did not provide chaperones and did not have a chaperoning policy in place. The consultations did not involve an examination, but no assessment had taken place to identify the need for patient chaperones.

The premises were clean and tidy and there was an infection control paragraph in the general policy. Staff told us they regularly cleaned the premises; however, there was no cleaning schedule or records kept of this, and no evidence that staff had undertaken infection prevention and control training. The clinic had not conducted an infection control risk assessment to determine if they needed to test for Legionella at the service (Legionellosis is the collective name given to the pneumonia-like illnesses caused by legionella bacteria.) Staff had access to alcohol gel and examination gloves in the consultation room.

At the time of the inspection, there were no procedures for the safe and legal disposal of unwanted medicines, including controlled drugs, and we did not see evidence of a pharmaceutical waste disposal contract. The manager told us that very few medicines needed to be disposed of, and we saw that waste medicines were segregated and stored appropriately; however, the system for the disposal of those medicines did not comply with the Misuse of Drugs Act 1971.

Electrical equipment had recently been tested to ensure that it was safe to use. Appropriate clinical equipment was available for use in the clinic, and was checked in-house to ensure it was working; however, the systems for calibration and maintenance of equipment were not in accordance with manufacturers' guidelines.

Risks to patients

Staffing levels were sufficient to meet patients' needs. The doctors worked in other locations for the same provider and were available to cover each other's absence. The clinic manager covered the reception area on days when the receptionist was not working.

This is a service where the risk of needing to deal with a medical emergency is low. However, emergency medicines and equipment were not available at the service, and the provider had not carried out a risk assessment of the need for emergency medicines or equipment, nor developed a policy detailing how emergencies would be managed should the need arise. The doctor at the service had received basic life support training.

Staff had an understanding of emergency procedures and building evacuation procedures. A fire risk assessment was in place and fire alarm checks were performed regularly by the building's landlord. The general policy at the clinic also stated that health and safety risk assessments were carried out every three years; however, this did not reflect practice at the clinic and there was no evidence of any risk assessments having been completed.

We saw evidence that the provider had indemnity arrangements in place to cover potential liabilities that may arise

Information to deliver safe care and treatment

Appointments were booked using a computerised system. Patients' medical information, clinical notes and record of medicines supplied were recorded on handwritten individual record cards. The cards were stored securely at the service and access was restricted to protect patient confidentiality.

We saw that the service had recently started confirming patients' identities using photographic identification if staff were concerned that patients were under 18 years old.

Safe and appropriate use of medicines

Are services safe?

This service prescribes Diethylpropion Hydrochloride and Phentermine.

The medicines 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 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 Slimmingmedics High Wycombe 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 version 71 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 saw that medicines were stored, packaged and supplied to people safely at Slimmingmedics High Wycombe, in line with the provider's medicines management policy. Medicines were received and packaged into containers at Slimmingmedics in Reading, and then transferred to the clinic in High Wycombe under the supervision of the doctor. We saw records of medicines received by the clinic, and prescribing records of medicines supplied by the service. Medicines prescribed by the doctor were supplied in appropriate, labelled containers, which included the name of the medicine, instructions for use, the person's name, date of dispensing and the name of the prescribing doctor. A record of the supply was made in the patient's record. Patients received information, including written leaflets, about their prescribed medicines.

We reviewed ten patient records, and saw that no patients under the age of 18 were prescribed medicines for weight loss.

Safe track record and learning

Responding to errors and near misses was mentioned in the clinic's general policy. Staff understood their responsibilities to raise concerns to the doctor, but told us that no unexpected or unintended safety incidents had ever occurred. We did not see evidence of a recording system in the event of an incident, or of lessons learned from incidents and the action taken as a result of investigations when things went wrong. The provider encouraged a culture of openness and honesty, and staff explained how they would be open and transparent with patients in relation to any unexpected or unintended safety incidents.

There were no arrangements in place to receive, review and act upon patient and medicines safety alerts issued through the national alert systems.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

We reviewed ten patient records and saw that, during the initial consultation, information including weight, height, medical history and any medicines being taken was collected for each person and recorded in the clinic notes, as well as information about their eating and exercise habits. Their body mass index (BMI kg/m²) was calculated, and waist circumference and body fat percentage was also recorded. The doctor discussed the treatments available, including common side effects to the medicines, and patients were provided with written information about medicines in the form of a patient information leaflet.

The assessment protocol used by the clinic stated people with a Body Mass Index (BMI) above 30 kg/m² would be considered for treatment with appetite suppressants; if their BMI was above 27 kg/m² and they had other, defined conditions then treatment would also be considered. For people with a BMI below the level where appetite suppressants would be considered, the clinic provided advice and sold a dietary supplement. People were also not prescribed medicines from the clinic for some clinical reasons, such as patients with high blood pressure or taking other medicines that meant that they could not have any new medicines prescribed from the clinic. We saw examples of patients taking recommended treatment breaks. Doctors re-checked patients' medical histories if they had a break from attending the clinic for several months.

Monitoring care and treatment

We saw that at subsequent visits to the clinic, each patient's weight was recorded and their weight loss monitored. We saw that information about the weight loss of some patients who routinely attended the clinic was collected and reviewed periodically, to audit the outcomes of patients' care at the clinic. The most recent review showed an average weight loss of 0.8kg per week.

Effective staffing

Doctors undertook consultations with patients, and prescribed and supplied medicines. Staff records showed that doctors had the appropriate qualifications, and the provider checked the doctors' appraisals and revalidation with the General Medical Council.

There were no formal in-house appraisals or records of staff performance reviews, and there was no evidence of ongoing staff training, learning or development to enable them to fulfil the requirements of their roles. However, the staff team was small and we were told informal meetings were held as and when required.

Coordinating patient care and information sharing

We saw that the clinic record cards contained a section for recording information about the patient's GP, and whether the patient agreed to information being shared with their own GP. We saw a letter had been recently introduced to inform a patient's GP about their treatment, if they consented to information sharing.

Supporting patients to live healthier lives

Patients had access to a range of dietary advice to help with weight, including leaflets and online videos as well as appointments for advice and guidance from the doctor. Staff referred patients to their GP if they were unsuitable for prescribed medicines from the clinic, for example because of high blood pressure.

Consent to care and treatment

Records showed that consent to treatment was obtained from patients and recorded at the initial consultation. Patients were asked to sign a document before treatments were prescribed, including information that the appetite suppressants phentermine and diethylpropion are unlicensed medicines. The doctor we spoke to was aware of ensuring capacity to consent to treatment in accordance with the Mental Capacity Act 2005.

The service offered full, clear and detailed information about the cost of consultation and treatment including the costs of medicines.

Are services caring?

Our findings

Kindness, respect and compassion

We observed staff at the service being polite and professional. We received 19 completed comment cards from patients telling us how they felt about the service. All comments were positive about the staff and the service. Patients commented on how friendly and supportive they found the staff to be, and were satisfied with the care and treatment they received at the service.

Involvement in decisions about care and treatment

Staff communicated verbally, by email and through written information to ensure that patients had enough information about their treatment. Patients were involved in decision-making and were encouraged to set treatment goals. We saw that information was available to patients, including information on nutrition and exercise.

Privacy and Dignity

Confidentiality was included in the general policy and we observed that patients' privacy was protected during consultations.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The facilities and premises were appropriate for the services being provided. However, the provider had not analysed the needs of patients in order to plan and deliver services.

Adjustments were not made for patients who may have had a disability, impairment or sensory loss. For example, information and medicine labels were not available in large print to help patients with a visual impairment. An induction loop was not available for patients with hearing difficulties. The clinic was located on the first floor of the building only accessed by stairs, which may not be accessible to patients with mobility difficulties.

Staff had not received any training on equality and diversity, or how to support people with protected characteristics.

There were no arrangements in place for patients who needed translation services. We asked staff how they communicated with patients who spoke another language.

The manager told us that patients brought in friends or relatives to translate for them if necessary. However, there was a risk that information may not be relayed accurately to people who may not understand English.

The treatments available at the clinic were only available on a fee basis. However, information on alternative methods of weight loss, such as diet and exercise, were available free of charge.

Timely access to the service

The service was open two days a week, on Wednesday and Saturday from 10am to 2pm. Appointments with doctors for weight management were pre-booked, and were available during opening hours at times to suit patients' needs

Listening and learning from concerns and complaints

The clinic had a complaints section in the general policy; however, this did not reflect practice at the clinic. Patients were not given any information about how they could complain or raise concerns, and there was no formal system for recording complaints. The manager told us that no complaints or concerns had been received.

Are services well-led?

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

Our findings

Leadership capacity and capability;

We found that the service had limited systems in place to assess, monitor and improve the quality of the service, or, therefore, to understand any current challenges. There was no clear leadership structure in place and limited opportunities for staff training or development.

Vision and strategy

There was a Statement of Purpose in place for the service and a plan for business growth and marketing. However, we did not see any business plan or strategy for service improvement or staff development. There were no minutes of meetings or discussions about service improvement around the needs of patients.

Culture

It was clear from patient feedback that the culture focused on the individual patient's experience.

Staff told us that they were aware of the need for openness and honesty with patients if things went wrong and had systems to ensure compliance with the requirements of the duty of candour. (The duty of candour is a set of specific legal requirements that providers of services must follow when things go wrong with care and treatment).

Governance arrangements

Appropriate arrangements were not in place to ensure good governance at this clinic. There were policies in place to govern activity at the clinic, but these frequently were limited in detail and did not reflect local practice. The medical director, as referred to in the clinic's policy, was not clear about what this role involved. The service did not

seek feedback from patients or relevant persons, for the purposes of continually evaluating and improving services, including the quality of the experience for people using the service.

Managing risks, issues and performance

The provider had no system in place to assess, record, monitor and mitigate the risks relating to the health, safety and welfare of staff or patients. There was no system to give assurance that safety issues would be escalated appropriately. There was some limited use of service performance measures, but no systematic programme of audit to monitor clinical care or quality.

Appropriate and accurate information

Patients provided doctors with information about their medical history and medicines use. The doctor told us they would contact the patient's GP for additional information if necessary, with the patient's consent.

Engagement with patients, the public, staff and external partners

The provider did not routinely survey patient satisfaction or seek feedback from its patients, the public or staff.

Continuous improvement and innovation

The clinic did not have a clear approach for reviewing or identifying problems with quality or safety, and we did not see evidence of action taken to develop and improve the service. For example, there were no audits of clinical care, infection prevention, or incidents and near misses. The provider was a member of a national obesity association and attended meetings twice a year, but we did not see any evidence of sharing of any improvement or innovation work.

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 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment</p> <p>How the regulation was not being met:</p> <p>The registered person had failed to establish systems to investigate and immediately act upon becoming aware of, any allegation or evidence of such abuse.</p> <p>In particular, the provider did not have an adequate safeguarding procedure and policy in place that informed staff what to do or who to contact if they had a safeguarding concern and staff did not have relevant safeguarding training at a suitable level for their role.</p> <p>This was in breach of regulation 13(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</p>
Regulated activity	Regulation
Services in slimming clinics	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>How the regulation was not being met:</p> <p>There were no systems or processes that enabled the registered person to assess, monitor and improve the quality and safety of the services being provided.</p> <p>In particular:</p> <p>The service lacked good governance to operate effectively and had no arrangements in place to review, monitor and improve the quality of the service being provided, including responding to patient complaints. There were no systems for assessing and mitigating the risks relating to the health, safety and welfare of staff or patients. There were no systems to ensure that equipment was appropriately calibrated and suitable for use</p>

This section is primarily information for the provider

Requirement notices

This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014