Silhouweight Limited

Slimmingmedics Reading

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 06 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 not 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.

Slimmingmedics (Reading) provides advice on weight loss and prescribed medicines to support weight reduction. The clinic consists of a reception and two consulting rooms; and is located on the first floor of a commercial building in the town centre. Staff include a manager, three part-time doctors and one receptionist. The clinic is open three part days a week

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 (Reading) 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.

The clinic manager is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Summary of findings

Patients completed CQC comment cards to tell us what they thought about the service. We obtained feedback about the clinic from 21 completed comment cards. The observations made were all positive and reflected that patients found staff to be friendly, helpful and efficient. They also said that the environment was safe, clean and hygienic. Patients said they felt supported to lose weight and were given lots of advice and support as well as prescribed medicines.

Our key findings were:

- We found feedback from patients was always positive about the care they received, the helpfulness of staff and the cleanliness of the premises.
- 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 incident reporting, emergency risk assessments, patient safety alerts and communication with the patient's own GP.
- Reception staff did not have appropriate recruitment checks and were not given suitable support, training, professional development and supervision as is necessary to enable them to carry out the duties they are employed to perform.
- Patients' records were not stored securely.

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
- Review the process for disposing of medicines so that it complies with the Misuse of Drugs Act 1971 and its associated regulations
- Review the system in place for regular calibration, maintenance and replacement of equipment
- Review the process for incident reporting and acting upon patient safety alerts
- Review the recruitment, training and appraisal requirements for all staff
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available
- 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 effective arrangements in place to keep people protected and safeguarded from abuse and some staff had no recruitment checks. Patient records were not stored securely to protect patient confidentiality. The provider had no system in place to receive and action patient safety alerts. The clinic should only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.

Are services effective?
We found that this service was not providing effective care in accordance with the relevant regulations.

We found areas where improvements should be made relating to the effective provision of treatment. This was because the provider did not share information with the patient's GP when they had been asked to do so and the provider should review the need for appraisals and training of clinical staff.

However, doctors screened and assessed patients prior to treatment and staff at the clinic ensured that individual consent was obtained prior to the beginning of treatment. Patient's ongoing care and treatment was monitored and adequate support and information was provided.

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 helpful and friendly. 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.

The facilities and premises were appropriate for the services being provided.

However, we found areas where improvements should be made relating to the responsive provision of treatment. This was because the provider had not ensured that staff were trained to be aware of and support patients with protected characteristics 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 to operate effectively and did not have systems to assess, monitor and improve the quality of the service being provided. In addition, the provider failed to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others which arise from the carrying on of the regulated activity.

Slimmingmedics Reading

Detailed findings

Background to this inspection

We carried out this inspection on 06 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 December 2013 and information submitted by the service in response to our provider information request. During our visit we saw video testimony from patients who used the service, interviewed staff and reviewed of documents.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to 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. Not all of the staff working at the clinic, including one doctor, the registered manager and receptionist had received training in the safeguarding of adults or children. There was no safeguarding lead in the clinic and staff did not fully understand what safeguarding meant or how to raise concerns.

Staff personnel files demonstrated that a safe recruitment process for doctors was followed; however, this was not the case for reception staff, who were recruited by word of mouth. Doctor's files contained full employment history and evidence of conduct in previous employment through references. Although doctors had Disclosure and Barring Service (DBS) checks in place, reception staff did not and this had not been risk assessed as safe for patients. The doctors had up to date revalidation with the General Medical Council.

The service did not have a chaperoning policy and no assessment had taken place to identify the need for patient chaperones. Staff told us that they had not been asked to chaperone.

There were no records of staff training. Staff we spoke with told us they had medicines handling training at induction, but there was no ongoing training, learning or development to enable them to fulfil the requirements of their role.

The clinic had not conducted an infection control risk assessment to determine if they needed to test for Legionella at the service, although there was no running or static water within the clinic rooms. (Legionellosis is the collective name given to the pneumonia-like illnesses caused by legionella bacteria.)

The premises were clean, tidy and in a good state or repair. There was an infection control paragraph in the general policy. There was no evidence that staff had undertaken infection control training although the risk of infection was extremely low. The registered manager told us staff cleaned the premises as part of their normal duties but did not keep records of this. Staff had access to alcohol gel and supplies of examination gloves in the consultation room.

There was not a clear procedure for the disposal of controlled drugs and we did not see evidence of a pharmaceutical waste disposal contract. The system for the disposal of medicines did not comply with the Misuse of Drugs Act 1971 and its associated regulations, although waste medicines were segregated and stored appropriately.

Electrical equipment had not been tested to ensure it was safe and there was no risk assessment to determine the level of maintenance needed to prevent an item becoming faulty. Clinical equipment was checked in house to ensure it was calibrated and working properly.

Risks to patients

Staffing levels were sufficient to meet patients' needs. Enough doctors were available to cover each other's absence and the manager covered the reception area on days when the receptionist was not working.

The risk of needing to deal with a medical emergency in this service was low however; the provider had not assessed the need for emergency medicines and equipment, or developed a policy detailing how emergencies would be managed should the need arise. One doctor was trained in basic life support; however, the reception staff did not have basic life support or first aid training. This meant life support was not provided if the doctor was absent. In the event of a medical emergency, staff would call the emergency services and were aware of local urgent care provision.

Staff had an understanding of emergency procedures and a building evacuation procedure was in place. A fire extinguisher was available and the building landlords held regular fire alarm checks.

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. Staff recorded patients' medical information, clinical notes and record of medicines supplied on written individual

Are services safe?

record cards. The cards were stored in an unlocked filing cabinet that was accessible to other users of the premises. This did not protect patient confidentiality. There was no process to check patient identity or to confirm that patients were aged 18 or over.

Safe and appropriate use of medicines

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 grantedthemmarketingauthorisations. 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 Slimmingmedics (Reading) 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 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.

We saw that staff were following their medicines management policy and that medicines were stored, packaged and supplied to people safely. Medicines were ordered and received when there was a doctor on the premises. Staff packed the medicines into appropriate containers under the supervision of the doctor. We saw the orders, receipts and prescribing records for medicines supplied by the clinic. At the time of the inspection, there were no procedures for the safe and legal disposal of unwanted medicines. The manager told us that very few medicines needed to be disposed of and that appropriate systems would be put in place following the inspection. Staff checked medicines after each clinic session to confirm that all the necessary records had been made. The manager and the doctor on duty signed to confirm that records were accurate. 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. Doctors recorded the supply of medicines in the person's records. Staff gave patients information leaflets about their prescribed medicines. We reviewed ten medical records, and saw that no patients under the age of 18 were prescribed medicines for weight loss.

Track record on safety

Details of how to respond to errors and near misses was laid out in the general policy. Staff understood their responsibilities to raise concerns to the doctor but no record was made when incidents occurred. We did not see evidence of examples of lessons learned from incidents and the action taken as a result of investigations when things went wrong. There were no arrangements in place to receive and act upon patient safety alerts, recalls and rapid response reports issued through the national alert systems. Although staff monitored medicines stock levels, there were no audits to check accuracy of patient's record cards or the safety of the service.

Lessons learned and improvements made

While not all staff were aware of the term duty of candour, they explained how they would be open and transparent with patients in relation to their care and treatment. The service had no systems in place for knowing about notifiable safety incidents, but there was evidence of response to a medicines recall from the manufacturer. We were told there had been no unexpected or unintended safety incidents.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

We checked ten patient records and saw that information was collected during the initial consultation including past medical history, weight, height, blood pressure, and any medicines the patient was taking. 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. Their body mass index (BMI kg/m2) was calculated and target weights or goals agreed and recorded. Their waist circumference was also measured if their BMI was below 30 kg/m2.

The assessment protocol used by the clinic stated if a person's BMI was above 30 kg/m2 they would be considered for treatment with appetite suppressants and if they had other defined conditions then treatment could start if their BMI was above 27 kg/m2. If the BMI was below the level where appetite suppressants could be prescribed, the clinic provided dietary advice and sold a dietary supplement. We saw evidence that patients were not prescribed medicines if there was a clinical reason. For example, 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. Doctor's rechecked medical histories if patients had a break from attending the clinic for several months.

Monitoring care and treatment

We saw that at subsequent visits to the clinic, weight was recorded and weight loss monitored. We saw an example where treatment was stopped because the target weight had been achieved. Information about the outcomes of some patient care was collected by way of an assurance audit. We saw that records of patients who routinely attended the clinic were reviewed to identify and record weight lost since the start of treatment or since the last treatment break. For patients reviewed in October 2017, the average weight loss was 0.7kg per week.

Effective staffing

Doctors undertook consultations with patients, prescribed and supplied medicines. Staff records showed that they had the appropriate qualifications and one doctor described how they kept up to date with new developments in weight management. Doctors were up to date with their revalidation. The manager explained that they have meetings with the doctors as issues arise but there was no formal appraisal process for the doctors or receptionist.

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 they agreed to their GP being contacted. This information had not been completed on three of the ten patient record cards we checked. A further two patients had agreed to their GP being contacted, yet this had not happened. The doctor explained that they would contact the GP for advice about a patient's medical history with their consent if needed. The manager told us that there was no standard letter to give to patients or to send to GPs. Immediately following the inspection, the provider shared a draft letter for patients to give to their GP and add this to their prescribing guidelines in line with GMC guidance.

Supporting patients to live healthier lives

Patients had access to a range of dietary advice to help with weight loss via leaflets and emailed links to videos. Staff referred patients to their GP if they were unsuitable for treatment, for example because of high blood pressure.

Consent to care and treatment

Doctors obtained and recorded consent to treatment from patients at the initial consultation. However, the doctor we spoke with could not explain 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.

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 received 21 completed cards from patients telling us how they felt about the service. All were positive and demonstrated that staff were helpful and friendly and that patients were satisfied with the treatment they received at the service. The manager showed us some patient testimonies that had been recorded. Patients described how the doctors "put me at ease and gave brilliant advice" and how with the support of the clinic, they were able to exercise and eat well.

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 there was a variety of patient information available, which included information on nutrition, alcohol consumption and exercise.

Privacy and Dignity

Confidentiality was included in the general policy and staff could explain how they would protect patients' privacy. Consultations took place in a private consultation room located next to the reception area. Conversations could not be overheard from outside the consultation room.

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 patient needs 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 and an induction loop was not available for patients with hearing difficulties. The clinic was located on the first floor of the building only accessible by stairs. Staff had not received training to support people with protected characteristics.

There were no arrangements in place for patients who need translation services. We asked staff how they communicated with patients who spoke another language. The manager told us that they do not have any patients who did not speak 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 as was the ability to be regularly weighed by clinic staff.

Timely access to the service

The clinic was open three days a week with doctor's appointments for weight management available on two of those days. The clinic offices were shared with another service so there were limited options to open on additional days. Appointments were made at times to suit patients' needs and were very rarely cancelled or delayed.

Listening and learning from concerns and complaints

The clinic had a complaints section in the general policy but no information was given to patients about how they could complain or raise concerns. No complaints or concerns had been received and patient feedback was gathered informally.

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 leaders lacked the capacity and capability to run the service with a view to ensuring high quality care. We found that the service had limited systems in place to assess, monitor and improve the quality of the service. There was no clear leadership structure in place and limited opportunities for staff training or development.

Vision and strategy

Although there was a Statement of Purpose in place this had not been shared with staff, who were not clear on the business vision and values. While the provider had a plan for business growth and marketing, 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

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). Staff were able to explain how they would deal with poor practice and gave an example where patients had been offered a free consultation because their appointments had been double booked.

Governance arrangements

Staff at the clinic did not have appropriate arrangements to ensure good governance at this clinic. There were no records relating to recruitment of reception staff, for example; proof of identity or employment history. Medical records were not stored securely. We saw that the provider had updated the services policies and procedures immediately prior to our inspection, but staff were not aware of these new policies. 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, monitor and mitigate the risks relating to the health, safety and welfare of patients. There was no system to give assurance that performance or patient safety issues would be escalated appropriately. Evaluation of data was used to improve business marketing and growth.

Appropriate and accurate information

Information about medical history and medicines use was provided from patients. The doctor explained how they would contact the patient's GP for additional information with their consent. Clear information was provided to patients with respect to their consultation and treatment including guidance on the costs.

Engagement with patients, the public, staff and external partners

The provider had sought patient feedback for the purposes of the inspection but otherwise did not survey patients or ask for feedback from staff.

Continuous improvement and innovation

The clinic did not have an effective approach for identifying if, or where, quality or safety was being compromised. Therefore, steps were not taken in response to any issues. For example, there were no audits of prescribing notes, infection prevention and risks, incidents and near misses.

The provider was a member of a national obesity association and attended meetings twice a year to network and learn.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Services in slimming clinics	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment How the regulation was not being met: The registered person had failed to establish systems to investigate and immediately act upon becoming aware of, any allegation or evidence of such abuse. 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. This was in breach of regulation 13, (1)&(2) 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: 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. In particular, the provider did not ensure that patient records were stored securely. The service lacked good governance to operate effectively and had no system in place to assess, monitor and improve the quality of the service being provided. There were no DBS risk assessments, recruitment records or training records for reception staff.

This section is primarily information for the provider

Requirement notices

This was in breach of regulation 17, (1)&(2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014