

Diet U.K. Limited

Diet UK Bolton

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 29 November 2017 to ask the service the following key questions: Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

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

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 providing well-led care in accordance with the relevant regulations

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.

Diet UK Bolton offers a private weight reduction service for adults over the age of 18. The clinic is on the first floor of a larger private health centre, and comprises of reception and office areas and one clinic room. The clinic is open for pre-booked consultations on Tuesdays from 11:00am to 2:00pm and on Wednesdays from 12:00pm to 2:00pm and 4:00pm to 5:30pm. The clinic employs two doctors, one of whom is the registered manager, one receptionist and a practice 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. There is also a branch location which is located in Preston town centre and patients can be seen at either location.

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 Diet UK Bolton, the

Summary of findings

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.

Our key findings were:

- The facilities were appropriate to meet people's needs
- There was an annual audit schedule in place, which included audits of administrative duties, medical records, and weight loss
- Staff were caring, supportive, and treated patients with dignity and respect
- The manager encouraged an open and honest culture, staff were given the opportunity to contribute, and they were respected and valued for their contributions

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

- Ensure that care and treatment is provided in a safe way for service users
- Ensure systems and processes are established and operated effectively to prevent the abuse of service users

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 risk assessments with regard to medical emergencies

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. The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of this occurring in the future is low once it has been put right. We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

There was a safeguarding policy in place, however clinicians and staff had not undertaken any safeguarding training. We observed the premises to be clean and tidy, in a good state of repair, and the facilities were appropriate to meet the needs of patients using the service. There was no record of calibration for blood pressure monitors and no process in place to ensure they were calibrated at the right time. The provider was aware of and complied with the requirements of the Duty of Candour. During our inspection we saw unlabelled bottles containing medicines. This was not safe as it was not clear what medicine was in each bottle; this can lead to dispensing errors. There were arrangements in place to receive and act upon patient safety alerts however, the provider did not keep records of the action they had taken in response.

Are services effective?

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

There was a prescribing policy in place which set out when medicines could safely be prescribed, however this was not in line with national guidance on the management of obesity. Patients had their blood pressure measured during their first visit but this was not routinely repeated at subsequent visits. We found one patient was supplied six weeks' worth of medicines on three occasions, but no clinical reason for this was recorded in the medical notes. There was an annual audit schedule in place, which included audits of administrative duties, medical records, and weight loss. Clinicians and staff had the necessary skills, knowledge and experience to undertake their role. Patients were provided with written information on eating healthily and dietary advice to aid weight loss.

Are services caring?

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

Patients said they felt staff were caring, supportive, and treated them with dignity and respect. We observed staff interacting with patients and found they were pleasant and professional.

Are services responsive to people's needs?

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

The facilities were appropriate to meet people's needs. Doctors were available for telephone advice outside of these hours, and the clinic aimed to respond to all enquiries within 24 hours. Information was displayed in the waiting area about the steps people could take if they were not satisfied.

Are services well-led?

We found that this service was providing well-led care in accordance with the relevant regulations.

Summary of findings

The registered manager and the doctor were aware of the need for openness and honesty with patients if things went wrong. The provider held regular staff meetings and a log of actions arising from these meetings was kept to ensure they were followed-up. There was a systematic programme of clinical audit to monitor and improve quality which was overseen by the clinical governance group. The provider encouraged and routinely sought feedback from patients.

Diet UK Bolton

Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection at diet UK Bolton on 29 November 2017. The team was led by a CQC pharmacist specialist and included a regional medicines manager.

Before visiting, we reviewed a range of information that we hold about the service which included information from the provider. The methods we used were talking to patients using the service, interviewing staff, observation, and review 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 a safeguarding policy in place which included contact details for local safeguarding teams. The registered manager was the safeguarding lead, however they had not undertaken any safeguarding training for this role. In addition, the second doctor working at the clinic had not undertaken any safeguarding training. Staff were able to describe the process to follow if they had any concerns. Although the service only treated adults the doctor we spoke with demonstrated an understanding of safeguarding responsibilities for children who may accompany adults to appointments.

The service did not routinely offer chaperones and staff had not received chaperone training. Some patients chose to see the doctor with a friend or partner but the consultations did not involve an intimate examination.

We observed the premises to be clean and tidy. Handwashing facilities were available in both clinics, and alcohol gel was available in the consultation rooms. The service employed a cleaner, had a cleaning schedule, and kept records when cleaning had been completed. The service did not have an infection control policy and had not carried out any infection control audits or Legionella risk assessments (Legionella is a term for a particular bacterium which can contaminate water systems in buildings).

The premises at Bolton were owned by the provider. The branch premises at Preston were rented, and the provider was responsible for maintaining the décor. We observed both premises were in a good state of repair and the facilities were appropriate to meet the needs of patients using the service. Consulting rooms were private and confidential and staff areas and consulting rooms were secured to prevent unauthorised access. We saw evidence that electrical equipment was checked to ensure it was safe to use. Fire safety equipment had been serviced in accordance with manufacturer's recommendations. A fire risk assessment had been undertaken and a fire evacuation procedure was in place, which was displayed in the waiting area. There was a record of calibration for weighing scales; however we found the scales at Preston were overdue calibration in October 2017. The registered manager sent us evidence that this had been carried out following the inspection. In addition, there was no record of calibration for blood pressure monitors and no process in place to

ensure they were calibrated at the right time. Following the inspection the registered manager sent us evidence of a new procedure to ensure blood pressure monitors were calibrated according to manufacturer's instructions.

We checked employment records for all of the staff at the clinic and found appropriate checks had been carried out, for example proof of identity and confirmation of registration with the appropriate professional body. However, we found one of the staff had not been checked through the Disclosure and Barring Service (DBS) and a second member of staff had not been checked since 2007 (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). No risk assessment had been carried out with regard to these checks. Following the inspection, the registered manager sent us evidence that a basic level check had been performed for both staff (a basic level check does not identify spent convictions or cautions). There was evidence that clinicians were up-to-date with revalidation and each had a designated body and responsible officer.

Risks to patients

Doctors at Bolton had access to a defibrillator and oxygen which was shared with the rest of the building. A system was in place to ensure these were fit for use, although this was not managed by the provider. In addition, the Bolton clinic held an adrenaline auto-injector for adults. There were no emergency equipment or medicines available at the Preston clinic. This is a service where the risk of needing to deal with a medical emergency is low, however no risk assessment had been carried out with regards to what may be needed in the event of a medical emergency.

Staff had not undertaken any life support training. In addition, at the time of our inspection there was no evidence that the doctors had undertaken any life support training.

There was no evidence available on the day of our inspection that the clinicians employed by the service had appropriate professional indemnity insurance to cover all potential liabilities that may arise from their work at Diet UK Bolton. The registered manager sent us evidence of appropriate indemnity insurance following the inspection.

There was an accident book and a first aid kit was available.

Are services safe?

Information to deliver safe care and treatment

Individual patient records were stored securely at the clinics and confidentiality was maintained. Records were paper-based and could be transferred between clinics by staff if patients required a consultation at the other site.

Safe and appropriate use of medicines

The doctors at this service prescribed Diethylpropion Hydrochloride and Phentermine. The approved indication for these products is “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 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.

Medicines are given licenses by the Medicines and Healthcare products Regulatory Agency (MHRA) following trials to show they are safe and effective. 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 Diet UK we found 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.

We checked how medicines were stored, dispensed and supplied to patients. We found that medicines were stored securely in an appropriate cupboard and access was restricted to authorised staff members. Doctors remained

in control of the handling of medicines. Records were made of medicines received, dispensed and supplied to patients. Stocks were managed and counted regularly by staff, but the recording system did not record actual stock levels. This made it difficult to fully audit and account for the medicines. Staff told us they would record this in the future to improve the system. There was a system in place, supported by a written process, for dispensing and labelling medicines. During our inspection we found this had not been properly followed and we saw unlabelled bottles containing medicines. This was not safe as it was not clear what medicine was in each bottle; this can lead to dispensing errors. Staff told us this did not normally happen and assured us this would not be repeated. Immediate action was taken to label the medicines.

We observed throughout our visit that the doctor prescribed medicines and patients were given their medicines at the end of their consultation. The doctor made a record of supply in the patient's clinic record. Medicines were appropriately labelled following regulations and guidance. Reception staff then double-checked the medicines and made an extra record for audit purposes.

Track record on safety, lessons learned, and improvements made

The provider was aware of and complied with the requirements of the Duty of Candour (observing the Duty of Candour means that patients who use the service are told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result). The provider encouraged a culture of openness and honesty with their staff, and staff understood their responsibilities to raise concerns, to record incidents, and to report them where appropriate. There had been no incidents recorded in the last 12 months. The service had systems in place for knowing about notifiable safety incidents. There were arrangements in place to receive and act upon patient safety alerts, recalls, and rapid response reports issued through the Medicines and Healthcare products Regulatory Agency (MHRA) and similar bodies. However, the provider did not keep records of the action they had taken in response to these alerts.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

New patients to the clinic completed a medical history form that included allergies, existing medical conditions and medicines, comorbidities and lifestyle questions. The doctor then reviewed this information and recorded the patient's height, current weight, waist measurement and blood pressure. The doctor calculated the patients BMI and, if appropriate, treatment was prescribed. The doctor also discussed and provided information about healthy eating and lifestyle.

There was a prescribing policy in place which set out when medicines could safely be prescribed, however this was not in line with national guidance on the management of obesity. For example, the clinic policy stated treatment could be prescribed if a patient had a BMI of greater than or equal to 30Kg/m² or 27Kg/m² with co-morbid factors. National Institute for Health and Care Excellence (NICE) guidance states that in the presence of associated risk factors, it may be appropriate to prescribe an anti-obesity drug to individuals with a BMI of 28kg/m² or greater. We checked 17 patient records at the Bolton clinic and eight records at the Preston clinic, and found that the clinic policy regarding BMI thresholds for prescribing had been followed. We saw patients received a break from treatment at least every twelve weeks. When a patient had not been seen at the clinic for some time, the policy was to review their medicines, repeat a medical history, and re-check their blood pressure before prescribing.

Patients had their blood pressure measured during their first visit but this was not routinely repeated at subsequent visits. Diet UK Bolton policy was to repeat blood pressure measurements every six months or if risks were identified. This is not in line with current best practice as the medicines being supplied list high blood pressure as a possible side effect. Therefore, initiation and titration of treatment should include closer monitoring of blood pressure. Doctors at the clinic told us they would review their policy and practice to include a more frequent measurement of blood pressure.

Diet UK Bolton had a policy for repeat prescriptions which could be placed over the telephone. This policy stated that patients must be seen at least every six months when their weight and blood pressure would be checked and recorded. Reception staff completed a repeat prescription

request form that prompted them to ask and record patient weight and any changes to medical history. The doctor would then decide if patients were suitable to have medicines supplied on a repeat basis, which could either be collected from the clinic or supplied by post. We found one patient was supplied six weeks' worth of medicines on three occasions in the previous four months, but no clinical reason for this was recorded in the medical notes. This was contrary to national guidance which states supplies of controlled drugs of more than 30 days should be exceptional, be based on clinical need, and the reason recorded in the patient's notes. The clinic policy also stated that a maximum of twelve weeks medicines could be supplied by post but this did not refer to national guidance that there should be a recorded clinical need for this. In addition, the provider had not risk assessed the practice of posting controlled drugs

Monitoring care and treatment

There was an annual audit schedule in place, which included audits of administrative duties, medical records, and weight loss. We reviewed an annual report from the weight loss audit for 2016 which showed effective weight loss across a group of patients. However, the audit did not specify how many individual patients had lost weight, it did not have set criteria to audit against (for example benchmarking against national guidance), and no outcome or improvement measures had been recorded.

Effective staffing

Clinicians and staff had the necessary skills, knowledge and experience to undertake their role. Staff had completed mandatory training in mental capacity and safeguarding. However, staff had not been trained in basic life support. This meant they may not be able to provide help in an emergency if the doctor was not on the premises. There was evidence of all staff having regular appraisals suitable for their role. The doctors were both members of the Association for the Study of Obesity (ASO).

Coordinating patient care and information sharing

Patients were encouraged to consent to the sharing of information about their treatment at Diet UK Bolton with their registered GP. This had been recorded correctly in all of the records we reviewed. The doctor told us where a patient did not consent to their information being shared, they would refuse to prescribe appetite suppressants if they felt it was unsafe to do so without informing the GP.

Are services effective?

(for example, treatment is effective)

Supporting patients to live healthier lives

Patients were provided with written information on eating healthily and dietary advice to aid weight loss. Doctors empowered patients using the service to manage their own health and gave additional information about the benefits of weight loss for patients who also had diabetes and heart disease.

Consent to care and treatment

Consent was obtained from each patient before treatment was commenced. The doctor we spoke with explained how

they would ensure a patient had the capacity to consent to treatment in accordance with the Mental Capacity Act 2005. Where unlicensed medicines were prescribed, the implications of this were explained by the doctor and the patient signed a consent form for unlicensed medicines use. Before treatment commenced, the provider gave patients details of the cost of the main elements of treatment which included the cost of medicines, and further treatment or follow-up.

Are services caring?

Our findings

Kindness, respect and compassion

Patients completed CQC comment cards to tell us what they thought about the service. We received 60 completed cards and all were positive. Patients said they felt staff were caring, supportive, and treated them with dignity and respect. We observed staff interacting with patients and found they were pleasant and professional. Staff displayed understanding and a non-judgemental attitude towards and when talking about patients who had a diagnosis of obesity.

Involvement in decisions about care and treatment

The doctor explained how patients were given information about their treatment which included a range of information on healthy eating. There was no support available to help patients with hearing or visual impairment, or those who did not speak English, to understand their diagnosis and treatment.

Privacy and Dignity

The provider had ensured that consultations could not be overheard, and that conversations with receptionists were not overheard in the waiting room. Patients told us their privacy and dignity needs were met at both clinics.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The facilities were appropriate to meet people's needs. There was wheelchair access to the front of the building, and a consultation room was available on the ground floor for patients with mobility difficulties. Information and medicine labels were not available in large print, Braille, or in any other languages. Staff were not aware of any translating services available, and no risk assessment had taken place looking at the different options in the event that this was required. There was no induction loop available for patients who experienced hearing difficulties.

Timely access to the service

Consultations were offered by appointment only; the registered manager told us they would always try to accommodate walk-in patients, but that this was not encouraged. The clinic was open on Tuesdays from 11:00am to 2:00pm and on Wednesdays from 12:00pm to 2:00pm and 4:00pm to 5:30pm. Doctors were available for

telephone advice outside of these hours, and the clinic aimed to respond to all enquiries within 24 hours. The majority of patients told us they could access care and treatment at a time to suit them, however one patient stated the choice of one other day per week would be more convenient for them.

Listening and learning from concerns and complaints

There was a procedure in place for handling complaints which was supported by a written policy. Information was displayed in the waiting area about the steps people could take if they were not satisfied. There had been one complaint received in the last 12 months, which we reviewed:

- The provider responded in a timely manner
- They had demonstrated openness and transparency
- The complaint was not upheld

The registered manager told us no changes had been made in response to complaints or patient feedback within the last 12 months.

Are services well-led?

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

Our findings

Leadership capacity and capability; Culture

The registered manager and the doctor were aware of the need for openness and honesty with patients if things went wrong, and would comply with the requirements of the Duty of Candour. Observing the Duty of Candour means that patients who use the service are told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result. We saw the manager encouraged an open and honest culture, and all staff were given the opportunity to contribute when changes or improvements to the service were needed. Staff we spoke with told us they felt supported by the registered manager, and they were respected and valued for their contributions.

Vision and strategy

The staff we spoke with were all aware of the vision for the service. The provider held regular staff meetings and a log of actions arising from these meetings was kept to ensure they were followed-up.

Governance arrangements; managing risks, issues and performance; appropriate and accurate information

The clinic had a limited set of policies and procedures covering the core elements of the service. There were no

policies covering infection control, medical emergencies or incident reporting on the day of our inspection. Staff we spoke with understood their roles and responsibilities. There was a clinical governance group which met six-monthly, and included external advisors. There was a systematic programme of clinical audit to monitor and improve quality which was overseen by the clinical governance group, although audits were limited in scope because they did not have set criteria to audit against, and outcome or improvement measures were not always recorded.

Engagement with patients, the public, staff and external partners

The provider encouraged and routinely sought feedback from patients. We reviewed the results of the latest patient survey which had been produced in November 2017. All of the patients who had completed the survey stated the service was good or excellent and no suggestions for improvement had been made.

Continuous improvement and innovation

Staff were encouraged to get involved when changes to the service or developments were made. Staff we spoke with felt comfortable sharing their ideas to improve the service.

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 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>The provider had not ensured care and treatment was provided in a safe way for service users. In particular:</p> <ul style="list-style-type: none">• There was unsafe management of medicines• The provider had not assessed the risks to the health and safety of service users receiving the care or treatment, and done all that was reasonably practicable to mitigate any such risks
Regulated activity	Regulation
Services in slimming clinics	<p>Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment</p> <p>The provider had not ensured systems and processes were established and operated effectively to prevent the abuse of service users. In particular:</p> <ul style="list-style-type: none">• There was no evidence that clinicians or staff at the clinic had completed appropriate safeguarding training