Harmony (Your Gentle Way To Slim) Limited

Harmony Medical Diet Clinic in Bedford

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 30 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 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 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.

CQC inspected the service on 6 July 2017 and asked the provider to make improvements regarding systems and policies to govern activities within the clinic to include: recruitment processes, electrical testing or regular calibration of equipment, infection control, fire safety, risks or response to medical emergencies and risks of lone working. We also required the provider to put in place a system to ensure the clinician had access to up to date safety alerts.

We checked these areas as part of this comprehensive inspection and found these had been resolved.

Harmony Medical Diet Clinic provides a private weight reduction service for adults and supplies medicines and dietary advice to the patients who use the service. The service operates from a first floor consulting room above a parade of shops in Bedford town centre. It is open from 10am to 4pm on Thursdays.

Summary of findings

The clinic was run by one doctor; there were no support staff. The registered manager was a doctor but did not work regularly within the business. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have a legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated regulations about how the service is run. The provider runs two further clinics in Coventry and London. The regulated manager provides supervision and support to the doctor who provides the service.

We collected feedback about the service by speaking to five patients during the inspection. Patients said the doctor was knowledgeable, and they received lifestyle and dietary advice in addition to medicines. Patients told us they felt supported to lose weight.

Our key findings were:

- Patients were provided with a range of information on diet, exercise and any medicines that were prescribed.
- Feedback from patients was positive about the care they received.
- The service was flexible to fit in with patient choice: patients could visit the doctor for weight management advice and be weighed as often as they wished. There was no charge for this type of consultation.
- The doctor was knowledgeable about strategies to improve weight loss and had produced information for patients to support healthy diets.
- The doctor had systems in place to monitor the clinical efficacy of the service provided
- The service used recognised screening processes to identify patients who could be at risk of eating disorders or co-morbidities.
- Medicines were prescribed in line with the service prescribing policy which reflected national guidance.

There were areas where the provider could make improvements and should:

- Consider the need to include information on the website for patients on how to raise a concern or complaint.
- Review the need to provide in-house appraisal for the doctor working in the service and formally record occasions of clinical supervision.
- Review and risk assess the appropriateness of having a family member or friend as a translator.

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 providing safe care in accordance with the relevant regulations.

The doctor employed to work in the clinic was aware of his safeguarding responsibilities and had an appropriate policy in place. The doctor had undertaken training and additional qualifications that related to his role. The provider did not offer a chaperone service but patients could see the doctor with a friend or family member if they wished. Patients medical information was checked periodically to ensure it remained safe for them to be treated.

The premises were clean and tidy. Medicines were stored securely and prescribed in accordance with the clinics prescribing policy. The premises were suitable and clean. The provider made the appropriate checks before staff were employed.

However, 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 providing effective care in accordance with the relevant regulations.

Appropriate records were kept of consultations and treatment supplied. Patients were advised to consult their GP before receiving treatment. The clinic doctor provided a letter to be taken to an NHS GP detailing the treatment being prescribed. Patients were provided with a range of information before consenting to treatment. Outcomes were audited and changes made as a result of audit to improve patient outcomes.

However, the provider should review the need for an in-house appraisal for the doctor working in the clinic.

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

Patients were very positive about the service provided at the clinic and told us the doctor was very knowledgeable and supportive. Patients felt they were supported to make decisions about their care and treatment. Information was provided to patients in formats accessible to them.

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. The doctor had information available in different formats to support patients to access the service. The clinic offered walk-in appointments and the doctor was available on the telephone on days the clinic was closed.

We found areas where improvements should be made relating to the responsive provision of treatment. This was because the provider relied on patients to provide their own translators.

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

Summary of findings

We saw policies and procedures to govern the activity of the clinic during our inspection. Staff were able to describe how they would handle safety incidents and were aware of the requirements of the Duty of Candour. There were governance arrangements in place to monitor the quality of the service. The provider sought the views of patients and used this information to drive improvement.

Harmony Medical Diet Clinic in Bedford

Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection at Harmony Medical Diet Clinic on 30 November 2017. The team was led by a member of the CQC medicines team and included another member of the CQC medicines team.

Before visiting, we reviewed a range of information that we hold about the service which included information from the provider.

The methods that were 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 patients' 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 the safeguarding team contact details at the local authority. The doctor working within the service was the safeguarding lead. The doctor had been trained in safeguarding adults and children up to level 3 and told us what action they would take in the event of a safeguarding concern.

The doctor demonstrated awareness of the possibility of patients being coerced to lose weight. He described refusing treatment for patients with low body mass index (BMIs). We saw a nationally validated questionnaire in use to identify patients at risk of anorexia.

The doctor was registered with the General Medical Council. He showed us evidence of regular appraisals and was taking part in revalidation.

The service did not provide chaperones. Some patients chose to see the doctor with a friend or partner. The consultations did not involve an examination and the doctor told us that they had never been asked to provide a chaperone. Patients told us they had never felt the need for a chaperone but would bring family members or friends if needed.

We observed the premises to be clean and tidy. Handwashing facilities were available and patients had access to toilets on the same floor as the consultation room.

The doctor carried out the cleaning as needed; we saw an infection control policy and a cleaning schedule was in use. The policy detailed regular infection control risk assessment and we saw evidence of an assessment having been completed.

The service had a policy on the management of the risk of Legionella and we saw an up to date risk assessment. Legionella is a term for a particular bacterium which can contaminate water systems in buildings.

The provider used a locum agency to recruit staff. We saw evidence of suitable information being obtained by the provider prior to the employment of the doctor. The policy for the service described using a locum agency to identify staff. We saw that the locum agency arranged appropriate checks, including 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).

Risks to patients

This is a service where the risk of needing to deal with a medical emergency is low. The service did not carry specific equipment to use in a medical emergency and a risk assessment had been completed. There was a policy in place describing action to be taken in an emergency situation. We discussed this with the doctor who confirmed how he would raise an alarm to access help. We saw evidence that the doctor had updated their basic life support training in June 2017. There was a first aid kit and an accident book.

We saw evidence that the provider had the appropriate indemnity arrangements in place to cover potential liabilities.

Information to deliver safe care and treatment

Individual records were managed in a way to keep patients safe. The service used computerised records and described the process for ensuring these were stored safely and backed up frequently. We saw evidence that the provider was registered with the Information Commissioners Office for the storage of computerised patient information. There was a policy in place to ensure that patient records would be managed in line with legislation if the company ceased trading.

Contemporaneous records of consultations were made. The doctor rechecked all patients' clinical details every three months to ensure it remained safe to treat them.

Safe and appropriate use of medicines

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 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

Are services safe?

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 Harmony Clinic Bedford 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. Information given to patients about these medicines included advising that these were unlicensed.

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 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 checked how medicines were stored, packaged and supplied in line with the medicines management policy. Medicines were stored securely in the possession of the prescribing doctor. We saw orders, receipts and prescribing records for medicines supplied by the clinic. Medicines were checked after each clinic session to confirm that all the necessary records had been made. A separate weekly check was also carried out. Medicines were dispensed into appropriately labelled containers and records were kept of medicines supplied to patients. Patients were given information leaflets about their prescribed medicines. We reviewed 10 medical records and saw that patients were treated in line with the policy for the service. No patients under the age of 18 were prescribed medicines for weight loss.

The doctor had developed a form to use if patients had lost or damaged their medicines. This was used to track any repeated instances of this type of request. We were told this reduced the risk of medicines being obtained fraudulently.

Track record on safety

The doctor told us that there had been no incidents in the last 12 months. The doctor was able to describe the process they would undertake to report and investigate an incident in line with the service policy. Information for patients on how to report concerns was provided when a patient initially visited the service.

The doctor received patient safety alert information for example from the Medicine and Healthcare products Regulatory Agency. There was a process in place to ensure action would be taken if information related to activities in the clinic. We saw evidence that the service had received information relating to the recall of one of the medicines they used. The doctor described the process they had followed to ensure patients had not received affected medicines.

Lessons learned and improvements made

The provider and the doctor running the service were aware of the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty. The doctor working in the service knew about notifiable safety incidents that would require reporting to CQC.

We did not see evidence of any unexpected or unintended safety incidents. We were told by the doctor working in the service that people would be given reasonable support, truthful information and a verbal and written apology.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

Patients accessing the service were provided with a detailed information leaflet describing processes for assessment, diagnosis and the treatments offered. When patients telephoned to make their first appointment preliminary screening questions were asked. This identified patients who would not be suitable for treatment and avoided patients making unnecessary journeys. The questions covered age, height, weight, blood pressure if known and medical conditions. The service only treated adults aged 18 and over; the doctor told us they had requested proof of age if this had been in doubt. The assessment process also included screening questions to exclude patients who were at risk of anorexia or other eating disorders.

We looked at 10 patient's records and saw that information was collected during the initial consultation. This included past medical history, weight, height, blood pressure and any medicines that the patient was taking. This information was updated every three months to ensure there were no changes to a patient's medical history that might affect their treatment.

The BMI of each patient was calculated and target weights agreed and recorded. If the initial risk assessment of the patient indicated it was needed, a check of blood glucose was also conducted. Those with raised readings were referred to their NHS GP. This process had recently been improved to request patients to attend a second time when they were fasting to obtain more reliable readings.

Care was delivered in line with relevant and current evidence based guidance and standards such as National Institute for Health and Care Excellence (NICE) best practice guidelines: Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. Treatment was only initiated if the BMI was greater than 30 kg/m2 or 28 kg/m2 if co-morbidities were present. In addition waist measurement was taken to determine the level of risk associated with overweight or obesity.

Monitoring care and treatment

The doctor demonstrated that they had the relevant skills, knowledge and experience to work in the sector. The doctor had analysed the weight loss data collected by the service to establish efficacy of treatments. The data demonstrated that 70% of patients receiving medicines lost weight. Data was analysed at six and 12 month intervals and the doctor had identified a cohort of patients who responded best to medicines to allow treatment regimes to be tailored to their needs. In addition, they had examined the GP referrals they had made to demonstrate the additional value of checking blood pressure and blood glucose. We saw that lifestyle changes were documented in patients notes and that these led to changes in the advice given, for example, emphasising ways to fit more activity into the day when a patient described moving to a sedentary job.

Effective staffing

We saw evidence of suitable information being obtained by the provider prior to the employment of the doctor. The policy for the service described using a locum agency to identify staff and we saw that the locum agency arranged appropriate checks.

We saw evidence that the doctor had updated their basic life support training in June 2017. Infection control training and fire safety training had been completed in October 2017. Mental capacity act training had been completed in October 2017. The doctor working for the service had undertaken training on obesity management, diabetes, smoking cessation, lipid management, cognitive behavioural therapy and had obtained a diploma in psychology. The service was a member of the Obesity Management Association.

The provider did not conduct in-house appraisals. We saw that the work within the slimming clinics was detailed in the doctor's annual General Medical Council appraisal. The doctor working in the clinic told us that they regularly spoke to the registered manager about cases and obtained clinical supervision in this way, but this was not formally recorded.

Coordinating patient care and information sharing

Patients were asked before they started treatment if they would like their GP informed. If they agreed to this they were given a letter detailing their consultation and the medicine prescribed to take to their GP. GP details were collected when a patient initially registered with the service. These were rechecked at three monthly intervals.

Are services effective?

(for example, treatment is effective)

Patients could refuse to give their GP details but the doctor described explaining why these were necessary.Once informed we were told patients usually consented to the details being recorded.

Patients were referred to their GP if they were unsuitable for treatment or if investigations within the consultation had identified other problems, for example high blood sugar levels. We saw evidence of treatment being refused and patients being referred back to their GP. Records were kept of these referrals within the patient's clinic record.

Supporting patients to live healthier lives

The service provided patients with detailed information on healthy diet choices and exercise. If patients struggled with literacy, this information was available in pictorial formats to support patient's weight loss. People who were on a break from treatment or for whom treatment was not suitable could still access the service for lifestyle advice and to be weighed regularly. This service was provided free of charge. Patients who were receiving medicines were given detailed information about the medicine. Patients were able to contact the doctor outside clinic hours to discuss any concerns.

Consent to care and treatment

Patients were asked to sign a registration form to confirm that the information they had provided on their medical history was correct. This also included their consent to treatment. The doctor was able to explain their obligations in assessing mental capacity.

The service provided unlicensed medicines and we saw that the information given to patients made this clear. Consent to treatment was recorded in the consultation records.

Information on the cost of treatment was set out in the patient guide which was given at the first consultation. There was no charge for advice and weighing only.

Are services caring?

Our findings

Kindness, respect and compassion

We spoke to five patients during our inspection. All of the patients we spoke to were positive about the care they received from the service**.** They told us the doctor was knowledgeable and gave good advice in a non-judgemental way that supported their weight loss. Patients appreciated that the doctor provided healthy lifestyle advice as well as medicines.

The provider also conducted their own patient survey which supported these findings.

Involvement in decisions about care and treatment

Patients told us they felt involved in decisions around their care**.** Patients were clear that weight targets were personalised and jointly agreed between the doctor and the patient.

We saw that patients spent as long as they needed with the doctor; consultations were not rushed.

The doctor explained that information could be provided in large print to aid patients with visual impairments.

Privacy and Dignity

We saw that consultations were held in a room with the door closed . Conversations could not be overheard by patients in the waiting room.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The clinic was on the first floor of a parade of shops and was accessed via a flight of stairs. There was no lift available. The doctor told us that patients could be seen at either of the other two clinic locations if Bedford was not suitable for them.

The doctor had information leaflets available in a range of languages to provide information to people whose first language was not English. He had obtained leaflets in the languages commonly spoken by people attending the clinic. The doctor told us that a person would be able to bring a family member or friend as an interpreter if they wished. However this would mean the doctor had no assurance that information was being relayed accurately.

The doctor told us that there was a group of patients who had difficulty reading and writing who regularly attended the clinic. We saw that pictorial information was available to describe food choices and information on the medicines. The doctor told us he would read the new patient information leaflet to a person who could not read themselves before they consented to treatment.

Timely access to the service

The clinic operates between 10am and 4pm every Thursday. There were no pre-bookable appointments since the service operates as a 'walk in' clinic. We asked about contingency plans in the event of the doctor being unable to attend a clinic. The doctor told us that another doctor would be sourced via the locum agency. However, this had never happened in practice. We saw that holiday closure dates were advertised well in advance to reduce patient inconvenience.

The doctor provided a telephone number for patients to call on days the clinic was closed if they had any concerns or queries. We saw this being used by patients during our inspection.

Listening and learning from concerns and complaints

There was a policy in place for handling complaints . Details of this were included in the information given to patients when they initially visit Harmony clinic. This information was not included on the clinic's website.

No complaints or concerns had been received. The clinic undertook a patient satisfaction survey to identify patient feedback. The patient survey had identified requests for additional days of opening. Unfortunately this was not currently possible as the doctor worked elsewhere during the week. Additional days for the clinic were being considered as part of the development of the business.

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;

The registered manager had retired from clinical practice and did not work on a day to day basis within the service. We spoke to the registered manager who confirmed they would discuss any concerns with the doctor working in the clinic. The provider was pursuing changing the registered manager responsibility to the doctor working in the clinics. There were two other locations of this service run by the same provider; one in London and one in Coventry. The doctor told us they worked across all three, ensuring a consistent service. He confirmed that the registered manager was available by telephone and email to discuss concerns and encouraged the doctor to develop the service.

The doctor was supported to keep clinically up to date and had accessed training opportunities to support their work in the clinic.

Vision and strategy

Although there was no written corporate vision or strategy the doctor described the aims of the service to help patient lose weight to improve their overall health and well-being.

Culture

The provider promoted a culture of learning and improvement through education and audit. The doctor was encouraged to attend courses appropriate to the service. The doctor emphasised the culture of providing support for patients outside of simply giving medicines. This was evidenced by patients being able to access the service for advice and weighing without charge.

The doctor was aware of the requirements of the Duty of Candour regulation. Observing the Duty of Candour means that patients who use the clinic would be told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result. The doctor described an open and honest approach in his consultations with patients.

Governance arrangements

In contrast to the previous inspection, we saw that the registered manager and the doctor had produced a comprehensive set of policies and procedures governing activities of the service. We saw evidence that these were in use during our inspection.

Managing risks, issues and performance

The doctor working in the clinic had day to day responsibility for the running of the clinic. He audited the activities within the clinic to identify areas for improvement.

The provider was registered with the Information Commissioner 's Office . There was a policy in place to describe how patient data would be handled if the provider ceased to operate.

Appropriate and accurate information

Patients provided their medical history and information about their medicines use. Consent to share information with GPs was sought and we saw examples where this sharing had resulted in improved patient care.

Engagement with patients, the public, staff and external partners

The provider encouraged and routinely sought patient feedback. A patient survey was given at the second consultation and then was subsequently available for patients to complete at each visit to the clinic. The results of this survey were analysed on an annual basis to determine whether changes to the service were needed. The doctor told us that urgent concerns would be reviewed by him and dealt with immediately.

Continuous improvement and innovation

The doctor providing the service took every opportunity to access learning relevant to their role and this was supported by the provider. The doctor had analysed weight loss data regularly. Analysis had resulted in tailoring treatments to better meet patients' needs . This included offering free of charge weight checks and advice outside of the schedule for providing medicines. Analysis of referral data demonstrated the value of physical monitoring. The doctor had adapted their approach to the checking of blood sugar levels to reduce patient inconvenience resulting from re-tests being needed if patients had not fasted. They offered follow up appointments for testing if an initial risk assessment had indicated a high risk of diabetes.

We discussed how the service might develop with the doctor (who was going to be the registered manager). Areas for future development included increasing the number of clinics offered, improving marketing of the clinic. This would include talking to GPs to increase awareness of the service offered.

Are services well-led?

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

These ideas for development had been shared with the registered manager. The doctor had been encouraged to implement them to improve the service offered.