Harmony (Your Gentle Way To Slim) Limited

Harmony Medical Diet Clinic in Coventry

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 4 October 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.

The clinic provided slimming advice and prescribed medicines to support weight reduction. It was a private service. The service operates from a third floor consulting room in an office block in Coventry town centre. It is open from 10am to 4pm on Wednesdays. 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 registered manager provides supervision and support to the doctor who provides the service.

Summary of findings

We collected feedback about the service from 11 patients through CQC comment cards and speaking to patients during the inspection. Patients said they received good advice, the doctor was knowledgeable and professional and 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 very positive about the care they received.
- The service was flexible to fit in with patient choice
- 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.

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

- Review and risk assess the appropriateness of having a family member of the patient as a translator.
- Review the necessity for chaperoning at the service and consider how this may be provided within this service.
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.

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 provider was not able to identify any incidents that had occurred in the past 12 months. The doctor was able to describe how they would report and investigate and comply with Duty of Candour if necessary. The doctor was aware of his safeguarding responsibilities and had an appropriate policy in place. The doctor employed by the service had undertaken training and additional qualifications that related to his role within the clinic. The provider did not offer a chaperone service but patients could see the doctor with a friend or family member if they wished. The premises were clean and tidy. Medicines were stored securely, and records of medicines stock levels were maintained. The provider made the appropriate checks before staff were employed. The premises were suitable and clean.

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.

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

Comments from patients were consistently positive. They were given information on the costs of treatment, and about diet and exercise to support their weight loss. Patients were able to access the service for advice and weighing without charge, to support their weight loss. Where literacy was a problem the provider had produced pictorial information. We saw that the doctor did not limit his consultation time. This was to ensure patients received enough information in a manner they could understand.

Are services responsive to people's needs?
We found that this service was providing responsive care in accordance with the relevant regulations.

The provider collected feedback on the service through a patient survey at the start of treatment. Patients were given a contact number in case of any concerns about their treatment. Patients did not have to make an appointment and could just walk in and be seen. Patients were encouraged to attend weekly to obtain frequent support and advice without the need to purchase medicines.

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

The doctor providing the service had an annual appraisal that reflected his role. The doctor regularly reviewed the effectiveness of interventions and described changes to his advice to patients as a result of his investigations. We saw policies and procedures to govern the activity of the clinic during our inspection.

Harmony Medical Diet Clinic in Coventry

Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection at Harmony Medical Diet Clinic on 4 October 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

Reporting, learning and improvement from incidents

The doctor told us that there had been no incidents in the last 12 months. The doctor described the process they would undertake to report and investigate an incident. The doctor was aware of the need for openness and honesty in keeping with the requirements of the duty of candour.

The doctor was aware that some incidents should be reported to the Care Quality Commission.

Reliable safety systems and processes (including safeguarding)

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.

The individual working within the service was the safeguarding lead and had undertaken both adult and child safeguarding training in September 2015. Theywere able to describe the process to follow if they had any concerns. The service only treated adults however the doctor demonstrated an understanding of safeguarding responsibilities for any children who may accompany adults to appointments. The doctor also demonstrated awareness of the possibility of patients being coerced to lose weight. He described refusing treatment for patients with low BMIs. We saw a nationally validated questionnaire in use to identify patients at risk of anorexia.

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.

Medical emergencies

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.

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, 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).

The doctor was registered with the General Medical Council and 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. We spoke to patients who told us they had never felt the need for a chaperone but would bring family members or friends if needed.

Monitoring health & safety and responding to risks

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

We asked about contingency plans in the event of the doctor being unable to attend a clinic. This is a lower priority since the service operates as a ‘walk in’ service and appointments are not booked. The doctor told us that another doctor would be sourced via the locum agency although this had never happened in practice. We saw that the closure dates were well advertised to reduce patient inconvenience.

Infection control

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.

Are services safe?

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.

Premises and equipment

The premises were rented by the provider and were in a good state of repair. We saw fire risk assessment and evidence that the doctor had undertaken fire safety in the workplace training. A formal Legionella risk assessment had been completed

We saw a policy describing the process for managing electrical equipment and weighing scales etc. The digital scales and blood pressure machine were replaced annually and the blood glucose meter was calibrated using control solutions by the doctor. We saw evidence of new equipment being obtained recently.

Safe and effective use of medicines

The doctor at this service prescribed 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 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 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 Medical Diet Clinic we found patients were treated with unlicensed medicine. 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, packaged and supplied. 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 and a separate weekly check was also carried out. Medicines were dispensed into appropriately labelled containers and records were kept of medicines supplied to patients.

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 to reduce the risk of medicines being obtained fraudulently.

Are services effective?

(for example, treatment is effective)

Our findings

Assessment 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 checked patient's records and saw that they had health checks on their first visit and information was recorded about relevant concerns. Patients' medical history, weight and blood pressure were taken at their initial visit. Their body mass index (BMI kg/m2) was calculated and target weights agreed and recorded. If the doctor felt it was necessary, 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. The service had a prescribing policy in place, however the stated criteria for prescribing appetite suppressants was not in line with current guidance. The policy allowed for patients with BMIs of 28kg/m2 with no co-morbidities to be treated. This increased the risk of patients experiencing adverse effects with little or no benefit from treatment. In addition we checked 10 patient records. We found one patient whose BMI had been greater than 30 at start of therapy but who had dropped to a BMI of 27 and had continued to receive treatment without documented review. This was discussed with the doctor in the clinic who agreed to review their policy.

Patients could access the service as frequently as they wished to obtain support or advice but could only obtain medicines on an agreed schedule. Medicines would usually be provided monthly but where more than one months supply had been issued the doctor recorded the reason for this in the patient's records. Patients could come and consult with the doctor for weight management advice and be weighed as often as they wished. There was no charge for this type of consultation.The records confirmed that patients had a break between courses of treatment at least every 12 weeks. Patients who were on a break from treatment could access the service to be weighed and discuss their progress with the doctor. The patients we spoke to confirmed they had been advised about treatment breaks.

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 3, 6 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.

Staff training and experience

The doctor was on the General Medical Council register and their last appraisal was in August 2017. We saw certificates to show they 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.

Working with other services

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. However not all patients wanted their GP to know about their treatment and the service did not routinely request GP contact details. This was discussed during the visit and the doctor agreed to reconsider this and showed us subsequently an amended data collection card that required GP details. Patients are now required to provide GP details before medicines may be obtained.

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. During the inspection we saw evidence of treatment being refused and a patient being referred back to their GP due to contraindications to the medicines used within the clinic.

Are services effective?

(for example, treatment is effective)

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 and that they consented to treatment. The doctor was able to explain their obligations in assessing mental capacity and we saw evidence of this being considered during a consultation.

The service prescribed some unlicensed medicines. Information about this was provided to patients in the registration form and information leaflet. These were given to everyone before medicines were provided and patients signed to indicate their consent.

Are services caring?

Our findings

Respect, dignity, compassion & empathy

Patients we spoke to or who completed comment cards told us what they thought about the service. We received comments from eleven patients which were all positive. They said 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.

Involvement in decisions about care and treatment

Patients told us they were given information about their treatment. A range of information on food choices and exercise was given.

Information on the cost of treatment was set out in a patient guide and patients recalled having been provided with this at their first appointment. There was no charge for advice and support only.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting patients' needs

The provider routinely carried out a survey of patients at the second consultation. The results of the survey were aggregated across the three clinics operated by Harmony Medical Diet Clinic as the same doctor ran each service. The doctor told us that a few patients had said they would like longer opening hours, but they were not able to provide this at the moment. The service will be moving to new premises shortly and we were told that opening hours and days of opening will be reviewed following the move.

Patients were given a number that they could contact at any time if they had concerns about their treatment.

Tackling inequity and promoting equality

The clinic was on the third floor of an office block in Coventry town centre and was accessed via lift. The clinic was wheelchair accessible

There had been no significant demand for the service from patients who did not speak English and so the provider had not made adjustments for this. The doctor told us that a person would be able to bring a family member 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 . 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. We heard from patients that this support was appreciated and we saw evidence of poor literacy being handled sensitively by the doctor.

Access to the service

The clinic is open on Wednesday from 10am to 4pm. Patients could walk in and be seen by the doctor promptly. Some preferred to visit once a month but others, who wanted more support, could be seen every one or two weeks. The doctor gave patients a contact phone number they could use to call for advice. The doctor confirmed they answered this out of hours and at weekends. We saw that advance notice of holidays was displayed to alert regular patients.

Concerns & complaints

We saw there was a complaints policy in place. The people we spoke to said they had not needed to make a complaint but knew how to do so. The complaints process was detailed in the initial information leaflet given to patients when they accessed the service. Patients could complain to the registered manager who was not the doctor working in the clinic. In addition, details for raising concerns with the Care Quality Commission were in the information leaflets

Are services well-led?

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

Our findings

Governance arrangements

The clinic was run by one doctor who was supported by the registered manager who was also a doctor. 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 Bedford. The doctor told us they worked across all three, ensuring a consistent service. We saw systems for initial patient assessments were recorded on a paper form and this was scanned onto a patient's electronic records. All subsequent consultations were recorded electronically and the doctor told us these were backed up to another server regularly. The service was registered with the Information Commissioners Office. We saw that the results of our previous inspection were displayed for patients to see.

We saw policies governing activities in the clinic (for example infection control, fire safety, calibration of equipment, complaints handling and medicines management)

Leadership, openness and transparency

The doctor was 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.

Learning and improvement

The doctor providing the service took every opportunity to access learning relevant to their role and this was supported by the provider. This had led to improvements in their advice on sweeteners and their role in weight loss. The doctor had analysed weight loss data which had resulted in tailoring treatments to better meet patients' needs. Analysis of referral data demonstrated the value of physical monitoring. Checking blood sugar levels and blood pressure had resulted in patients seeing their GP for additional monitoring or treatment.

Provider seeks and acts on feedback from its patients, the public and staff

The clinic collected patient feedback through a questionnaire which showed that patients were satisfied with the service provided. The doctor told us they were able to share ideas to improve the service with the registered manager.