Harmony Medical Diet Clinic in Bedford

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Requires improvement
Are services safe?	**Requires improvement**
Are services effective?	**Requires improvement**
Are services caring?	**Good**
Are services responsive?	**Good**
Are services well-led?	**Requires improvement**

Overall summary

This service is rated as Requires improvement overall.
(Previous inspection November 2017 – not rated)

The key questions are rated as:

Are services safe? – Requires improvement

Are services effective? – Requires improvement

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Requires improvement

We carried out an announced comprehensive inspection at Harmony Medical Diet Clinic in Bedford to rate the service for the provision of safe, effective, caring, responsive and well-led services as part of our current inspection programme.

Harmony Medical Diet Clinic provides weight loss services for adults, including the prescription of medicines for purposes of weight loss. The service is run by a doctor and there are no other staff.

The doctor 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.

Nine people provided feedback about the service through comment cards and speaking with us. Their comments were positive about the service. However some were disappointed that, in line with national guidance, they were not eligible for prescription medicines or could not obtain a large quantity of medicines at one time.

Our key findings were:

- The provider prescribed and supplied medicines in line with current national guidance
- Patients said they were given the information they need and had the opportunity to ask questions
- Policies did not always include sufficient detail to ensure consistent care
- The service monitored risks and activities but did not always take follow up action to improve care

The areas where the provider **must** make improvements as they are in breach of regulations are:

- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care

The areas where the provider **should** make improvements are:

- Improve the process for information sharing with other organisations
- Provide up to date information in the patient leaflet
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available

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Chief Inspector of Primary Medical Services and Integrated Care

Our inspection team

Our inspection team was led by a member of the CQC medicines team and included another member of the CQC medicines team.

Background to Harmony Medical Diet Clinic in Bedford

Harmony Medical Diet Clinic in Bedford is a private weight loss service provided by Harmony (Your Gentle Way To Slim) Limited. It is located in first floor premises in Bedford city centre. The service is provided on a walk-in basis. Patients are weighed at each visit. There is a charge for any medicines supplied. The service is available to adults aged 18 and over, and is open on Thursdays from 10.00am to 4.00pm. The provider also runs clinics in Coventry and Wood Green which are registered with CQC. They have been inspected as part of our programme.

How we inspected this service

Prior to the inspection we reviewed information about the service, including previous inspection reports and information given to us by the provider. We spoke to the registered manager, reviewed a range of documents and got feedback from patients through comment cards and speaking with them.

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.

Requires improvement

Are services safe?

We rated safe as Requires Improvement because:

there were no clear processes for recording acting on significant events and safety incidents.

Safety systems and processes

The service had systems to keep people safe and safeguarded from abuse.

- The provider conducted safety risk assessments. It had appropriate safety policies, which were regularly reviewed. They outlined clearly who to go to for further guidance.
- The service was aware of how to contact other agencies to support patients and protect them from neglect and abuse.
- The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. Disclosure and Barring Service (DBS) checks were undertaken where required. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable).
- The doctor had up-to-date safeguarding and safety training appropriate to their role. They knew how to identify and report concerns.
- There was a system to manage infection prevention and control. There was a policy on the management of legionella but it included information which was not relevant to the service. The provider told us the building landlord was responsible for the arrangements and that testing was not necessary but they were not able to provide records to confirm this.
- The provider ensured that facilities and equipment were safe and that equipment was maintained according to manufacturers' instructions.
- The provider carried out appropriate environmental risk assessments, which took into account the profile of people using the service and those who may be accompanying them.

Risks to patients

There were systems to assess, monitor and manage risks to patient safety.

- As a single handed practice operating a walk in service, there was limited scope to plan and monitor the number and mix of staff needed.
- The doctor understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention.
- The provider had assessed that the risk of a medical emergency was low and therefore they did not hold any emergency medicines. The doctor had up to date training in basic life support and the policy required them to call the emergency services if needed.
- When there were changes to services or staff the service assessed and monitored the impact on safety.
- There were appropriate indemnity arrangements in place covering professional practice and public liability

Information to deliver safe care and treatment

Staff had the information they needed to deliver safe care and treatment to patients.

- Individual care records were written and managed in a way that kept patients safe. The provider had recently started to record target weights.
- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading.

Safe and appropriate use of medicines

The service had systems for appropriate and safe handling of medicines.

- The systems and arrangements for managing medicines, including controlled drugs, minimised risks.
- The service had recently updated their medicines policy to bring it into line with best practice guidelines for safe prescribing. The policy included a plan to audit every three months.
- The service prescribed medicines including Schedule 3 controlled drugs (medicines that are controlled due to their risk of misuse and dependence). They had appropriate storage arrangements and records.
- The doctor prescribed, administered or supplied medicines to patients and gave advice on medicines in line with legal requirements and current national guidance. Processes were in place for checking medicines and there were accurate records of medicines. The policy had recently been updated to include discussion with another clinician where there was a plan to take a different approach from national guidance.

Requires improvement

Are services safe?

- The medicines this service prescribes for weight loss are unlicensed. 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. These medicines are no longer recommended by the National Institute for Health and Care Excellence (NICE) or the Royal College of Physicians for the treatment of obesity. The British National Formulary states that 'Drug treatment should never be used as the sole element of treatment (for obesity) and should be used as part of an overall weight management plan'.

Track record on safety and incidents

The service had a good safety record.

- The service monitored and reviewed activity. This helped it to understand risks and gave a clear, accurate and current picture that led to safety improvements.

Lessons learned and improvements made

The service did not always learn and make improvements when things went wrong.

- There was no clear system for recording and acting on significant events or for reviewing and investigating when things went wrong.
- The provider was not able to give examples of where they had learned lessons, identified themes or taken action to improve safety in the service.
- The provider was aware of and complied with the requirements of the Duty of Candour.
- There were no examples of unexpected or unintended safety incidents and the provider was not able to demonstrate a system for keeping written records of verbal interactions.
- The service had a mechanism in place to receive and review patient safety alerts.

Requires improvement

Are services effective?

We rated effective as Requires improvement because:

There was an audit plan in place but completed audits did not include an action plan to resolve concerns and improve quality. The service did not always record patient consent to share information with their GP. Information given to patients had not been updated in line with national guidance. Although patients were given information about the unlicensed medicines used in the service, consent to care and treatment was not always recorded in the electronic record and available during the consultation.

Effective needs assessment, care and treatment

The provider had systems to keep clinicians up to date with current evidence based practice. We saw evidence that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service)

- The provider had recently revised their policy to ensure that they assessed needs and delivered care in line with relevant and current evidence based guidance and standards. There were clear criteria for treatment and the records we reviewed showed that new patients presenting with a body mass index of less than 30, or less than 28 with co-morbidities, were not prescribed medicines. The patient information sheet had not been updated to explain who was eligible for treatment.
- Patients' needs were assessed and where appropriate this included their clinical needs and their mental and physical wellbeing. The registered manager told us they reviewed patients' medical history regularly but did not have a policy to ensure it was recorded consistently.
- We saw no evidence of discrimination when making care and treatment decisions.
- The service had updated their policy to ensure they only supplied a maximum of 30 days treatment in line with Department of Health guidance on controlled drugs. The registered manager told us that when patients arranged for a representative to collect medicines on their behalf, the patient would need to attend in person every third prescription. Records were kept when this happened but they did not have a policy to ensure it was managed consistently.

Monitoring care and treatment

The service was involved in monitoring quality but did not always undertake improvement activity

- The service monitored care and treatment. Clinical audit was used to monitor outcomes for patients. The audit plan had recently been expanded to include monitoring the quality of consultation records and prescribing decisions against national guidance. One audit had been carried out since the introduction of the new policy but there was no action plan in place to resolve concerns and improve quality. For example 69% of records included a recorded target weight but there was no plan to improve this figure.

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles.

- The doctor was registered with the General Medical Council and was up to date with revalidation
- The doctor understood their learning needs and undertook training to meet them. Up to date records of skills, qualifications and training were maintained.

Coordinating patient care and information sharing

Staff did not always work with other organisations to deliver effective care and treatment.

- Patients received coordinated and person-centred care but we did not see any examples of co-ordination with other services.
- Before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history.
- All new patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP but in some of the electronic records we looked at this was not clearly documented and was not reviewed at each consultation. Patients who agreed to share their information would be given a letter to give to their GP but we did not see any examples where this had happened in line with GMC guidance.

Supporting patients to live healthier lives

Staff were consistent and proactive in empowering patients, and supporting them to manage their own health and maximise their independence.

Requires improvement

Are services effective?

- Where appropriate, the doctor gave people advice so they could self-care. New patients were given an information sheet including suggestions for diet and exercise.
- Patients were informed about the risks and possible side effects of medicines.

Consent to care and treatment

The service did not always obtain consent to care and treatment in line with legislation and guidance.

- Staff understood the requirements of legislation and guidance when considering consent and decision making.
- Staff supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision.
- There was a process for obtaining consent to care and treatment, for example patients were given information about the unlicensed medicines prescribed by the clinic, but this was not clearly documented in some of the electronic records we looked at.

Good

Are services caring?

We rated caring as Good

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- The service sought feedback on the quality of clinical care patients received.
- Feedback from patients was positive about the way staff treated people and said the doctor gave them time to ask questions and made helpful suggestions on how they could achieve weight loss.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.
- Patients told us that the service gave them timely support and information.

Involvement in decisions about care and treatment

Staff helped patients to be involved in decisions about care and treatment.

- The service had assessed the need for interpretation services and determined that it was not necessary for their population.
- Patients told us in person and through comment cards, that they felt listened to and supported by staff and had sufficient time during consultations to make an informed decision about the choice of treatment available to them.
- The doctor communicated with people in a way that they could understand. Instructions such as when to take the medicines and certain foods to avoid at the same time were available in pictorial form.

Privacy and Dignity

The service respected respect patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect.
- Patients were seen in a private consulting room

Good

Are services responsive to people's needs?

We rated responsive as Good

Responding to and meeting people's needs

- The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.
- The provider understood the needs of their patients and improved services in response to those needs. Information was available in pictorial form.
- The facilities and premises were appropriate for the services delivered.
- There were limited facilities to allow people in vulnerable circumstances to access and use services on an equal basis to others. The consulting room was on the first floor and accessed via stairs. The provider could signpost to their other step-free locations but they were not local. There were no arrangements for people with visual or hearing impairments.

Timely access to the service

Patients were able to access care and treatment from the service within an appropriate timescale for their needs.

- Patients had timely access to initial assessment and treatment.
- Clinic closing dates, for example public holidays, were communicated well in advance on the website and in the clinic.
- Patients told us that as a walk-in service they understood the need to wait occasionally while the doctor spend additional time with a patient.

Listening and learning from concerns and complaints

The service took complaints and concerns seriously and responded to them appropriately.

- Information about how to make a complaint or raise concerns was available.
- The service informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint.
- The service had a complaint policy in place but it did not include guidance on how complaints should be recorded, assessed and reviewed. There were no recent examples of complaints.

Requires improvement

Are services well-led?

We rated well-led as Requires improvement because:

Policies were in place but were not sufficiently detailed to ensure consistency. Risk assessments were not all documented. There was a policy for managing complaints but it relied on verbal resolution. There was no process to ensure that concerns, complaints and incidents were identified, recorded and reviewed to take action to improve. Audits and patient surveys were carried out but there were no action plans to drive improvement.

Leadership capacity and capability;

Leaders had some capacity and skills to deliver high-quality, sustainable care.

- The provider was knowledgeable about some of the issues and priorities relating to the quality and future of services. They understood the challenges and were addressing them.
- The provider had processes to develop leadership capacity and skills, including planning for the future leadership of the service.

Vision and strategy

The service had a vision and strategy to deliver high quality care and promote good outcomes for patients.

- There was a vision and set of values. The service was considering strategies and supporting business plans to achieve priorities.

Culture

The service had a culture of sustainable care.

- The service focused on the needs of patients.
- The provider was aware of, and had systems to ensure compliance with, the requirements of the duty of candour. The doctor undertook training and development relevant to their role, and met the requirements of professional validation

Governance arrangements

There were some systems of accountability to support governance and management.

- Structures, processes and systems to support governance and management were understood and effective.
- The provider had established policies, procedures and activities to ensure safety, but they relied solely on the registered manager who was the doctor. They were not sufficiently detailed to ensure consistency if for example a locum doctor was ever required. For example there was no policy to ensure that the doctor reviewed the patient's medical history regularly or recorded a target weight.

Managing risks, issues and performance

Processes for managing risks, issues and performance were ineffective.

- There was a process to identify, understand, monitor and address current and future risks including risks to patient safety but it was not always clearly documented, for example there was no documented legionella risk assessment.
- Performance of clinical staff could be demonstrated through audit of their consultations and prescribing but it was not comprehensive and had not identified that consent to treatment and to sharing information was not always recorded.
- Individual safety alerts, incidents, and complaints were managed but there was no policy to ensure they were recorded consistently in a way that allowed themes to be identified.
- Clinical audit was used to monitor quality of care and outcomes for patients but there were no examples of positive action to improve. There was evidence of recent change to bring the service into line with national guidance on prescribing

Appropriate and accurate information

The service collected appropriate and accurate information but did not always act on it.

- Quality and operational information was used to monitor performance.
- The service had performance information which was reported and monitored.
- The information used to monitor performance and the delivery of quality care was accurate. There were limited plans to address any identified weaknesses.
- There were robust arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.

Engagement with patients, the public, staff and external partners

Requires improvement

Are services well-led?

The service involved patients in a limited way to support services.

- The service encouraged and heard views and concerns from patients but did not always act on them to shape services and culture. Patients were given feedback forms but there was no process to review and plan changes based on the comments.

Continuous improvement and innovation

There was limited evidence of systems and processes for learning, continuous improvement and innovation.

- There was evidence of learning. The doctor had completed e-learning modules provided by an obesity professional education organisation.
- There was no effective process to record and review incidents and complaints and no evidence that learning was used to make improvements.

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 the service provider was not meeting. The provider must send CQC a report that says what action it is going to take to meet these requirements.

Regulated activity	Regulation
Services in slimming clinics	Regulation 17 HSCA (RA) Regulations 2014 Good governance Systems or processes must be established and operated effectively to ensure compliance with the requirements of the fundamental standards as set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 The registered person had systems or processes in place that operated ineffectively in that they failed to enable the registered person to ensure that accurate, complete and contemporaneous records were being maintained securely in respect of each service user. In particular: Consent to information sharing with their GP was not clearly recorded in the electronic patient records in eight out of 15 records we reviewed. Paper records were not always available at point of consultation. Consent to treatment was not clearly recorded in the electronic patient records in ten out of 15 records we reviewed. Paper records were not always available at point of consultation. The registered person had systems or processes in place that operated ineffectively in that they failed to enable the registered person to evaluate and improve their practice in respect of the processing of the information obtained throughout the governance process. In particular: The audit carried out on 2 March 2020 was not followed up with an action plan for improvement. The policy for handling complaints relied on verbal resolution, there was no documented process for recording or reviewing complaints to identify themes. There was no policy for recording incidents and concerns and reviewing them to identify themes.