

# Harmony (Your Gentle Way To Slim) Limited

## Harmony Medical Diet Clinic in Wood Green

### Inspection report

Express Pharmacy  
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### Ratings

Overall rating for this service	Requires improvement	
Are services safe?	Inadequate	
Are services effective?	Requires improvement	
Are services caring?	Good	
Are services responsive to people's needs?	Good	
Are services well-led?	Requires improvement	

### Overall summary

**This service is rated as Requires improvement overall.** The previous inspection in January 2017 was not rated.

The key questions are rated as:

Are services safe? – Inadequate

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 at Harmony Medical Diet Clinic in Wood Green as part of our inspection programme.

# Summary of findings

Harmony Medical Diet Clinic provides weight loss services for adults, including the provision of medicines for the purposes of weight loss under a doctor's supervision.

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.

11 people provided feedback about the service and their comments were all positive. They told us it was a friendly, effective service.

## Our key findings were:

- Patient feedback was positive and they found the service effective
- Patient leaflets were available in a range of languages and in pictorial form
- Processes to ensure the proper and safe management of medicines were not effective
- Equipment had not been calibrated
- Processes to assess and monitor risks and quality of service were not effective

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

- Ensure that care and treatment is provided in a safe way.

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

(Please see the specific details on action required at the end of this report).

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

- Review the need for chaperones and, if the service is offered, ensure suitably trained and competent staff are available.
- Review the policy for disposal of medicines to ensure it is in line with controlled drugs regulations and followed in practice.
- Consider including a question on the quality of clinical care provided when asking patients for feedback
- Review the arrangements for ensuring that the service only treats patients aged 18 and over
- Review the arrangements for the retention of medical records if the provider ceases trading, in line with Department of Health guidance.
- 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

# Harmony Medical Diet Clinic in Wood Green

## Detailed findings

### Background to this inspection

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

Harmony Medical Diet Clinic in Wood Green is a private weight loss service provided by Harmony (Your Gentle Way To Slim) Limited. It is located on the ground floor of a community pharmacy at 214 High Road, Wood Green, London N22 8HH. The service is provided on a walk-in basis, and patients wait in the pharmacy until the doctor is available to see them. 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 Mondays and Tuesdays from 9.30am to 4.30pm. The provider also runs clinics in Bedford and Coventry which are registered with CQC. The other locations have been inspected but not yet rated.

### How we inspected this service

Prior to the inspection we reviewed information about the service, including the previous inspection reports from all locations and information given to us by the provider. We spoke to the registered manager and reviewed a range 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

### We rated safe as Inadequate because:

Systems and processes did not ensure that care was provided in a safe way.

#### Safety systems and processes

##### The service did not have all systems necessary to keep people safe and safeguarded from abuse.

- The provider conducted safety risk assessments. It had appropriate safety policies, which were regularly reviewed. The service had systems to safeguard children and vulnerable adults from abuse.
- The service worked with other agencies to support patients and protect them from neglect and abuse. Staff took steps to protect patients from abuse, neglect, harassment, discrimination and breaches of their dignity and respect.
- 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.
- The doctor had up-to-date safeguarding and safety training appropriate to their role. They knew how to identify and report concerns. The doctor told us that no patients had requested a chaperone but they would ask a member of staff from the pharmacy to act as chaperone if needed. However the service had not checked that the staff were trained, that they had DBS checks or that they were willing to provide the service.
- The system to manage infection prevention and control was not effective. There was a legionella policy in place but the provider had not carried out a risk assessment to determine whether legionella testing was necessary. The clinic was cleaned regularly and alcohol gel and wipes were available.
- The provider had not ensured that facilities and equipment were safe and that equipment was maintained according to manufacturers' instructions. The weighing scales were purchased three years ago and the three blood pressure monitoring devices were purchased up to four years ago. They had not been calibrated since purchase and there was no schedule for calibration or replacement.

- 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, the arrangements for planning and monitoring the number and mix of staff needed were limited.
- Staff 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 was trained in basic life support and the policy required staff 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 including professional indemnity.

#### Information to deliver safe care and treatment

##### Staff did not have all 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 care records we saw showed that information such as patient's height, weight, body mass index and blood pressure were recorded. However discussions with the patient about target weight were not recorded, and any medicines supplied to the patient were recorded in an abbreviated form. The name, form and strength and quantity were not recorded in full so may not be understood if the records needed to be shared.
- The service had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment.
- The service did not have 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

## Are services safe?

### **The service did not have reliable systems for appropriate and safe handling of medicines.**

- The systems and arrangements for managing medicines, including controlled drugs, did not minimise risks. The policy for the disposal of out of date or returned medicines did not comply with the Controlled Drugs regulations and was not followed in practice.
- The service carried out audits on patient weight loss but did not assess prescribing against current best practice guidelines to ensure safe prescribing.
- 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. Patients were able to nominate a representative to collect medicines on their behalf. Although records were maintained, there was no policy to define how often the patient must attend in person for review with the doctor.
- Staff did not prescribe, supply and give advice on medicines in line with legal requirements and current national guidance. The prescribing policy included subjective descriptions about not prescribing for people who were under weight or very over weight rather than objective inclusion and exclusion criteria such as body mass index (BMI). We saw patient records which indicated that the service supplied medicines to people with a BMI of 23 and over and excluded people with a BMI of 22 and under. The evidence used to support this approach was from 2004 and not robust. The provider had not updated the prescribing policy in line with current national guidance. There was no process to ensure that patients were aged 18 and over. Processes were in place for checking medicines and staff kept accurate records of medicines.
- 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 did not have a good safety record.**

- The service did not monitor and review activity in a way that helped it to understand risks and give an accurate 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 a system for recording and acting on significant events however they were recorded in the patient’s individual care records which meant the provider was not able to identify themes and take action to improve safety in the service.
- The provider was aware of and complied with the requirements of the Duty of Candour.

When there were unexpected or unintended safety incidents:

- The service gave affected people reasonable support, truthful information and a verbal apology. There were no examples of written apologies.
- They kept written records of verbal interactions but there were no examples of written correspondence.
- The service had a mechanism in place to receive patient and medicine safety alerts.

# Are services effective?

(for example, treatment is effective)

## Our findings

### We rated effective as Requires improvement because:

Patients needs were not effectively assessed and care was not delivered in line with current guidance.

#### Effective needs assessment, care and treatment

**The provider did not have systems to keep clinicians up to date with current evidence based practice. We saw evidence that clinicians did not assess needs and deliver care and treatment in line with current legislation, standards and guidance (relevant to their service)**

- The service did not have a documented policy for eligibility for treatment, other than subjective descriptions such as underweight and very overweight. The doctor prescribed medicines to patients with a body mass index of 23 and over, based on outdated evidence. They had not reviewed this approach in line with current guidance such as the National Institute for Health and Care Excellence (NICE) clinical guideline on obesity which gives a minimum body mass index of 30, or 28 with one or more co-morbidities. Patients' immediate and ongoing needs were assessed but although the doctor told us they discussed a target weight this was not recorded. Where appropriate the assessment included patients' clinical needs and their mental and physical wellbeing.
- We saw no evidence of discrimination when making care and treatment decisions.
- There was no effective process to deal with repeat patients. The duration of the prescription and the frequency of review varied according to the distance the patient had to travel and their working hours. Patients could nominate someone else to collect their medicines. Although the rationale for this was usually documented, it meant the doctor may not see some patients regularly and the frequency of face to face reviews was not planned or monitored.

#### Monitoring care and treatment

**The service was actively involved in quality improvement activity.**

- The service monitored care and treatment. Clinical audit was used to monitor outcomes for patients but did not monitor the quality of care against current national

guidance. Audits in the last year included patients who experienced side effects from the medicines and patients who achieved the average weight loss (based on the previous year's data). The audit showed that one of the reported side effects was a dry mouth and as this continued to be reported in successive years, the doctor advised people about it before starting treatment.

#### 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 provider 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 well with other organisations, to deliver effective care and treatment.**

- Patients received person-centred care but there were no examples of co-ordination with other services. When treating patients referred from another provider, the service did not share information with the referring organisation.
- 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 patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP. We did not see any examples of letters sent to their registered GP 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.**

- Where appropriate, staff gave people advice so they could self-care. New patients were given an information sheet, and there were photographs of meal suggestions to give people ideas for a healthy diet.
- Patients were informed about the risks and possible side effects of medicines

# Are services effective?

(for example, treatment is effective)

- Where patients needs could not be met by the service, staff redirected them to the appropriate service for their needs.

## **Consent to care and treatment**

**The service obtained 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.
- The service monitored the process for seeking consent appropriately.

# Are services caring?

## Our findings

### We rated caring as Good

#### Kindness, respect and compassion

#### Staff treated patients with kindness, respect and compassion.

- The service sought feedback on the care patients received and used annual weight loss as a measure of patient satisfaction.
- Feedback from patients was positive about the way staff treat people.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.
- The service gave patients 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 translated the information leaflet into a range of languages relevant to the patients who used the service and gave this to patients where appropriate.
- Patients told us 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.
- Staff 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 patients' privacy and dignity.

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



# Are services responsive to people's needs?

(for example, to feedback?)

## Our findings

### 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 sheets were available in a range of languages and in pictorial form.
- The facilities and premises were appropriate for the services delivered.
- Reasonable adjustments had been made so that some people in vulnerable circumstances could access and use services on an equal basis to others. The consultation room was accessible to a wheelchair user via a ramp. 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. Patients were encouraged to call in to have their weight monitored in between visits to collect medicines, for additional support.
- Clinic closing dates, for example public holidays, were communicated well in advance on the website and in the clinic.
- As a walk in service there was sometimes a longer wait at busy periods.

#### Listening and learning from concerns and complaints

##### **The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.**

- Information about how to make a complaint or raise concerns was available. Staff treated patients who made complaints compassionately.
- 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. There were no recent examples of complaints to show that the service learned lessons from individual complaints and from analysis of trends.

# Are services well-led?

Requires improvement 

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

## Our findings

### We rated well-led as Requires improvement because:

Risks were not effectively identified and monitored, and there was limited evidence of monitoring and learning from incidents.

#### Leadership capacity and capability

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

- Leaders were 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 clear vision and set of values. The service was considering strategies and supporting business plans to achieve priorities.
- The service monitored progress against delivery of the strategy.

#### Culture

##### The service had a culture of high-quality 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.
- There were processes for providing staff with the development they need. Staff received regular appraisals. Staff undertook the requirements of professional revalidation.

#### Governance arrangements

##### There were systems of accountability to support good governance and management.

- Structures, processes and systems to support good governance and management were understood and effective.

- Staff were clear on their roles and accountabilities.
- Leaders had established policies, procedures and activities to ensure safety, but they relied solely on the registered manager who was also the doctor. They were not sufficiently detailed to ensure consistency if for example a locum doctor was ever required.

#### Managing risks, issues and performance

##### There was no clarity around processes for managing risks, issues and performance.

- There was no effective process to identify, understand, monitor and address current and future risks including risks to patient safety. The criteria for treatment had not been updated in line with current clinical guidance.
- The service did not have processes to manage current and future performance. Performance of clinical staff could not be demonstrated through audit of their consultations and prescribing. Prescribing was not monitored to ensure it was in line with current guidance. Leaders had oversight of safety alerts and individual incidents and complaints, but these were not monitored to identify themes.
- Clinical audit had an impact on quality of care and outcomes for patients. There was some evidence of action to change services to improve quality.
- Staff were trained to manage major incidents.

#### Appropriate and accurate information

##### The service acted on appropriate and accurate information.

- Quality and operational information was used to ensure and improve performance.
- The information used to monitor performance and the delivery of quality care was accurate and useful. There were limited plans to address any identified weaknesses.
- The service submitted data or notifications to external organisations as required.
- There were robust arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data and records. However there was no policy for records retention and secure disposal, and no arrangements to retain medical records in the event that they cease trading.

#### Engagement with patients, the public, staff and external partners

# Are services well-led?

Requires improvement 

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

## **The service involved patients to support sustainable services.**

- The service encouraged views from patients to shape services and culture. Patients were given a feedback form with their introductory information pack.
- The service was transparent, collaborative and open with stakeholders about performance.

## **Continuous improvement and innovation**

## **There was limited evidence of learning, continuous improvement and innovation.**

- There was a focus on continuous learning and improvement. The doctor had completed e-learning modules provided by an obesity professional education organisation.
- The service did not made use of internal and external reviews of incidents and complaints since these were not recorded in a way that allowed trends to be identified.

This section is primarily information for the provider

## Requirement notices

### Action we have told the provider to take

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

Regulated activity	Regulation
Services in slimming clinics	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p><b>How the regulation was not being met:</b></p> <p>The provider had not established systems or processes to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk</p> <p>The provider had not established systems or processes to assess, monitor and improve the quality and safety of the services provided</p>

This section is primarily information for the provider

## Enforcement actions

### 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><b>How the regulation was not being met:</b></p> <p><b>The provider had not established effective systems or processes to ensure safe care and treatment.</b> In particular,</p> <ul style="list-style-type: none"><li>· The provider was not able to demonstrate that they had assessed the risk of disease from legionella</li><li>· Equipment use to measure blood pressure and weigh patients had not been calibrated</li><li>· Medical records did not follow national guidance for clear, accurate and legible record keeping</li><li>· Prescribing was not in line with current national guidance, and the local policy was not effective in ensuring consistent safe prescribing.</li><li>· The clinical audit process did not effectively monitor prescribing and record keeping against national guidance or local policy.</li></ul> <p><b>The enforcement action we took:</b></p> <p>Warning notice</p>