

Review of compliance

Harmony (Your Gentle Way To Slim) Limited Harmony Medical Diet Clinic in Wood Green

Region:	London
Location address:	Express Pharmacy 214 High Road, Wood Green London N22 8HH
Type of service:	Doctors consultation service
Date of Publication:	October 2011
Overview of the service:	Harmony Medical Diet Clinic in Wood Green Slimming Clinic is a private clinic providing a walk-in consultation and slimming service for persons aged 18 years and over. The clinic is owned and run by Dr Hirsch who provides the service from rented premises at Express Pharmacy in Wood Green. The service includes slimming consultations, weight loss and dietary advice and the use of appetite suppressants. The clinic

	operates on Mondays and Tuesdays during the week.
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Summary of our findings for the essential standards of quality and safety

Our current overall judgement

Harmony Medical Diet Clinic in Wood Green was not meeting one or more essential standards. Improvements are needed.

The summary below describes why we carried out this review, what we found and any action required.

Why we carried out this review

We carried out this review as part of our routine schedule of planned reviews.

How we carried out this review

We reviewed all the information we hold about this provider, carried out a visit on 26 July 2011, checked the provider's records, observed how people were being cared for, reviewed information from people who use the service, talked to staff and talked to people who use services.

What people told us

People told us they were satisfied overall with their service and would recommend the service to others. However our review found that people were not given sufficient information about their medicines to fully inform their decision making.

What we found about the standards we reviewed and how well Harmony Medical Diet Clinic in Wood Green was meeting them

Outcome 02: Before people are given any examination, care, treatment or support, they should be asked if they agree to it

People using the service are given information about appetite suppressants and the risks involved in taking them. However, this information does not include an explanation of licensing arrangements for the appetite suppressants. As a result, people are not fully informed about the risks associated with taking the medication. Overall, we found that improvements are needed for this essential standard.

Outcome 04: People should get safe and appropriate care that meets their needs and supports their rights

People receive appropriate dietary and exercise advice to assist in the management of their weight reduction plan. Overall, we found that Harmony Medical Diet Clinic was meeting this essential standard.

Outcome 09: People should be given the medicines they need when they need them, and in a safe way

The service does not always protect people against the risks associated with the unsafe use and management of medicines because they are prescribed without following current published guidance. Overall we found that improvements are needed for this essential standard.

Outcome 16: The service should have quality checking systems to manage risks and assure the health, welfare and safety of people who receive care

Harmony Medical Diet Clinic has a system in place for assessing and monitoring the quality of service provided for the benefit of people who use the service. Overall, we found that Harmony Medical Diet Clinic was meeting this essential standard.

Actions we have asked the service to take

We have asked the provider to send us a report within 14 days of them receiving this report, setting out the action they will take to improve. We will check to make sure that the improvements have been made.

Where we have concerns we have a range of enforcement powers we can use to protect the safety and welfare of people who use this service. Any regulatory decision that CQC takes is open to challenge by a registered person through a variety of internal and external appeal processes. We will publish a further report on any action we have taken.

Other information

Please see previous reports for more information about previous reviews.

**What we found
for each essential standard of quality
and safety we reviewed**

The following pages detail our findings and our regulatory judgement for each essential standard and outcome that we reviewed, linked to specific regulated activities where appropriate.

We will have reached one of the following judgements for each essential standard.

Compliant means that people who use services are experiencing the outcomes relating to the essential standard.

A **minor concern** means that people who use services are safe but are not always experiencing the outcomes relating to this essential standard.

A **moderate concern** means that people who use services are safe but are not always experiencing the outcomes relating to this essential standard and there is an impact on their health and wellbeing because of this.

A **major concern** means that people who use services are not experiencing the outcomes relating to this essential standard and are not protected from unsafe or inappropriate care, treatment and support.

Where we identify compliance, no further action is taken. Where we have concerns, the most appropriate action is taken to ensure that the necessary improvements are made. Where there are a number of concerns, we may look at them together to decide the level of action to take.

More information about each of the outcomes can be found in the *Guidance about compliance: Essential standards of quality and safety*

Outcome 02: Consent to care and treatment

What the outcome says

This is what people who use services should expect.

People who use services:

- * Where they are able, give valid consent to the examination, care, treatment and support they receive.
- * Understand and know how to change any decisions about examination, care, treatment and support that has been previously agreed.
- * Can be confident that their human rights are respected and taken into account.

What we found

Our judgement

There are moderate concerns with Outcome 02: Consent to care and treatment

Our findings

What people who use the service experienced and told us

People we spoke with said they had been recommended to the service by others. They said that they were asked for their views throughout their consultation. When asked whether they were aware of the medicines being unlicensed for their use people told us that they knew nothing about the licensing of the drugs. One person said she was told about the name of the drug, how to take it and possible side effects only.

Other evidence

The doctor told us that patients are able to make well informed decisions following the advice and guidance he gives them. People who are unable to give consent or choose to withhold consent are not accepted for treatment. The doctor does not provide treatment for people who he considers do not need to lose weight. Once a recommendation is made by the doctor, if the patient agrees, they follow this course of action. The doctor informed that if the patient does not agree the recommended course of action, the consultation ends and the patient does not have to pay for the doctors' consultation time. The doctor provides written information to patients, including the cost of the service and side effects they may experience. However the information did not include an explanation of the licensing arrangements for appetite suppressants. As a result patients were not aware of all the risks involved in taking the appetite suppressants provided by the clinic and could not therefore make fully informed decisions about accepting the treatment (see also outcome 9).

Our judgement

People using the service are given information about appetite suppressants and the risks involved in taking them. However, this information does not include an explanation of licensing arrangements for the appetite suppressants. As a result, people are not fully informed about the risks associated with taking the medication. Overall, we found that improvements are needed for this essential standard.

Outcome 04: Care and welfare of people who use services

What the outcome says

This is what people who use services should expect.

People who use services:

* Experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights.

What we found

Our judgement

The provider is compliant with Outcome 04: Care and welfare of people who use services

Our findings

What people who use the service experienced and told us

People we spoke with told us they were happy with the service they had been given. For one person it was their first time seeing the doctor and another person told us they had visited the doctor three or four times over a couple of months. One person said, "He was very thorough. He gave lots of advice about dieting, what to eat and what not, and about exercise." People told us they were encouraged to return to the doctor within two weeks to be weighed and that they were given the doctors' mobile number to call him any time they needed to.

Other evidence

The doctor wrote in his Provider Compliance Assessment, "I discuss with the patient their overall health situation as well as the different aspects of their overweight situation, the risks involved with not addressing it, and the best course of remedial action in terms of medication, diet, exercise and lifestyle, as well as the medications' possible side effects. Treatment and other courses of remedial actions are based on published research evidence. This is a highly personalised process where all the patient's need are taken into account. I give my patients unlimited free access either through my mobile phone at all times or by being able to come on consultation day without appointment. All aspects are reviewed at each consultation. Every new patient is provided with a letter for their GP and are actively encouraged to inform him/her of my prescriptions and guidance, and to inform me of all treatment and guidance given to them by their GP or other care providers."

Each person is weighed at every clinic. The doctor informed that their usual procedure

is to see clients every two to four weeks, adding that some people attend the clinic less frequently if they live at a distance or if they are working. The doctor explained the consultation process to us. People complete a medical information form. Every patient is weighed, their blood pressure is measured and their BMI (Body Mass Index) measurement is taken at the first visit. People continue to be weighed and have their blood pressure taken at every visit. After considering the information the patient has given the doctor, the patients' risk profile is discussed and a personalised weight loss strategy is agreed. The doctor spends time explaining the recommended diet and the importance of exercise. It is free of charge for people to be weighed at subsequent visits so as to motivate people to revisit the clinic and be checked again. If people are unable to visit the surgery frequently and are given more than a months' supply of medicine, they are advised to visit their GP or local pharmacy to have their blood pressure checked. The importance of monitoring their blood pressure is explained due to the risk of high blood pressure whilst taking the medication. People are encouraged to return to the clinic if they are not losing weight to discuss their needs.

Our judgement

People receive appropriate dietary and exercise advice to assist in the management of their weight reduction plan. Overall, we found that Harmony Medical Diet Clinic was meeting this essential standard.

Outcome 09: Management of medicines

What the outcome says

This is what people who use services should expect.

People who use services:

- * Will have their medicines at the times they need them, and in a safe way.
- * Wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf.

What we found

Our judgement

There are major concerns with Outcome 09: Management of medicines

Our findings

What people who use the service experienced and told us

We spoke to people who used the service for the first time or had recently used the service who had been supplied with medicines. One person told us the doctor had refused her appetite suppressant medication as she was not considered to be overweight. The doctor told us that that people were informed on their first visit that the medicines were unlicensed but produced under a special manufacturers licence. People we spoke to however told us they did not know anything about the licensing of the drugs and were told only of the name of the drug prescribed. People told us they were given an information leaflet for their medicine that included the side effects.

Other evidence

The registered manager, a doctor, was at the clinic on our arrival. During our visit, we asked the doctor to provide us with several pieces of information. We looked at how the clinic ensures medicines are prescribed safely and found published guidance was not always followed. Two medicines used by the clinic are not recommended for use in the treatment and management of obesity by the National Institute for Health and Clinical Excellence (NICE) and the Royal College of Physicians. People were given a patient information leaflet for one medicine, but not for the other and the information supplied did not highlight the fact the medicines are not recommended by NICE or used by the National Health Service (NHS). There was no evidence that patients were fully advised of the specific risks associated with the use of the drugs they were prescribed.

Each person had a medical record card that contained information about their general

medical information including a medical history and a record of any medicines that were being taken at the first visit, any further information was recorded electronically. If people experienced side effects these were not noted in their records. The records showed that at the first visit the client's height, weight and blood pressure were recorded and their weight and blood pressure was recorded at subsequent visits. The person's Body Mass Index (BMI) was calculated and recorded at the first visit, but the doctor stated that he would supply medicines to clients at a lower BMI that was stated within National Institute for Health and Clinical Excellence (NICE) or The Royal College of Physicians anti-obesity guidance, therefore current national guidance is not being followed.

We looked at the length of time people were receiving medication. Some people had attended the clinic for over a year although this had not always been continual. All the client records identified that they had a break from treatment in accordance with guidance.

We looked at the information that is provided to new people for slimming services, this included dietary and exercise advice. The doctor stated that he asks the person if they have had medicines before and which medicine they would prefer, if they are a new patient he supplies an appetite suppressant and he then records the supply on the electronic client record and in a record book. If the person experienced side effects he would change the appetite suppressant, or supply a different type of medicine. There is a central record kept of the quantities of medicines received and supplied by the clinic, therefore there is an audit trail of the medicines.

We checked how medicines were stored, packaged and supplied to patients. Medicines were stored under the control of the doctor at the premises and in transit, with only the doctor having access to them. Medicines were repackaged by the doctor into suitable labelled containers.

Our judgement

The service does not always protect people against the risks associated with the unsafe use and management of medicines because they are prescribed without following current published guidance. Overall we found that improvements are needed for this essential standard.

Outcome 16: Assessing and monitoring the quality of service provision

What the outcome says

This is what people who use services should expect.

People who use services:

* Benefit from safe quality care, treatment and support, due to effective decision making and the management of risks to their health, welfare and safety.

What we found

Our judgement

The provider is compliant with Outcome 16: Assessing and monitoring the quality of service provision

Our findings

What people who use the service experienced and told us

People told us they were asked if they were satisfied with the service and told us they thought they received a good service. One person commented in their survey, "I have wasted time on diet things to no avail. This diet plan is fabulous." Another person said, "Was very good...very satisfied and will be recommending people to visit."

Other evidence

The doctor sent us a range of surveys completed by people using the service over the last two years. People using the service are asked to complete these surveys every time they visit the clinic. The survey asked questions such as, "Did the doctor explain the reasons for any treatment in a way you could understand?" "Were you given enough information about the purpose of the medicine?" "Were you given enough information about how to use the medicine?" These had not been analysed overall. However they demonstrated that people felt positively about their service and there was a high level of patient satisfaction with the service.

Our judgement

Harmony Medical Diet Clinic has a system in place for assessing and monitoring the quality of service provided for the benefit of people who use the service. Overall, we found that Harmony Medical Diet Clinic was meeting this essential standard.

Action we have asked the provider to take

Compliance actions

The table below shows the essential standards of quality and safety that **are not being met**. Action must be taken to achieve compliance.

Regulated activity	Regulation	Outcome
Services in slimming clinics	Regulation 18 HSCA 2008 (Regulated Activities) Regulations 2010	Outcome 02: Consent to care and treatment
	<p>How the regulation is not being met: People using the service are given information about appetite suppressants and the risks involved in taking them. However, this information does not include an explanation of licensing arrangements for the appetite suppressants. People are unable to make an informed decision about treatment if they are unaware of the risks associated with the treatment. Overall, we found that improvements are needed for this essential standard.</p>	
Services in slimming clinics	Regulation 13 HSCA 2008 (Regulated Activities) Regulations 2010	Outcome 09: Management of medicines
	<p>How the regulation is not being met: Medicines are prescribed without following current published guidance. The service does not always protect people against the risks associated with using medications that are not licensed or recommended for use as slimming drugs. Overall, we found that improvements are needed for this essential standard.</p>	

The provider must send CQC a report that says what action they are going to take to

achieve compliance with these essential standards.

This report is requested under regulation 10(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

The provider's report should be sent to us within 14 days of this report being received.

Where a provider has already sent us a report about any of the above compliance actions, they do not need to include them in any new report sent to us after this review of compliance.

CQC should be informed in writing when these compliance actions are complete.

What is a review of compliance?

By law, providers of certain adult social care and health care services have a legal responsibility to make sure they are meeting essential standards of quality and safety. These are the standards everyone should be able to expect when they receive care.

The Care Quality Commission (CQC) has written guidance about what people who use services should experience when providers are meeting essential standards, called *Guidance about compliance: Essential standards of quality and safety*.

CQC licenses services if they meet essential standards and will constantly monitor whether they continue to do so. We formally review services when we receive information that is of concern and as a result decide we need to check whether a service is still meeting one or more of the essential standards. We also formally review them at least every two years to check whether a service is meeting all of the essential standards in each of their locations. Our reviews include checking all available information and intelligence we hold about a provider. We may seek further information by contacting people who use services, public representative groups and organisations such as other regulators. We may also ask for further information from the provider and carry out a visit with direct observations of care.

When making our judgements about whether services are meeting essential standards, we decide whether we need to take further regulatory action. This might include discussions with the provider about how they could improve. We only use this approach where issues can be resolved quickly, easily and where there is no immediate risk of serious harm to people.

Where we have concerns that providers are not meeting essential standards, or where we judge that they are not going to keep meeting them, we may also set improvement actions or compliance actions, or take enforcement action:

Improvement actions: These are actions a provider should take so that they **maintain** continuous compliance with essential standards. Where a provider is complying with essential standards, but we are concerned that they will not be able to maintain this, we ask them to send us a report describing the improvements they will make to enable them to do so.

Compliance actions: These are actions a provider must take so that they **achieve** compliance with the essential standards. Where a provider is not meeting the essential standards but people are not at immediate risk of serious harm, we ask them to send us a report that says what they will do to make sure they comply. We monitor the implementation of action plans in these reports and, if necessary, take further action to make sure that essential standards are met.

Enforcement action: These are actions we take using the criminal and/or civil procedures in the Health and Social Care Act 2008 and relevant regulations. These enforcement powers are set out in the law and mean that we can take swift, targeted action where services are failing people.

Information for the reader

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