

The North London Slimming Clinic Limited

North London Slimming Clinic

Inspection report

North London Slimming Clinic 16 Uvedale Road Enfield Middlesex EN2 6HB Tel: 020 8363 1098

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Overall summary

We carried out an announced comprehensive inspection on 13 November 2017 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

We found that this service was not providing safe care in accordance with the relevant regulations.

Are services effective?

We found that this service was not 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 not providing responsive care in accordance with the relevant regulations.

Are services well-led?

We found that this service was not 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.

North London slimming clinic is located in Enfield, London. The clinic is in a residential property with the reception, waiting room and consulting room on the ground floor and staff office on the first floor. It is accessible by public transport, and there is limited parking on the street. The clinic also operates from another premises located at Broxbourne Borough Buildings, Cheshunt EN8 9XQ on Thursday evenings.

The clinic is open on Mondays (6pm – 8pm) and Saturdays (9am-11am) at the Enfield location and Thursdays (6pm – 9pm) at the Cheshunt address. Patients are able to attend without appointments. They are provided with slimming advice and prescribed medicines to support weight reduction.

The clinic manager is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like

Summary of findings

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.

The clinic is staffed by a registered manager, a nominated individual and a doctor. There were also two administrative staff members employed on an adhoc basis. The registered manager told us they were not permanent staff but work as and when required by the clinic. If for any reason, the doctor is unable to cover a shift, staff told us that the clinic would be closed.

Patients completed CQC comment cards to tell us what they thought about the service. We received twenty one completed cards and all were positive. We were told that the service was excellent, and that staff was always helpful and made people to feel comfortable.

Our key findings were:

- People using the service told us that staff were always available to them including out of hours.
- Medicines were not prescribed safely to patients who fit the treatment criteria as defined in clinical guidelines.
- There were no effective systems and processes in place to prevent abuse of service users.
- The provider did not have systems and processes in place to monitor and improve the quality of services being provided. This included incident reporting, emergency medicine risk assessments, patient safety alerts, communication with the patient's own GP, procedures that were appropriate to the service provided, up to date and understood by all staff.

- Staff did not have appropriate recruitment checks or given suitable support, training, professional development and supervision as is necessary to enable them to carry out the duties they are employed to perform.
- Patients' records were not stored securely.

We identified regulations that were not being met and the provider must:

- Ensure care and treatment is provided in a safe way to patients.
- Ensure patients are protected from abuse and improper treatment.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.
- Ensure sufficient numbers of suitably qualified, competent, skilled and experienced persons are deployed to meet the fundamental standards of care and treatment.

You can see full details of the regulations not being met at the end of this report.

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

- Review and establish methods to ascertain the age and identity of patients accessing the clinic services.
- Review and action the necessity for chaperoning at the service and staff training requirements.
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available

You can see full details of the regulations not being met at the end of this report.

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 not providing safe care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

The provider did not have effective arrangements in place to keep people protected and safeguarded from abuse and some staff had no employment checks. The provider had no system in place to receive and action Patient Safety Alerts.

Are services effective?

We found that this service was not providing effective care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

Patients were provided with written information about medicines in the form of a patient information leaflet. The provider had a policy of not sharing information directly with patients' GPs. A brief assessment of each patient took place before medicines were prescribed. However, in some cases, patients did not fit the treatment criteria as defined in the clinical guidelines.

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations. Patients told us that staff were caring, helpful and friendly.

Are services responsive to people's needs?

We found that this service was not providing responsive care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

The facilities and premises were appropriate for the services being provided. We saw that staff gave patients information on consumption of alcohol and had some information to accommodate people who did not eat meat. We saw that information and medicine labels were not available in large print and there was no induction loop available for patients who experienced hearing difficulties.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

The service lacked good governance to operate effectively and did not have systems to assess, monitor and improve the quality of the service being provided. In addition, the provider failed to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.

All policies and procedures were out dated and staff were not aware these existed.

The provider did not have comprehensive assurance systems and there was no systematic programme of clinical or internal audit to monitor the quality of the service.



North London Slimming Clinic

Detailed findings

Background to this inspection

We carried out this inspection on 13 November 2017. Our inspection team was led by a member of the CQC medicines team, and was supported by another member of the CQC medicines team. We gathered information from the provider prior to this inspection. Whilst on inspection, we interviewed staff and reviewed documents and CQC patient comment cards. We looked at patient records in order to evidence safe and effective treatment.

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

Safety systems and processes

There was no adequate safeguarding policy or procedure in place that informed staff of what to do or who to contact if they had a safeguarding concern. There was no safeguarding lead in the clinic and staff did not fully understand what safeguarding meant. None of the staff working at the clinic, including the doctor and the registered manager had received any training in the safeguarding of either adults or children.

Disclosure and Barring Service (DBS) checks were not in place for all staff working at the clinic, including the clinic's only doctor. References had not been obtained for members of staff working at the clinic on an adhoc basis and there was no specific HR policy to support recruitment.

We saw that the doctor was in the process of undergoing their revalidation with the General Medical Council, and had an appropriate responsible officer.

We were told that staff were able to act as a chaperone to patients that requested this. However, chaperones were rarely requested because of the nature of the service and no chaperone training had been done by these staff members.

There were no records of staff training and staff we spoke with told us they had not had any training. Therefore staff did not undertake any training, learning and development to enable them to fulfil the requirements of their role.

The clinic had not conducted an infection control risk assessment to determine if they needed to test for Legionella at the service. (Legionellosis is the collective name given to the pneumonia-like illnesses caused by legionella bacteria.)

The clinic maintained appropriate standards of cleanliness and hygiene. We observed the premises to be generally clean and tidy although cleaning activities were not documented.

We were told that the weighing scales were calibrated by an external company, and the blood pressure (BP) monitor was checked to ensure it was working properly. However, we did not see any evidence that the BP monitoring records were kept by the provider.

Risks to patients

Although this service was not designed or expected to deal with medical emergencies, the provider had not assessed the need for emergency medicines and equipment, or developed a policy detailing how emergencies would be managed should the need arise. Staff had not received formal first aid training although the doctor told us that they had completed basic life support training. We were told that if someone became unwell whilst at the clinic, staff would call 999 emergency number.

We saw evidence that the provider had indemnity arrangements to cover potential liabilities that may arise. We also saw that the doctor had personal medical indemnity insurance to cover their activities within the service.

Information to deliver safe care and treatment

Individual patient's records were legible and complete. We saw that patients' medical records were stored in open boxes in the corridor, adjacent to the patient waiting room and near the entrance door. This was not secure and potentially puts patients' confidentiality at risk.

Safe and appropriate use of medicines

Records showed that North London Slimming Clinic prescribed appetite suppressants (Diethylpropion Hydrochloride and Phentermine) to people who used the service. 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 granted them marketing authorisations. 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.

Medicines can also be made under a manufacturer's 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.

Are services safe?

At North London Slimming Clinic we found that patients were treated with unlicensed medicines. Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy.

The British National Formulary states that Diethylpropion and Phentermine are centrally acting stimulants that are not recommended for the treatment of obesity. The use of these medicines are also not currently recommended by the National Institute for Health and Care Excellence (NICE) or the Royal College of Physicians. This means that there is not enough clinical evidence to advise using these treatments to aid weight reduction.

People could also be prescribed a diuretic medicine (Bendroflumethiazide), to help reduced fluid retention to support weight loss in the short term. This medicine is not recommended or licenced for this indication.

Medicines were stored securely and the keys were kept under the supervision of the doctor at all times. We found that medicines could be accessed by members of staff whilst under the supervision of the same doctor.

Appropriate records were kept of the medicines and the orders, and at each clinic a full stock check was done. Invoices and orders were kept for longer than two years as per requirements. The doctor supervised the medicines being packed down into smaller quantities before being dispensed. Medicines were packaged and labelled in accordance with legal requirements.

The provider had made arrangements with a local community pharmacy to dispose of unwanted or expired medicines, including controlled drugs. At the time of the inspection the provider told us they had not needed to do this before, so we were unable to confirm if this was the case via physical records. The service confirmed that they did not have a T28 waste exemption certificate from the Environment Agency. T28 exemption allows pharmacies and other similar places to comply with the requirements of the Misuse of Drugs Regulations 2001 by denaturing controlled drugs (making them unsuitable for consumption) before being disposed.

We reviewed 18 patient records, and saw that no patient under the age of 18 was prescribed appetite suppressants.

We noted that patients were given an appropriate treatment break after 12 weeks of consecutive treatment as per recommendations, and had blood pressure checks before being prescribed these medicines.

However, we did not see evidence or records when patients were refused treatment. Some of the reasons the doctor told us for treatment refusal were: co-existing medical conditions, patients aged less than 18 years and drug interactions with existing medicines.

The provider did not follow guidance from NICE about treatment with medicines only for patients with a BMI above 30, or BMI above 28 with co-morbidities. Out of the 18 records we saw, four patients had a BMI of 26 to 30 with no co-morbidities. These patients were prescribed appetite suppressants.

We were told that there was no policy or procedure in place for medicines handling or medicines competency checks for staff handling medicines. We saw a medicines policy that was created in March 2009, with a review date of March 2010, although it had not been reviewed.

Track record on safety

We found that there was a policy in place for incident reporting but it was also out of date. Staff understood their responsibilities to raise concerns to the doctor but no record was made when incidents occurred. We did not see evidence of examples of lessons learned from incidents and the action taken as a result of investigations when things went wrong.

There were no arrangements in place to receive and act upon patient safety alerts, recalls and rapid response reports issued through the MHRA and CAS system.

Lessons learned and improvements made

The provider told us that they were aware of and complied with the requirements of the Duty of Candour. The provider told us that they encouraged a culture of openness and honesty. The service had no systems in place for knowing about notifiable safety incidents. We were told there had been no unexpected or unintended safety incidents:

- The service told us that affected people would be given reasonable support, truthful information and a verbal and written apology should such incident occur.
- They kept written records of verbal interactions as well as written correspondence.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

Each patient was seen by a doctor who established a medical history and checked to see if people were contraindicated for treatment with appetite suppressants. The doctor weighed patients, calculated body mass index (BMI), and took an up-to-date medical and drug history. They also did a blood pressure reading. All the medical records seen confirmed that an up-to-date medical history was taken for each patient.

There was an explanation of the treatment supported by written information for the patient to look at. 13 of the 18 records looked at had a treatment break at three months documented. The remaining five patient records we reviewed showed the patient had not had treatment for longer than three months.

We saw evidence that repeat weights and BP readings were completed at subsequent clinic visits. However, we saw evidence of patients being treated with a BMI below 30 with no co-morbidities. This meant that care was not delivered in line with relevant and current evidence based guidance and standards such as NICE guidelines: 'Obesity: identification, assessment and management of overweight and obesity in children, young people and adults'.

Monitoring care and treatment

Staff told us that clinical audits were not carried out to assess the effectiveness of the service provided. Of the 18 records we saw, four patients had weight loss of up to 1 stone, but none had achieved their target weight setting. This meant the provider had not demonstrated effective weight loss over a period of time and staff did not use information to monitor and improve patient outcomes.

Effective staffing

Staff were not provided with any training, or learning and development to enable them to fulfil the requirements of

their role. For example there were no records of training in infection control, safeguarding, and the handling of medicines, fire safety or the Mental Capacity Act. They were also not provided with the clinic policies to read and sign.

We did not see evidence of regular staff appraisals and learning needs that had been identified for staff.

Coordinating patient care and information sharing

Patients were encouraged to consent to sharing of information with their registered GP. Out of the 18 records we saw, one person consented to sharing their information with their GP, the others confirmed that they would not like their GP to be contacted.

Where patients did not provide consent to share their treatment information, the doctor told us the service would contact the patient's GP if they thought it was in their best interest to justify the continuation of treatment and prescription of medicines in line with GMC guidance. However, we did not see any evidence of where the service had communicated with patients' GPs.

Supporting patients to live healthier lives

Patients were provided with written information about medicines in the form of a patient information leaflet. This included information on how and when to take the medicine, the purpose of the medicine, what side effects may occur and the action to take if they do. We also noticed that patients were given information about calorific content of alcohol.

Consent to care and treatment

Staff at the clinic ensured that patient consent was obtained prior to the beginning of treatment. The written information given to patients in the medicines leaflet clarified that the treatments offered at the clinic were not licensed. However, a record of this discussion was not made in the patients' medical notes.

Before treatment, the provider gave patients details of the cost of the main elements of the treatment including the cost of medicines, and further treatment or follow up if required.

Are services caring?

Our findings

Kindness, respect and compassion

Patients completed CQC comment cards to tell us what they thought about the service. We received twenty one completed cards and all were positive. We were told that the service was excellent, helpful and always put patients at ease by listening to people even outside the clinic opening hours.

Involvement in decisions about care and treatment

Information relating to treatment options and the cost of treatment was readily available. We saw that there were a variety of patient information leaflets available which included information on nutrition, alcohol consumption and exercise.

Privacy and Dignity

Consultations took place in a private consultation room located next to the reception area. Conversations could not be heard from outside the consultation room. We saw that some staff working at the clinic had no contract in place and had not signed any confidentiality clause with regards to maintaining patients' confidentiality.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The facilities and premises were appropriate for the services being provided. The clinic was located a residential building with patients accessing the ground floor. It consisted of a reception area with seats, a consultation room, and a first floor office for staff only.

Slimming and obesity management services were provided for adults from 18 to 65 years of age by a walk in service.

Whilst some provisions had been made for patients with protected characteristics, information and medicine labels were not available in large print or in other languages. An induction loop was not available for patients who experienced hearing difficulties.

Timely access to the service

The clinic was open three days a week. Staff were available for enquiries by telephone during normal business hours. Patients could attend the clinic without an appointment as a walk in patient. Pre-booked appointments were not available. There were times when the clinic had planned closures (generally Easter, summer and Christmas holidays). Clinic closures were planned well in advance and patients were informed ahead of time.

Listening and learning from concerns and complaints

There was no process of documenting incidents or complaints and staff told us that no incidents or complaints had been received in the last 12 months. There was evidence that incidents had clearly occurred, such as discrepancies with medicines stock levels, which were not documented as incidents. There was no complaints or incidents policy available to staff and the complaints procedure was not made available to patients either in the clinic waiting room or welcome pack.

Are services well-led?

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

Our findings

Leadership capacity and capability;

We found on the day of inspection that the service leaders lacked the capacity and capability to run the service and ensure high quality care. We found that the service was lacking in good governance to operate effectively and had no systems in place to assess, monitor and improve the quality of the service being provided.

There was no clear leadership structure in place and no staff meetings were held.

Vision and strategy

The service told us their vision was "to be part of a valid contribution to the management and resolution of the obesity crisis in the United Kingdom".

We did not see any business plan or strategy for service development. There were no minutes of meetings or discussions about service improvement around the needs of patients.

Culture

Staff told us that they were aware of the need for openness and honesty with patients if things went wrong and had systems to ensure compliance with the requirements of the duty of candour. (The duty of candour is a set of specific legal requirements that providers of services must follow when things go wrong with care and treatment). Whilst this had never happened, staff was able to explain how they would deal with poor practice.

Governance arrangements

Staff at the clinic did not have appropriate arrangements to ensure good governance at this clinic. There were no

records relating to recruitment, for example; proof of identification and DBS checks. Medical records were paper based and were not stored securely. We saw that the service did not have up to date policies and procedures in place to govern its activities, and staff were not aware if any policies existed.

The service did not seek, and act on feedback from patients or relevant persons, for the purposes of continually evaluating and improving services, including the quality of the experience for people using the service.

Managing risks, issues and performance

The provider had no system in place to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.

Appropriate and accurate information

Clear information was provided to patients with respect to their consultation and treatment including guidance on the costs.

Engagement with patients, the public, staff and external partners

The provider did not actively seek feedback from patients and staff.

Continuous improvement and innovation

The clinic did not have an effective approach for identifying if or where quality and safety was being compromised. Therefore steps were not taken in response to any issues.

For example, there were no audits of clinical care, prescribing notes, infection prevention and risks, incidents and near misses.

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	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment
	How the regulation was not being met:
	The registered provider had not done all that was reasonably practicable to mitigate risks to the health and safety of service users receiving care and treatment. In particular:
	Medicines were being prescribed to patients who did not fit the treatment criteria.
	A risk assessment in relation to the use of emergency medicines was not available.
	Consideration was given to communicating with patients' own GPs but this was not followed in line with GMC guidance.
	This was in breach of regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations
	2014

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	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment
	How the regulation was not being met:
	The provider did not have an adequate safeguarding procedure and policy in place which informed staff what to do or who to contact if they had a safeguarding concern.
	Staff at the clinic did not fully understand safeguarding principles, and that it is relevant in the service being provided.
	This was in breach of regulation 13, (1)&(2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Regulated activity	Regulation
Services in slimming clinics	Regulation 17 HSCA (RA) Regulations 2014 Good governance
	How the regulation was not being met:
	The service lacks good governance to operate effectively and no system in place to assess, monitor and improve the quality of the service being provided.
	The provider failed to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.
	Employment checks had not been performed and patients' records were not securely stored.
	This was in breach of regulation 17 (1) of the Health and Social Care Act 2008 (Regulated Activities)
	Regulations 2014.

Enforcement actions

Regulated activity

Regulation

Services in slimming clinics

Regulation 18 HSCA (RA) Regulations 2014 Staffing

How the regulation was not being met:

Staff had not received appropriate support, training, professional development, supervision or appraisal as is necessary to enable them to carry out the duties they are employed to perform. In particular:

There was no evidence that staff had received first aid training, fire safety, infection control or any form of training updates with regards to the policies and procedures.

This was in breach of regulation 18 (2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.