

Codegrange Limited

National Slimming & Cosmetic Clinics

Inspection report

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Date of inspection visit: 28 November 2017, 15 December 2017
Date of publication: 21/02/2018

Overall summary

We carried out an announced comprehensive inspection on 28 November 2017 and an unannounced second inspection on 15 December 2017 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

We found that this service was providing safe care in accordance with the relevant regulations

Are services effective?

We found that this service was 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 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.

National Slimming & Cosmetic Clinics (Newcastle) provides advice on weight loss and prescribed medicines to support weight reduction. The clinic consists of a reception, one consulting room, staff /office area and toilet; and is located on the first floor of a commercial building near to the city centre. Staff include a clinic manager, three part-time doctors and one receptionist. The clinic is open four days a week, including Saturday.

Summary of findings

This service is registered with CQC under the Health and Social Care Act 2008 in respect of the provision of advice or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of 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 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.

Patients completed 25 CQC comment cards to tell us what they thought about the service. The observations made were positive and reflected that patients found staff to be friendly, helpful and welcoming. They also said that the environment was safe, clean and tidy. We spoke to two patients on the day of the inspection who were also satisfied with the service.

Our key findings were:

- Staff told us that they felt supported to carry out their roles and responsibilities.

- We found feedback from patients was always positive about the care they received, the helpfulness of staff and the cleanliness of the premises.
- The provider had processes for reporting, learning, sharing and improving from incidents.

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

- Ensure that care and treatment is provided in a safe way for the service users.
- Ensure that systems and processes are in place to effectively monitor and improve the quality of services being provided.

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:

- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.
- Review the need for appraisals of clinical staff.
- Review and risk assess the appropriateness of having a family member/ friend as a translator.

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found that this service was providing safe care in accordance with the relevant regulations.

We found areas where improvements should be made relating to staff training and appraisal.

Guidelines for medical emergencies were available and there was a risk assessment for the equipment kept. The clinic was clean and tidy and infection control audits were undertaken.

The clinic had processes for reporting, learning, sharing and improving from incidents. The registered manager had received level 3 safeguarding training; however whilst we were told all doctors had safeguarding training, there was no evidence of safeguarding training for two out of the three doctors working in the clinic.

Are services effective?

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

There was a prescribing policy in place that set out when medicines could safely be prescribed, however this was not in line with national guidance on the management of obesity and this was not followed for two people whose records we looked at. Patients had their BMI recorded during their first visit but this was not always repeated at subsequent visits in line with the provider's policy.

Staff at the clinic ensured that individual consent was obtained prior to the beginning of treatment but this was not always confirmed after treatment breaks in line with the provider's policy.

The provider's audit of clinical records had not identified the issues we found.

We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

All staff had received relevant training to enable them to carry out their roles; however, the provider should review the need for appraisals of clinical staff.

Are services caring?

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

Patients were very positive about the service provided at the clinic and told us that staff were helpful and friendly. Patients felt they were treated with dignity and respect and were supported to make decisions about their care and treatment.

Are services responsive to people's needs?

We found that this service was providing responsive care in accordance with the relevant regulations. We found areas where improvements should be made relating to the provision of treatment. This was because whilst the provider had information available in other languages, it also relied on patients to provide their own translators and there was no information available for people with visual or hearing difficulties or limited mobility.

The facilities and premises were appropriate for the services being provided. Patients could call or walk in to book appointments. The clinic had a system for handling complaints and concerns.

Summary of findings

Are services well-led?

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

Staff were able to describe how they would handle safety incidents and were aware of the requirements of the duty of candour. Duty of Candour requires service to be open and transparent with patients in relation to their care and treatment.

Staff felt confident to carry out their role and described an open and supportive culture.

There were governance arrangements in place to monitor the quality of the service; however, clinical audits were not effective. Medicines were prescribed outside of clinic policy and this had not been identified as part of the audit process.

The provider sought the views of patients however where negative comments were made it was not clearly documented what action was taken.

We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

National Slimming & Cosmetic Clinics

Detailed findings

Background to this inspection

We carried out the main part of this inspection on 28 November 2017 and returned on 15 December 2017 to review the arrangements for medicine management because we were unable to access them at the first inspection because the doctor had already left the premises. The inspection was led by a CQC Pharmacist Specialist accompanied by a second Pharmacist Specialist.

Before visiting, we looked at a range of information that we hold about the clinic. The methods that were used during our visit included interviewing staff, observations and a review of documents. We looked at patient records in order to evidence the safe and effective treatment of patients'.

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 a safeguarding policy in place, which included the safeguarding team contact details at the local authority and was accessible to staff. The Registered manager was the safeguarding lead and had level 3 safeguarding training. We were told that doctors working in the clinic had training in safeguarding and the doctor we spoke with demonstrated an understanding of safeguarding responsibilities for children who may accompany adults to appointments.

The service had decided that patient chaperones were not required following risk assessment and no requests from patients.

The premises were clean and tidy with an infection control policy in place. The cleaning schedule records indicated cleaning was undertaken on a regular basis. Staff had undertaken infection prevention training. Staff had access to alcohol gel and there was a sink for handwashing and supplies of examination gloves in the consultation room.

We saw that policies were in place for the management of waste and safe disposal of sharps. We saw that waste was segregated and stored appropriately. However, a sharps bin in use was not dated or signed. The service held an on-going contract with a clinical waste contractor and had the required exemption from the Environment Agency to authorise denaturing of controlled drugs before disposal.

The premises were in a good state of repair. All electrical equipment was tested to ensure that it was safe to use. Clinical equipment was checked to ensure it was calibrated and working properly.

Staff personnel files demonstrated that there was a recruitment process; however, there was no evidence of identity checks for one of the doctors working in the service. Files contained full employment history and evidence of conduct in previous employment through references. Disclosure and Barring Service (DBS) checks had been reviewed recently and were being renewed where necessary in line with the service's policy. The doctors had up to date revalidation with the General Medical Council.

Risks to patients

Staffing levels were sufficient to meet patients' needs. The reception staff covered each other's absence. This ensured continuity of staff which patients appreciated.

Staff had an understanding of emergency procedures. A fire risk assessment was in place and fire equipment was available with a service schedule. There was a fire evacuation policy displayed in the waiting area.

This was a service where the risk of having to deal with a medical emergency was low. The manager and receptionist were first aid trained. The service had a risk assessment in place to determine what would be required to respond to medical emergencies. In the event of a medical emergency, staff would call the emergency services and were aware of local urgent care provision.

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

Information to deliver safe care and treatment

Appointments were booked using a computerised system. Patients' medical information, clinical notes and record of medicines supplied were recorded on written individual record cards. The cards were stored securely at the clinic and access was restricted to protect patient confidentiality.

Safe and appropriate use of medicines

The medicines Diethylpropion Hydrochloride and Phentermine 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 manufacturers special 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 National Slimming and Cosmetic Clinics (Newcastle), 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.

We saw that staff were following their medicines management policy and that medicines were stored, packaged and supplied to patients safely. Medicines were ordered and received when there was a doctor on the premises. They were packaged into appropriate containers by a second member of staff under the supervision of the doctor. We saw the orders, receipts and prescribing records for medicines supplied by the clinic. The medicines were checked after each clinic session to confirm that all the necessary records had been made and a separate weekly

check was carried out. Medicines prescribed by the doctor were supplied in appropriate labelled containers that included the name of the medicine, instructions for use, the person's name, date of dispensing and the name of the prescribing doctor. A record of the supply was made in the person's records. Patients were given information leaflets about their prescribed medicines. We reviewed sixteen medical records, and saw that no patients under the age of 18 were prescribed medicines for weight loss.

Safe track record and learning

There was a system in place for reporting, recording and monitoring significant events. Staff were able to tell us what they would do in the event of an incident, and we saw that an incident reporting form was available. Staff told us the provider circulated an incident summary report every three months. These contained anonymised details of incidents reported, investigated and shared learning across the company. Doctors received this information via email.

The provider was aware of and complied with the requirements of the Duty of Candour. Duty of Candour requires service to be open and transparent with patients in relation to their care and treatment. The provider encouraged a culture of openness and honesty. The service had systems in place for knowing about notifiable safety incidents and responding to relevant patient safety alerts.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

We checked sixteen patient records and saw that information was collected during the initial consultation including past medical history, weight, height, blood pressure, blood glucose level and any medicines the patient was taking. The doctor discussed the treatments available, including common side effects to the medicines, and patients were provided with written information about medicines in the form of a patient information leaflet. Their body mass index (BMI kg/m²) was calculated and waist circumference was measured if their BMI was below 30 kg/m². We found that target weights were not routinely set at their initial appointments and for some patients no targets were set at all. We also found that BMI was not always recorded on subsequent visits in line with the provider's policy.

The assessment protocol used by the clinic stated if a person's BMI was above 30 kg/m² they would be considered for treatment with appetite suppressants and if they had other defined conditions then treatment could start if their BMI was above 27 kg/m². If the BMI was below the

level where appetite suppressants could be prescribed, the clinic provided dietary advice and had a herbal supplement for sale.

The records showed that one person was prescribed medicines with a starting BMI less than 30kg/m² with no comorbidities recorded and no rationale was recorded by the doctor.

We also saw evidence that one patient over the age of 75years was prescribed medicines not in line with the provider policy. Their age had not been identified by the call centre making the appointment or by clinic reception staff. This person had also been prescribed and supplied with medicines at higher than the recommended starting dose. The person's history indicated an underlying medical condition that was contraindicated in the doctors' manual and treatment protocol. Prescribing had also taken place before information had been received from their NHS general practitioner; this was not in line with the provider's doctors manual.

Monitoring care and treatment

Information about the outcomes of patients care was collected by way of a six monthly quality assurance audit where 20 patient records were reviewed to identify and record weight lost since the start of treatment or since the last treatment break, a doctor had not signed this audit. A record card audit was also completed three monthly, however, whilst a clinician signed off these audits they were not fully involved in the process and the audit process had not identified some of the issues we found.

Effective staffing

Doctors undertook consultations with patients, prescribed and supplied medicines. The registered manager and receptionist had undertaken first aid training and had completed the internal training programme, which included fire training, infection control, safeguarding, data protection and health

and safety. Reception staff received annual performance reviews and in-house appraisals. The provider checked the doctor's revalidation and recorded their GMC appraisal. The manager explained that they have meetings with the doctors as issues arise but there was no Provider appraisal process for the doctors.

Coordinating patient care and information sharing

Patients were asked before treatment started if they would like the information sharing with their GP. A record was made in their card if the information was to be shared and a letter was given to the patient regardless of whether they consented or not. The clinic would only contact the GP directly if there were any concerns and on these occasions, a record was kept.

Supporting patients to live healthier lives

Patients had access to a range of dietary advice to help with weight loss. Staff told us that patients were referred to their GP if they were unsuitable for treatment, for example because of high blood pressure or high blood sugar levels.

Consent to care and treatment

Consent to treatment was obtained from patients at the initial consultation and recorded on patient's medical cards. Patients had to sign to confirm they would inform clinic staff of any change in their health or circumstances and take reasonable precautions not to become pregnant during treatment with appetite suppressants. For two records we looked at where patients returned after a break

Are services effective?

(for example, treatment is effective)

in treatment, consent was not obtained in line with the provider policy. Consent was obtained via a family member or friend for two other people who did not have English as their first language. Another person who had associated risk factors was supplied with medicines before information was received from their NHS general practitioner.

The service offered full, clear and detailed information about the cost of consultation and treatment including the costs of medicines.

Are services caring?

Our findings

Kindness, respect and compassion

We observed staff at the clinic being polite and professional. We received 25 completed cards from patients telling us how they felt about the service. All were positive and demonstrated that staff were helpful and friendly and that patients were satisfied with the treatment they received at the service. We spoke with two patients on the two days of the inspection who also told us they were satisfied with the service provided.

Involvement in decisions about care and treatment

Staff communicated verbally and through written information to ensure that patients had enough information about their treatment. Patients felt that they were involved in decision-making and had sufficient time in their consultations to make informed choices about their treatment.

Privacy and Dignity

There was a confidentiality policy and staff could explain how they would protect patients' privacy.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

Records showed that staff had received equality and diversity training.

Information and medicine labels were not available in large print to help patients with a visual impairment and an induction loop was not available for patients with hearing difficulties.

The service was located on the second floor of a shared building. There was no lift at the service. No information was available to signpost patients with poor mobility to alternative services.

The treatments available at the clinic were only available on a fee basis. However, information on alternative methods of weight loss, such as diet and exercise, were available free of charge as was the ability to be regularly weighed by clinic staff.

We asked staff how they communicated with patients who spoke another language. The manager told us that some information was available in other languages however; patients usually brought a family member or friend to act as a translator. This meant that the doctor could not be assured that information was being relayed accurately.

Timely access to the service

The clinic was open four days a week with doctor's appointments for weight management available at various times to suit patients' requirements.

Listening and learning from concerns and complaints

The clinic had a complaints policy and information was available to patients in the waiting room about how they could complain or raise concerns. The clinic undertook a patient satisfaction survey to identify patient feedback. These were analysed by the registered manager, however it was not always clear when comments were negative what action had been taken.

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

The registered manager had worked at the clinic for many years and was respected by colleagues. The registered manager worked collaboratively with other managers in the area.

Vision and strategy

Although there was a Statement of purpose in place staff were not clear on culture, vision and values. The manager described the aim of the service as helping patients and supporting them to lose weight through a safe service of prescribed medicines and dietary advice. This led to improved self-esteem, confidence and health outcomes.

Culture

The manager promoted an open culture. The staff we spoke to, including the doctor, felt supported, respected and valued by the provider. It was clear from patient feedback that the culture centred on the patients' experience and staff were very positive about working in the service.

Staff had an awareness of the requirements of the Duty of Candour regulation. Observing the Duty of Candour means that patients who use the clinic are told when they are affected by something that goes wrong, given an apology, and informed of any actions taken as a result. Staff were encouraged to be open and honest and were able to demonstrate this.

Governance arrangements

The clinic had a number of policies and procedures to govern activity and these were available to the doctors and staff. Staff understood their role within the clinic and interacted appropriately.

Managing risks, issues and performance

The registered manager had responsibility for the day-to-day running of the clinic and there were regular audits of different aspects of the service. However, a non-clinician completed the audits and the audit system did not identify the clinical concerns, which we saw. The doctors signed the record card audits but were not fully involved in the audit process and so information was not always shared effectively or learnt from. The last quality assurance audit scored 75% and had not been signed by a doctor.

Engagement with patients, the public, staff and external partners

The views of patients using the service were gathered through satisfaction surveys and informal feedback, however on the few occasions where negative comments were made it was not clear that these had been identified and there was no information on what action had been taken to address the issues. There was also a feedback box located in the reception area and patients were encouraged to share their views. Staff described how they could suggest changes to systems and processes.

Continuous improvement and innovation

There was a system in place to review and set an action plan following the audit however we saw the same action plan repeated over a number of audits with no improvement noted.

The clinic kept a diary which recorded the tasks for the day, where these were not achieved they were carried forward to make sure that the task was not missed. There was a system in place to learn from significant events and incidents, as a result different medicines and strengths were segregated in drawers to reduce the risk or errors.

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 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>How the regulation was not being met:</p> <p>The registered person had not ensured that care and treatment was provided in a safe way for service users. In particular, there were unsafe prescribing practices, prescribing did not always follow clinic policies and basic monitoring requirements were not always recorded.</p> <p>This was in breach of regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation</p>
Regulated activity	Regulation
Services in slimming clinics	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>How the regulation was not being met:</p> <p>The registered person had not ensured that systems and processes were in place to effectively monitor and improve the quality of services being provided. In particular, audits failed to identify risks and clinicians were not fully involved in audit process to drive improvement.</p> <p>This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</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.