Care Quality Commission

Codegrange Limited

National Slimming Centres (York)

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 6 September 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.

Our key findings were:

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:

- Carry out a risk assessment for medical emergencies.
- Review the labelling of medicines.
- Review effectiveness of safeguarding training.
- Review the system for dissemination of information from head office.

Summary of findings

- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available

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 could be made relating to the safe labelling of medicines in line with legislation. The provider did not have appropriate training records to ensure that staff had the necessary skills and competence.

Are services effective?

We found that this service was not providing effective care in accordance with the relevant regulations. We identified examples of medical records which lacked clinical detail, medicines were prescribed below the thresholds set out in the clinic protocol and national guidance and treatment breaks were not adhered to. The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of this occurring in the future is low once it has been put right. We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations. Patients told us that they felt well supported when making choices about their care and treatment and were treated with dignity and respect.

Are services responsive to people's needs?

We found that this service was providing responsive care in accordance with the relevant regulations. Patient questionnaires were reviewed every six months and feedback was assessed and acted.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations. We found areas were improvements should be made. Clinical audits were not effective and the doctors were not fully involved in the clinical audit process to drive improvements. 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 Centres (York)

Detailed findings

Background to this inspection

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.

The inspection took place on 6 September 2017. The inspection was led by a CQC Pharmacist Specialist inspector and a second Pharmacist Specialist as support.

National Slimming Clinic York is based on the second floor of a shared building located near to the centre of the city of York. The service comprises of a Reception/waiting area, kitchen area and two clinic rooms. Toilet facilities are available at the clinic. The service is open Wednesday 10am to 2 pm and Saturday 10 am to 1 pm. Slimming and obesity management is provided either by a walk in or appointment based system for clients aged 18-65 years of age.

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. At National Slimming Clinic York, the aesthetic cosmetic treatments that are also provided are exempt by law from CQC regulation. Therefore, we were only able to inspect the treatment for weight reduction but not the aesthetic cosmetic services.

The service employs a 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.

We obtained feedback about the service from 21 Care Quality Commission comment cards. All comments made were positive about the service. Patients found staff were always welcoming and helpful, staff were always professional and the premises were always clean and tidy.

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

Reporting, learning and improvement from incidents

The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty. The service had systems in place for knowing about notifiable safety incidents. Staff were able to tell us what they would do in the event of an incident and there was a form available to complete in the event of an incident. We were told that there had been no incidents at this service in the last 12 months. Across the provider, a system was in place to share learning from incidents and we saw evidence of this communication.

We were told that safety alerts would be received by email and action taken if needed however no safety alerts had been received as none were appropriate for the medicines used at this service.

Reliable safety systems and processes (including safeguarding)

The service had a safeguarding policy and a separate document, which guided staff who in the local area to contact if referals were needed. Safeguarding training had been completed for all staff at the service however, staff were not always confident in describing their roles and responsibilities.

Appointments were booked on a computerised system and manual paper records of appointments were made. These were stored in a secured area of the service and access to this confidential information was restricted.

Medical emergencies

This is a service where the risk of needing to deal with a medical emergency is low. In the event of a medical emergency, it was the provider's policy to call 999. No emergency medicines or equipment were stored at the premises. A standard operating procedure was in place to cover this however, there was no risk assessment. The registered manager had undergone first aid training and the doctor had basic life support training.

Staffing

The service employed one registered manager and one doctor attended each clinic session. The staffing arrangements were adequate to meet the needs of people using the service.

We reviewed three personnel files; we found that appropriate recruitment checks had been undertaken for all staff. This included professional registration checks.

Disclosure and Barring Services (DBS) checks were recorded in all staff records. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable). The service had not risk assessed the need for DBS checks to be recent upon employment and although plans had been put in place to renew some DBS checks, one doctor had not been employed by the provider for less than one year however their DBS was dated 2013 this had not been identified as requiring a reassessment at the time of this inspection.

Both doctors had undergone professional revalidation and we saw evidence of this in their staff records. We were shown the clinical care protocol, which was available to use in the clinic room to ensure safe care and treatment.

Chaperoning was not available at this service. There was no policy in place for chaperoning and no assessment had taken place to identify it's need at the service. Staff had not undertaken training for this role and we were told that no one had ever asked for a chaperone. Subsequent to the inspection the provider informed us that a decision was made not to provide a chaperoning service.

Monitoring health & safety and responding to risks

Risk assessments had taken place to ensure the safety of staff and service users. Where risks had been identified appropriate actions had been taken to mitigate these risks and actions were recorded.

We were shown evidence that electrical equipment had been appropriately tested and was safe to use. Fire safety equipment had been appropriately tested and serviced in line with manufacturer's guidance.

Professional indemnity was recorded in the doctor's records and although evidence was not available on the day of inspection it was supplied after the inspection.

Infection control

Are services safe?

The premises were clean and tidy. An infection control policy was in place. The registered manager had undertaken infection control training, and evidence of infection control training was present for one of the doctors employed by the service. The registered manager completed the cleaning after each clinic and a record was held at the service. Infection control audits were undertaken every three months; at the previous audit no issues had been identified. Staff and clients had access to a toilet and appropriate handwashing facilities were provided. Examination gloves and alcohol hand gel were available for the doctors in the clinic room.

A waste management policy was in place and the appropriate exemption certificates were in place. The service held an on-going contract for clinical waste removal. Waste was segregated correctly.

A Legionella risk assessment had been undertaken and no action had been identified as required.

Premises and equipment

The service was located on the first floor of a shared building with access via a staircase. The property was in a good state of repair. The service consisted of a reception area, two consultation rooms which were private and ensured conversations could not be overheard, a kitchen and a toilet.

The service had a fire alarm and this had been tested regularly and there was a fire evacuation policy and guidance located in the reception area. Staff had completed fire training and fire equipment had been appropriately serviced. Staff knew where the assembly point was in the event of a fire and there was a log of fire drills taking place.

A first aid kit was available on the premises and the registered manager had undergone first aid training. The doctors at the service had basic life support training.

Blood pressure monitors and weighing scales had been calibrated and there was a schedule in place to ensure this was done at the right time.

Safe and effective use of medicines

This service prescribes Diethylpropion Hydrochloride and Phentermine.

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 grantedthemmarketingauthorisations. 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 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.

At National Slimming Centre York, 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 checked how medicines were stored, packaged and issued at the service. We found that medicines were stored securely and access was restricted to authorised members of staff. We saw that records were appropriate and that medicines were handled in accordance with the provider’s policy.

When medicines were prescribed and given by the doctor the containers were labelled appropriately, however some clients requested their medicines were decanted into one pot by the reception staff. This meant that the label did not demonstrate the correct quantity. We brought this to the attention of the registered manager during the inspection

Are services safe?

who said they would address this concern. A record of supply was made in the person's records as well as a running tally, which ensured that stock could be accounted for at the end of each clinic.

Reporting, learning and improvement from incidents

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Are services effective?

(for example, treatment is effective)

Our findings

Assessment and treatment

At the first consultation patients were asked to complete a medical history form, this covered key information including allergies, weight history, existing medical conditions and comorbidities. During this consultation, the doctor reviewed the medical history including the patient's comorbidities and recorded their height, current weight, target weight, blood pressure and a record was made of the patient's eating patterns and habits.

We reviewed nine patient records in detail and found that target weight and target Body Mass Index (BMI) had not been recorded for five patients at their first consultations. We found that health checks had taken place on the first visit and records showed that the core patient information was completed which included blood pressure, weight and BMI however this was not recorded monthly thereafter for some records we reviewed.

The National Slimming Centres Doctor's protocol stated that patients would only be started on treatment with a centrally acting appetite suppressant (CAAS) if their starting BMI was greater than 30kg/m2 or 27kg/m2 with Comorbid factors and that treatment would be for 13 weeks, after which a break should occur. From the records we reviewed, we found that this was not always followed. Three records indicated that medicines had been prescribed when the patient's starting BMI was less than 30kg/m2 with no comorbidities recorded. This is not in line with clinic protocol or national guidance which states medicines should not be prescribed for patients with no comorbidities under 30kg/m2 or with comorbidities 28kg/m2.

When patients returned to the clinic after a treatment break we found that their medical histories were not always reviewed to confirm if changes had occurred. We saw that records of consultations were often brief and lacked detail. Where prescribing had continued below the NICE guidance thresholds no reasons had been recorded to account for continued prescribing.

Staff training and experience

We were shown records of staff training for two of the three staff at the service. The registered manager had undertaken internal training, which covered infection control, fire safety, safeguarding, data protection and health and safety. They were also first aid trained. One doctor had provided evidence of external training in safeguarding, fire training, infection control, equality and human rights training and basic life support. We requested the training records for the second doctor however, these were not available or provided following the inspection.

Proof of revalidation was available for both doctors employed at the service.

Working with other services

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 generated to be sent to the GP.

The doctor described how patients were encouraged to attend their GP if they had abnormal blood pressure results and we saw evidence of communication between a GP practice and the service regarding one patient's on-going health needs. However a second person who had presented with breathlessness and other known risk factors, was not referred to another service and the action taken by the doctor had not been recorded in detail in the patient's records. Breathlessness is a recorded side effect of the medicine which requires further investigation to ensure the treatment remains safe for the patient to take.

Consent to care and treatment

Consent was clearly documented in the patient's care record for all records we look at and this was reviewed after a break in treatment for three records where breaks had been recorded.

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

Are services caring?

Our findings

Respect, dignity, compassion & empathy

We observed staff at the clinic and found them to be polite and professional. We saw how confidentiality was maintained within the restrictions of the environment. Consultations could not be overheard and there was a system in place to ensure all records were held securely.

Patients completed CQC comment cards and all comments about the staff and environment of the clinic were positive. All patients stated they were happy with the service and were satisfied with the treatment they received from the clinic.

Involvement in decisions about care and treatment

The service provided a range of information to guide patients with decision-making. Comment cards indicated that patients felt they were listened to and were involved in decisions regarding their care. Patients stated that they felt well supported and that concerns or changes in their needs were always responded to during consultations.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting patients' needs

The service completed a six monthly audit of feedback received from patients through questionnaires. These were analysed and if action was needed then a template was available. All comments in the last two questionnaire audits were positive.

We saw that the clinic had a system in place to ensure that medicines were closely monitored to ensure there were sufficient stocks. This ensured that there were no delays in treatment for patients.

The registered manager met patients at reception. The facilities at the service were warm and welcoming with adequate seating in the waiting area. The consultation room was private and contained the appropriate equipment for the consultation.

Tackling inequity and promoting equality

The service was located on the second floor of a shared building. Access was only available via stairs as no lift was available. The registered manager stated that if patients with poor mobility came to the clinic they would signpost them to alternative services. No inforamtion was available on the services website to direct patients to other locations if patients had poor mobility. Patient information leaflets and diet guides were available in other languages.

Information and medicines labels were not available in large print. An induction loop was not available for patients with hearing difficulties.

Treatment at the service was only available on a fee basis. However, information was freely available regarding weight loss methods including information on diet and exercise.

Access to the service

Appointments were available on a walk in and pre-booked basis two days a week. On Wednesday between 10 am and 2 pm and Saturday between 10 am and 1 pm.

Concerns & complaints

The service displayed their complaints procedure in the reception area which set out how to complain and which other services complaints could be raised with. A written policy was also available to guide staff. We were told that no complaints had been made at the service in the last 12 months.

Are services well-led?

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

Our findings

Governance arrangements

The service had a 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.

The service had a statement of purpose and this was available for staff. The clinic had a number of policies and procedures and these were all in date and had been recently reviewed. Staff had signed to state they had read the updated documents. Staff had access to electronic or paper copies of the policies and procedures.

Staff had annual appraisals and these were documented in their personnel files.

Leadership, openness and transparency

The registered manager was aware of and complied with the requirements of the Duty of Candour. They were able describe the process by which complaints would be handled and described how the culture of the service encouraged an open and honest environment. No concerns had been raised by or about the service in the last 12 months; however staff could describe the process they would follow if this did occur.

Learning and improvement

The service completed a series of audits on a three monthly or six monthly basis. This included medicines control, dispensing sheet audit, record card audit and clinical effectiveness. The clinical effectiveness audit looked at the degree of weight loss that was achieved over a 12 week period however this audit was not reviewed by the clinician. Actions resulting from all audits were documented however when we asked how the information gained from the audits was used to improve practice the registered manager told us that at present no thorough analysis took place. In addition, the audit system did not identify the clinical concerns we saw. The doctors were also not fully involved in the audit process and so information was not always shared effectively or learnt from.

There was a system in place to learn from significant events and incidents, which had occurred within the provider group. We asked the doctor how this information was shared with them and we could not be assured that the information was passed through to them.

Provider seeks and acts on feedback from its patients, the public and staff

The service engaged with their patients regularly through a client satisfaction questionnaire, which was reviewed every six months.

The registered manager stated that as part of their annual appraisal, they discussed the service and feedback which had been obtained to ensure any improvements could be identified and actioned.

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	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **How the regulation was not being met:** 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 protocol and basic monitoring requirements were not always recorded. Clinical notes did not always contain sufficient clinical detail regarding the decisions made when patients presented with co-morbidities or contra-indications.

Regulated activity	Regulation
Services in slimming clinics	Regulation 17 HSCA (RA) Regulations 2014 Good governance **How the regulation was not being met:** The registered person had not ensured that systems or processes were established and operated effectively to assess, monitor and mitigate the risks arising from the carrying on of the regulated activity, or to maintain an accurate, complete and contemporaneous record in respect of the care and treatment provided to each service user. In particular, employment and training records were not up to date for all staff, the effectiveness of safeguarding training had not been assessed, audits failed to identify risks and clinicians were not involved in audit process to drive improvement.