

Marie Swoboda Limited

National Slimming & Cosmetic Clinics

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 26 January 2016 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 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 providing well-led care in accordance with the relevant regulations.

Background

The National Slimming and Cosmetic Centres (Salisbury) provides weight loss treatment and services, including medicines and dietary advice to people accessing the service. The clinic is on the first floor of a shared building in a city centre location. The clinic is open for half a day on Tuesdays and Fridays.

The clinic is run by doctors and a clinic manager who is also 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.

We received feedback about the clinic from three completed Care Quality Commission comment cards. The observations made on the comment cards were all positive and reflected that people found staff to be helpful, respectful and caring. On the day of the inspection we spoke with one person that used the service.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of the provision of advice

Summary of findings

or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of weight reduction. At the National Slimming and Cosmetic Centre (Salisbury) 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.

Our key findings were:

We found the service to have good governance arrangements and quality assurance processes in place.

- Feedback from patients was consistently positive about the care they received.
- The provider did not have clearly defined and embedded systems, procedures and processes to keep people protected and safeguarded from abuse.
- The provider did not always supply medicines in line with evidence based practice.
- There were appropriately qualified staff in the clinic and staff felt supported to carry out their roles and responsibilities.

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

- Have robust systems and processes in place to prevent abuse of service users.
- Make sure there are effective arrangements in place to manage any medical emergency and that staff are trained to carry out the process.

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**:

- Ensure all staff have an understanding of the duty of candour and how it would be applied in the service if things went wrong.
- Review the policies and procedures to ensure they are up-to-date, reflect current practice and legislation, and encourage continuous improvement.
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.
- Review the ordering process for controlled drugs in line with changes in legislation.
- Ensure that medicines are supplied in accordance with recognised clinical guidance and best practice.
- Assess how they will make their services accessible to non-English speaking and disabled people to ensure that they are not disadvantaged compared with English speaking and non-disabled people.
- Have a process to manage the risk of Legionella infection in the water supply.
- Have a robust system in place for regular and appropriate inspection, calibration, maintenance and replacement of equipment.

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 the 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 section at the end of this report).

- The provider did not have robust arrangements in place to keep people protected and safeguarded from abuse.
- Medicines were not prescribed in line with evidence based practice.
- The service could not demonstrate effective arrangements for managing medical emergencies.
- Employment checks were done when staff were recruited to ensure staff had the skills and knowledge to carry out their roles.
- There were procedures in place for monitoring and managing risks to patient and staff safety.

Are services effective?

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

- Patients had a medical assessment to ensure that treatment was safe and in line with the clinic's policies.
- Staff received annual appraisals and were supported to carry out role relevant training.
- Patient consent was sought and documented.

Are services caring?

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

- We observed members of staff at the clinic being polite, professional and helpful, and treating patients 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.

- The provider was responsive to patient's needs and had systems in place to maintain the level of service provided.
- The service did not always make reasonable adjustments for people but referred people to services that could meet their needs.
- There was a complaints procedure that was easily accessible to patients.

Are services well-led?

We found that this service was providing well-led care in accordance with the relevant regulations.

- The clinic had policies and procedures in place to govern activity, but the documents had not been recently reviewed and referred to out of date regulations.
- Staff told us they felt supported by management and that they were clear on the responsibilities of their roles.
- The clinic encouraged and valued feedback from people who used the service.

National Slimming & Cosmetic Clinics

Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection at National Slimming and Cosmetic Centres (Salisbury) on 26 January 2016 as part of the independent doctor services inspection pilot. The inspection team was led by a CQC pharmacist specialist and included another CQC pharmacist specialist.

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.

Before visiting, we looked at a range of information that we hold about the clinic. We reviewed the last inspection report from 6 March 2013, notifications received and the information submitted by the service in response to the provider information request.

The methods that were used during our visit included talking to people using the service, interviewing staff, observations and reviewing documents.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

Are services safe?

Our findings

Reporting, learning and improvement from incidents

There was a system in place for reporting and recording 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 and record form was available. We were told there had been no incidents in the previous 12 months. The incident reporting policy at the clinic referred only to recording notifiable incidents, reducing the opportunity for learning and improvement from clinical incidents and near misses not requiring statutory notification to the regulatory body. We could not establish if the policy was current as the document was not dated.

We were told that safety alerts were received by the provider and relevant alerts were forwarded to the registered manager; no alerts had been received in the past 12 months.

Reliable safety systems and processes (including safeguarding)

The clinic did not have clearly defined and embedded systems, procedures and processes to keep people protected and safeguarded from abuse. Staff told us that they did not think that the safeguarding principles were relevant to the clinic's registered activity. There was no evidence of adult or children safeguarding training for any of the clinic's members of staff, nor information on a documented reporting system aligned to the local authority. There was no evidence that staff had completed Mental Capacity Act (2005) training.

Patients' medical information, clinical notes and record of medicines supplied were documented manually on record cards. The cards were stored securely at the clinic, and were only accessible to staff, which protected patient confidentiality.

We were shown a duty of candour statement but not all staff were aware of what it meant or how it applied to the clinic. Observing the Duty of Candour means that people who use services are told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result. It is not possible to say if the service would be open, transparent and apologetic with patients if things went wrong.

Medical emergencies

We did not see effective arrangements for managing medical emergencies in the clinic. However, there were some emergency medicines in the treatment room and the clinic doctors had received basic life support training. Staff told us they would dial 999 in a medical emergency.

Staffing

There was adequate staffing to meet the demands of the service.

We reviewed three personnel files, and found that recruitment checks had been undertaken prior to employment, including references and checks through the Disclosure and Barring Service (DBS). (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 doctors had appropriate professional registration with the General Medical Council.

Information on chaperoning was included in the patient guide, which was available to people in the waiting room.

Monitoring health & safety and responding to risks

There were procedures in place for monitoring and managing risks to patient and staff safety, and we saw records of health and safety awareness training for staff.

We saw evidence that electrical equipment and fire safety equipment was checked to ensure it was safe to use. There were risk assessments in place to monitor safety in the clinic; these included fire risk, premises risks and for substances covered by the control of substances hazardous to health (COSHH) regulations.

There was building and medical indemnity insurance policies in place. The buildings indemnity insurance policy was displayed in the reception area.

Infection control

The practice maintained appropriate standards of cleanliness and hygiene. We observed the premises to be clean and tidy. We were told that staff received infection control training during induction but no update training was provided to staff once in employment.

We saw daily and weekly infection control check sheets in use.

Are services safe?

We saw policies in place for the management of waste and safe disposal of sharps. The clinic had a contract with a clinical waste contractor, and we saw that waste was appropriately segregated and stored.

We did not see evidence that the clinic checked the water supply to manage the risk of Legionella.

Premises and equipment

The clinic was located on the first floor of a shared building. The clinic had an open plan reception and waiting area, one clinic room, a kitchen and two toilets for patients and staff. There was an additional room on the second floor that was not routinely used although we were told that it could be used for confidential conversations if the treatment room was occupied.

We observed the premises to be in a good state of repair; building maintenance was carried out by the landlord. Rooms were uncluttered and well-lit. Appropriate clinical equipment was available, which appeared clean and in good working order. The blood monitoring machine was calibrated in accordance with the manufacturer's guidelines. We were told that the scales were calibrated with a 2 kg weight. However, there were not robust systems in place for regular and appropriate inspection, calibration, maintenance and replacement of equipment.

Safe and effective use of medicines

We were told by staff and records showed us that appetite suppressants were prescribed 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 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 Centres (Salisbury) 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.

Medicines were stored securely in appropriate cupboards in the clinic; only the doctors had the code to allow access to the medicines. During clinic opening hours medicines were kept safely in the possession of the prescribing doctor. We were told that they were packaged into containers by a second member of staff under the supervision of the doctor. Medicines were ordered and received when there was a doctor on the premises. However, we did not see use of the mandatory requisition form for requesting stock of Schedule 3 Controlled Drugs, in line with recent changes in legislation.

When medicines were prescribed by the doctor they were supplied in labelled containers which included the name of the medicine, instructions for use, the person's name and date of dispensing. We saw that a record of the supply was made in the patient's clinical notes.

Are services effective?

(for example, treatment is effective)

Our findings

Assessment and treatment

Prior to the consultation each person had to complete a medical history form where people had to identify if they had other illnesses or were taking any other prescribed medicines.

During the initial consultation, the following information was collected from each person; blood glucose reading, weight, height, and answers to questions around their eating habits. The doctor also checked for contraindications to treatment such as uncontrolled diabetes and uncontrolled high blood pressure.

We checked six patient records and saw that the medical history, weight and blood pressure were taken at their initial visit. A body mass index (BMI) was calculated and target weights agreed and recorded. Weight was recorded at subsequent visits.

The assessment protocol used by the clinic stated if a person's BMI was above 30 they would be considered for treatment with appetite suppressants and if they had comorbidities then treatment could start if their BMI was above 27. If the BMI was below the level where appetite suppressants could be prescribed the clinic provided dietary advice and also had a herbal supplement for sale.

We looked at the medical notes for six patients and saw that some people had been attending the clinic for more than two years. The patients had received multiple prescriptions for diethylpropion hydrochloride tablets or phentermine capsules during that time. Information published by the MHRA and British National Formulary says that these medicines are only effective for 'short-term' use. We therefore cannot be sure that the doctors were providing clinically effective and safe treatments for the patients.

Staff training and experience

The clinic had an induction programme for newly appointed staff that covered topics such as confidentiality, infection control and fire procedures.

We saw evidence of a formal system of appraisals in place for staff. We were told that they were given opportunities to undertake training, for example, training on the new computer system. We saw that the clinical staff had regular professional appraisals and were registered with the General Medical Council. The doctors completed revalidation in 2015; their designated body was the Independent Doctors Federation and we saw evidence of a named responsible officer.

Working with other services

People who attended the clinic were asked before treatment commenced if they would like their GP informed. We saw that the decision was documented in the patient notes next to the person's signature. We were told that every new patient was issued with a letter for their GP detailing the medicines and treatment given. This was only sent to the GP if the patient consents; otherwise it was given to the patient for their own future use.

Consent to care and treatment

Staff sought patient's consent before treatment was commenced, which was documented and kept in the clinical records. Patient's were given information leaflets about their treatment; this included information that the medicine was unlicensed and it explained what that meant.

The provider offered full, clear and detailed information about the cost of consultations and treatments.

Are services caring?

Our findings

Respect, dignity, compassion & empathy

We observed members of staff at the clinic being polite, professional and helpful, and treating patients with dignity and respect. Staff we spoke with were aware of the importance of protecting patient confidentiality.

Patients completed CQC comment cards to tell us what they thought about the clinic. All of the comments were

positive about the clinic. Patients said they found staff to be helpful, caring, friendly and respectful. We spoke with one patient on the day of inspection, who told us they were satisfied with the service provided by the clinic .

Involvement in decisions about care and treatment

We saw a range of information available to patients in the clinic, including information leaflets about the medicines.

Patient comments indicated that people found the service provided good support to achieve their treatment goals.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting patients' needs

We found the provider was responsive to patient's needs and had systems in place to maintain the level of service provided. We saw effective systems to ensure that medicines and materials were kept in stock which avoided delays in assessment and treatment.

The clinic was comfortable and welcoming for patients, and the facilities were suitable for the service provided. The consultation room was well designed and well equipped.

The clinic gathered patient feedback via an online patient satisfaction survey. The management reviewed responses to assess if there were ways to improve the service.

Tackling inequity and promoting equality

We asked staff to explain how they communicated with patients who had different communication needs such as those who spoke another language. Staff told us that they very rarely had customers with different communication needs. Patient information was only provided in English and there were no translation services.

The service was located on the first floor, and was accessed via a flight of stairs. There were no adjustments in place for people with disabilities. We were told that if people with disabilities wanted to access the service they would be provided with details of alternative clinics. The clinic information leaflet had a disability statement that publicised this limitation.

Access to the service

Patients could make appointments directly with the clinic or via the national call centre that was open six days a week. We saw that people were not rushed at their appointment. Patients could choose to see one of two doctors.

Concerns & complaints

There was a designated responsible person who handled complaints at the clinic. Information for patients about how to make a complaint was available in the clinic waiting room and in the clinic patient guide. This included contact details of other agencies to contact if a patient was not satisfied with the outcome of the investigation into their complaint.

We were told no complaints had been received by the clinic 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 clinic had policies and procedures in place to govern activity, and these were available to the staff. The documents had not been recently reviewed and referred to out of date regulations.

The service had quality assurance systems in place, which were reported and monitored by the provider. There was a systematic programme of audits to monitor clinical records, medication, environment and cleanliness. For example, we saw regular reviews of a sample of patient records but we did not see any evidence of improvements in practice identified by the audit cycle.

There was a clinical lead who oversaw governance for the organisation nationally.

Leadership, openness and transparency

Staff told us they felt supported by management and that they were clear on the responsibilities of their roles. The

registered manager had responsibility for the day to day running of the clinic. The registered manager met informally with the doctors to discuss changes or updates in practice. The clinic received information from the national office via regular emails and telephone calls.

Staff told us that there was an open culture in the clinic and they had the opportunity to raise any issues and were confident in doing so and felt supported if they did.

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

The service encouraged and valued feedback from customers. The clinic proactively sought patient feedback following delivery of the service through an online survey. We saw that the client satisfaction survey was reviewed by the national office and outcomes were sent to the registered manager. We saw that patients had requested longer opening hours through the online survey comments. The clinic manager had trialed extended opening hours but that it was not continued beyond the trial period for business reasons.

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 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment</p> <p>How the regulation was not being met</p> <p>We found that clinical staff did not understand that safeguarding principles were relevant in the service and staff had not received safeguarding training. This meant there were gaps in the systems and processes which operated to effectively prevent abuse of service users.</p> <p>Staff were not aware of how the Mental capacity Act 2005 applied to the service and staff had not received appropriate training.</p> <p>This was in breach of regulation 13 (2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</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 provider did not have effective arrangements in place to manage a medical emergency.</p> <p>This was in breach of regulation 17 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</p>