

SDC (UK) Limited

SDC UK Limited t/a Prime Health & Beauty Clinic - Nottingham

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 9 February 2016 to ask the service the following questions; are the 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

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 (Regulated Activities) Regulations 2015, and to look at the overall quality of the service, under the Care Act 2014.

Prime Health and Beauty Clinic provides a private weight reduction service for adults and supplies medicines and dietary advice to the patients accessing the service. The clinic operates from a first floor consulting room in the centre of Nottingham. It is open from 10.30am to 6.00pm on Tuesdays and Saturdays.

The clinic is run by one doctor who 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 a legal responsibility

Summary of findings

for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run. There is another clinic in Derby run by the same provider.

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 Prime Health & Beauty - Nottingham, 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 and not the aesthetic cosmetic services.

At our last inspection on 19 November 2013 we asked the provider to make improvements regarding sharing information with other health professionals, prescribing medicines outside national guidance and the complaints procedure. We checked these areas as part of this comprehensive inspection and found that they had been resolved.

We spoke with three people on the day of the inspection and received feedback from 52 people who completed comment cards before our visit. People said they found staff at the clinic friendly, helpful and supportive. They said the doctor made time for them and felt she was thorough in her approach.

Our key findings were:

- Overall the clinic provided an effective service
- Arrangements were in place to manage medicines in a way that kept people safe

- There was a treatment protocol in place which was followed
- Feedback from patients was positive. People told us that staff were helpful, and that additional time was allowed for the first appointment
- There were a number of policies and procedures in place to govern activity

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

- Ensure that staff undertake training on safeguarding vulnerable adults appropriate to their role
- Ensure that recruitment procedures are followed and that the relevant checks are made on clinical staff in line with Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

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 a system is in place for regular and appropriate cleaning, inspection, calibration, maintenance and replacement of equipment
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available
- Review their arrangements for dealing with medical emergencies
- Consider how to make the service accessible to patients who don't speak English

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 follow an effective recruitment process and had not ensured that staff were trained to keep people protected and safe from abuse. Arrangements were in place to manage medicines in a way that kept people safe, however unlicensed medicines should only be supplied when there is no suitable licensed medicine available to meet the needs of the patient. The premises looked clean and patients told us they had no concerns about infection control, but there was no schedule in place for ensuring that premises and equipment were cleaned regularly. Patient information was recorded and stored securely, however the provider had not registered with the Information Commissioner's Office.

Are services effective?

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

A treatment protocol was in place which was followed by the doctor. We saw that patients were assessed, and that medicines were not prescribed for patients who did not meet the criteria. Patients were advised to inform their GP when they were prescribed appetite suppressants.

Are services caring?

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

People told us that staff at the clinic were friendly, helpful and supportive.

Are services responsive to people's needs?

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

Appointments were available on Saturdays. The doctor provided information on diet and exercise. The provider did not make adjustments such as interpretation services for people who spoke another language.

Are services well-led?

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

The clinic had policies and procedures in place to govern activity, and collected patient feedback through a questionnaire which showed that patients were satisfied with the service.

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Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection at Prime Health and Beauty Clinic- Nottingham on 9 February 2016. The team was led by a CQC inspector and included a GP specialist adviser and a member of the CQC medicines team.

Before visiting, we reviewed a range of information that we hold about the clinic which included the last inspection report from 19 November 2013, any notifications received and information from the provider.

The methods that were used were talking to people using the service, interviewing staff, observation and review of 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 recording incidents, staff were able to tell us what they would do in the event of an incident, and we saw that there was a reporting form available which supported the recording of notifiable incidents under 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). We saw that there had been no incidents in the previous 12 months.

Reliable safety systems and processes

The clinic had a safeguarding policy which included details of local authority contacts, and the process to follow if there were any concerns about keeping people protected and safe from abuse. The policy applied to adult patients and any children who may accompany them to appointments. However the provider told us that none of the staff including the doctor had undertaken training on safeguarding children or vulnerable adults so they may not have been able to identify or protect people at risk.

A policy was in place to control access to confidential personal information. We saw that patients' medical record cards were stored securely at the clinic and were only accessible to staff, which protected patient confidentiality. We noted that the provider was not registered with the Information Commissioner's Office as required by the Data Protection Act 1998.

Medical emergencies

The provider did not hold a stock of emergency medicines or equipment, but we were told that there was always a doctor on site when the clinic was open in the event of an emergency. There were no records to show that staff had received basic life support training.

Staffing

There was adequate staffing to meet the needs of the service. The doctor was registered with the General Medical Council and had professional indemnity insurance in place. There were no records to show that the provider undertook recruitment checks on reception staff prior to employment, for example proof of identity and references.

Infection control

We observed the premises to be clean. Hand washing facilities were available. Patients told us they found the clinic clean and had no concerns about cleanliness or infection control. The clinic had an infection control policy but did not carry out any procedures which generated clinical waste or sharps waste.

Premises and equipment

The consulting room was cluttered and we observed the wallpaper was peeling. Staff told us they cleaned the consulting room and equipment but there was no schedule in place to ensure it was done regularly. We saw that electrical equipment was checked every 2 years.

Safe and effective use of medicines

The doctor told us, and we observed during our visit, that appetite suppressants were prescribed to patients at the clinic.

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 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.

At Prime Health and Beauty Clinic - Nottingham 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.

Are services safe?

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.'

The doctor told us that since our last inspection she had stopped prescribing bendroflumethiazide, a medicine which is used to promote water loss and which is not indicated for weight loss.

We checked how medicines were stored, packaged and supplied to people. We were told that medicines were delivered directly to the doctor and we saw that they were stored securely in the possession of the doctor.

We saw that the doctor dispensed medicines into appropriately labelled containers which included name of medicine, instructions, patient's name and date of dispensing, and made a record of the medicines supplied.

Are services effective?

(for example, treatment is effective)

Our findings

Assessment and treatment

We saw that there was a treatment protocol in place for people attending the clinic. This set out the information to be collected by the doctor, the guidance to be given to patients and the records to be kept.

We checked 8 people's records and saw that the protocol was followed. At the initial consultation the doctor asked people about their medical history including ways in which they had tried to lose weight in the past. We saw that their blood pressure, weight and height were recorded, their body mass index was calculated and target weights agreed. The doctor checked for contraindications to treatment such as high blood pressure and poorly controlled diabetes, and we saw that appetite suppressants were not prescribed in these circumstances. People told us that the doctor allowed more time for the initial consultation.

Patients were given follow up appointments every two to four weeks. During our visit a patient came for a follow up appointment. We saw that the doctor gave the person the opportunity to ask questions before dispensing phentermine tablets and vitamins for them. A further appointment was arranged in two weeks and the doctor told the person to telephone her if there were any problems before that.

Another patient returned to the clinic having put weight on since last year. Their weight and blood pressure was checked. The doctor reminded them that the appetite suppressant was unlicensed and advised them to lose weight gradually over three months. They provided an exercise log and a diet chart and advised the person to develop good eating patterns by eating small meals and keeping a food diary.

We saw that some patients attended the clinic for several years but the records we saw showed that medicines were not being supplied to people for more than 12 weeks without a treatment break.

Staff training and experience

The doctor who worked at the clinic was a member of the Obesity Management Association and they told us that they were doing some on-line training on obesity management.

We saw evidence that the doctor had an annual appraisal with the Independent Doctor's Federation and their registration with the General Medical Council was revalidated in November 2015. The doctor told us they were undergoing continuing professional development using online training, and we saw records of attendance at a conference in 2015.

Working with other services

The doctor told us that they strongly advised people to allow them to inform their GP that they were prescribed appetite suppressants. We saw records which showed that most people did not agree to this in which case they were given a letter and advised to tell their GP themselves.

Consent to care and treatment

The doctor obtained consent from each patient before treatment commenced. Patients were given a declaration which stated that some phentermine and diethylpropion preparations were manufactured under a 'specials' licence.

They were asked to sign to confirm that they understood this, and that they had been made aware of the side effects, risks and benefits of the medicines.

Patients were also asked to sign a form to confirm that they had given the doctor a complete history of any medical conditions, and we saw records which showed that the doctor encouraged patients to give a complete history.

Are services caring?

Our findings

Respect, dignity, compassion and empathy

Patients completed CQC comment cards to tell us what they thought about the clinic. We received 52 completed cards and all were positive about the service. People said they found staff at the clinic friendly, helpful and supportive. They said the doctor made time for them and felt they were thorough in their approach.

We observed that consultations were carried out in the privacy of a consulting room.

Involvement in decisions about care and treatment

People who completed comments cards and those we spoke with on the day of our visit told us that health issues were discussed with them and that they were given plenty of advice and information about their treatment. They said the doctor allowed additional time in the initial appointment for them to make an informed decision.

We saw a policy which stated that the doctor would provide patients with information on the cost of treatment during the initial consultation.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting patients' needs

Patients told us that their needs were met by the service provided at the clinic. A receptionist was available to greet patients. We saw that the doctor provided guidance on healthy eating and regular exercise. The provider carried out an annual patient survey to ensure that they understood the needs of their patients.

Tackling inequity and promoting equality

The provider did not make adjustments for people who did not speak English. The doctor told us that if a patient did not speak English well enough to understand the information needed in order to make a decision about treatment, they asked them to bring a family member as an interpreter. This meant the doctor had no assurance that information was being relayed accurately.

The premises were on the first and second floors, reached by flights of stairs. The doctor told us that her clinic in Derby was on one level and that she would suggest to people with mobility difficulties that they saw her there.

Access to the service

The clinic is open on Tuesdays and Saturdays from 10.30am to 6pm. Patients were encouraged to make appointments but during our visit the doctor saw someone who had arrived without an appointment. Two people who completed comment cards said that they sometimes had to wait even when they had an appointment.

Concerns and complaints

The provider had a policy for handling complaints which we saw was reviewed and updated regularly. Information on how to make a complaint was displayed in the waiting room and included details of other agencies to contact if a patient was not satisfied with the outcome of the investigation into their complaint. We were told there had been no complaints 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 a number of policies and procedures in place to govern activity which were reviewed and updated regularly.

The doctor showed us an audit that she had completed during 2015, which collected data on patients who were not prescribed appetite suppressants. The reasons for not prescribing were recorded. These included raised blood pressure, body mass index of 27 or less, and the patient not wanting to return for regular consultations. This data showed that the doctor was following the clinic's treatment protocol.

The registered manager had day to day responsibility for the running of the clinic including clinical records, medicines management, environment and cleanliness. We did not see evidence that these activities were audited to identify whether improvements in practice were needed.

Leadership, openness and transparency

The provider was not aware of the requirements of the Duty of Candour but they were able to describe the need to be open with patients if things went wrong. Observing the Duty of Candour means that people who use the service are told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result.

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

The clinic collected patient feedback through a questionnaire which showed that patients were satisfied with the service provided and rated it good or excellent.

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

Services in slimming clinics

Regulation

Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment

The provider must ensure that safeguarding training appropriate to their role is undertaken by all staff

Regulation 13(1) & 13(2)

Regulated activity

Services in slimming clinics

Regulation

Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed

The provider must show that they have carried out the appropriate recruitment checks prior to employment in line with Schedule 3 of the Health and Social Care Act 2008

Regulation 19(1) & 19(2), Regulation 19(3)