

SDC (UK) Limited

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

## Inspection report

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## Overall summary

We carried out an announced comprehensive inspection on 24 February 2016 to ask the service the following 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**

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 who use the service. The clinic operates from a ground floor consulting room on Burton Road in Derby. It is open from 11am to 8pm on Monday, Wednesday, Thursday and Friday.

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 a clinic in Nottingham 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 - Derby, 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.

We spoke with three people on the day of the inspection and received feedback from 68 people who completed comment cards before our visit. People said the staff at the clinic were caring and supportive and that they were given helpful information and advice. They said the doctor listened to them and treated them with respect.

## **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 which we saw was followed
- Feedback from patients was positive. People told us that staff were caring, and that they were given information about their treatment
- The clinic had 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 (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 this service was not providing safe care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Requirement Notices 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. Information was recorded and stored securely, but the provider was not registered with the Information Commissioner's Office.

### **Are services effective?**

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

People told us that staff at the clinic were welcoming, caring and supportive.

### **Are services responsive to people's needs?**

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

Appointments were available in the evenings as well as during the day. The premises were on the ground floor with step free access, however the provider did not make adjustments such as interpretation services for people who spoke another language.

### **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, and collected patient feedback through a questionnaire which showed that patients were satisfied with the service.

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

## Detailed findings

### Background to this inspection

We carried out an announced comprehensive inspection at Prime Health and Beauty Clinic - Derby on 24 February 2016. The team was led by a CQC inspector and included 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 8 January 2014, 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?
- 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 and near misses, staff were able to tell us what they would do in the event of an incident, and we saw that there was an incident 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). The doctor told us 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 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.

### Monitoring health & safety and responding to risks

There were policies in place for monitoring and managing risks to patients and staff safety. We saw that electrical and fire safety equipment was checked every 2 years. We saw cleaning products stored in an unlocked cupboard which was accessible to any children attending the clinic with parents or carers. We brought this to the attention of staff and since the inspection they have fitted a lock to the cupboard.

### 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

Staff told us they cleaned the consulting room and equipment but there was no schedule in place to ensure that it was done regularly. We noted that there was no lock on the door of the toilet used by patients and visitors – this has been rectified since our visit.

### 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

## Are services safe?

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 & Beauty Clinic - Derby 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 supplied to people. We saw medicines were stored securely in the possession of the prescribing doctor. We were told that medicines were delivered directly to the possession of the registered 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 3 people's records and saw that the protocol was followed. One person we spoke with said the doctor was "rigorous" in her approach. 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, poorly controlled diabetes or BMI below the threshold for treatment, and we saw that they did not prescribe appetite suppressants in these circumstances. Information on healthy eating and exercise was provided. Patients were given follow up appointments every two to four weeks. 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 clinic was run by one doctor who was a member of the Obesity Management Association. We saw evidence that

the doctor had an annual appraisal with the Independent Doctors Federation and their registration with the General Medical Council was revalidated in November 2015. The doctor told us they were undertaking 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 said that some phentermine and diethylpropion formulations 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 possible side effects, risks and benefits of the medicines.

The doctor also asked patients to sign a form to confirm that they had given a full 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 68 completed cards and all were positive about the service. People said the staff at the clinic were welcoming, caring and supportive and that they were given helpful information and advice. They said the doctor listened to them and treated them with respect.

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 the information they needed.

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 they found the clinic welcoming, and were satisfied with the service provided. A receptionist was available to greet patients. The provider carried out an annual patient survey to ensure that they understood the needs of patients and the doctor told us they got ideas for changing the service by talking to patients.

### **Tackling inequity and promoting equality**

The provider did not make adjustments for people who did not speak English. Staff told us that some patients brought family members with them to act as interpreters which meant the doctor had no assurance that information was being relayed accurately. We found that the service was accessible to people with a disability. The premises were on the ground floor with step free access to the waiting room, consulting room and toilet.

### **Access to the service**

The clinic is open on Monday, Wednesday, Thursday and Friday from 11am to 8pm. Patients were encouraged to make appointments but we observed during our visit that the receptionist was flexible when people telephoned and asked to be seen at short notice.

### **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. They carried out clinical audits for example the doctor showed us an audit that they had completed during 2015, which collected data on patients who did not meet the criteria for treatment. The audit showed that these patients were not prescribed appetite suppressants therefore 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 doctor told us that they gained ideas through feedback from their patients. The clinic collected patient feedback through an annual 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) (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 (Regulated Activities) Regulations 2014**

Regulation 19 (1) (2) (3)