

# Slim Holdings Limited

# National Slimming & Cosmetic Clinics

## Inspection report

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## Overall summary

We carried out an announced comprehensive inspection on 20 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 not 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 National Slimming and Cosmetic Clinic Middlesbrough 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.
- Ensure that chaperoning arrangements are in place to protect service users.
- Ensure that recruitment checks are completed prior to employment.

You can see full details of the regulations not being met at the end of this report.

# Summary of findings

There were areas where the provider could make improvements and should:

- Review effectiveness of safeguarding training.
- Review the system for dissemination of information from head office.
- Review the systems and process for contacting GPs.
- Review signposting information for patients with mobility concerns.
- 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 not providing safe care in accordance with the relevant regulations. No assessment had taken place regarding the use of staff as chaperones and when staff were used as chaperones, no training was given. Recruitment records were not always thorough and completed before the staff member was employed. DBS checks had not been completed and reviewed in a timely manner. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

### **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 detail scope and rationale, prescribing was not always in line with national guidance or provider policy. Some records were not accurately completed and treatment breaks were not always adhered to. We have told the provider to take action (see full details of this action in the Enforcement section 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 listened to and that they were involved in decisions regarding their care. Patients 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. Systems were in place to ensure adequate stock of medicines and feedback from patients was reviewed every six months.

### **Are services well-led?**

We found that this service was not providing well-led care in accordance with the relevant regulations. Clinical audits were not effective and the doctors were not fully involved in the clinical audit process to drive improvements. Medicines were prescribed outside of clinic policy and this had not been identified as part of the audit process. Governance arrangements for recruitment were not effective. We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

# National Slimming & Cosmetic Clinics

## Detailed findings

### Background to this inspection

We carried out 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 20 September 2017. The inspection was led by a CQC Pharmacist Specialist inspector and a second Pharmacist Specialist as support.

National Slimming and Cosmetic Clinic Middlesbrough is based on the second floor of a shared building located in the centre of Middlesbrough town. The service comprises of a Reception/waiting area, three office rooms and a clinic room. At the time of inspection the clinic was not providing cosmetic services. Cosmetic services are exempt by law from CQC regulation. Toilet facilities were not available at the clinic for patients. The service is open Wednesday 10.30 – 2.30pm, Thursday 10 – 2pm Friday 9.30 – 1.30pm and Saturday 9.00 – 1pm. Slimming and obesity management is provided 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.

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 28 Care Quality Commission comment cards. All comments made were positive about the service. Patients found staff were always caring, helpful, 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

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

### 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. A form was available online to complete in the event of an incident. We were told that there had been one incident at the service in the last 12 months. We saw the incident report and the investigation. Actions had been taken in light of the incident, which involved two bottles of missing medicines. The provider had also introduced an incident sharing briefing, which was communicated to each location on a quarterly basis.

We were told that safety alerts were received at head office and emailed out if actions were needed. We were told that there had been no alerts relating to this type of service in the last 12 months.

### 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 referrals 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 and the doctor did not know where to locate contact details for safeguarding teams in the local area.

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 equipment was stored at the premises. The service had decided through a risk assessment to keep an injection used for severe allergies for the use in an emergency this

had been risk assessed. A standard operating procedure was in place to cover this and an accident book was located in the reception area. The registered manager had undergone first aid training and the doctor had basic life support training.

### Staffing

The service employed one registered manager, two receptionists and one doctor. A second doctor was available from a local clinic if needed. The staffing arrangements were adequate to meet the needs of the people using the service.

We reviewed four personnel files; we found that three members of staff had been employed at the service for greater than 20 years. Their personnel files had been updated and contained the required information. The newest member of staff who had started at the service in July 2017 had not had appropriate recruitment checks recorded prior to starting work. At the time of the inspection, no Disclosure and Barring Services (DBS) check had been completed and no references had been received. No risk assessment had taken place to determine if the new member of staff required a 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).

For all other staff DBS checks were recorded in records. The service had not risk assessed the need for DBS checks to be checked at regular intervals and one person's DBS was dated March 2008.

The doctor 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.

A chaperoning service was not advertised as available at the service however, the doctor stated that they had asked reception staff to chaperone on a number of occasions when they felt this was necessary. No assessment had taken place regarding the need for this service. There was no policy in place and staff had not undertaken training for this role.

### Monitoring health & safety and responding to risks

# Are services safe?

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

We checked several appliances at the service, all were appropriately tested and were safe to use. Fire safety equipment had been tested and serviced in line with manufacturer's guidance.

The provider showed us records of professional indemnity, which covered all staff working at the service.

## Infection control

A checklist was in place for cleaning and this was completed after each clinic. The premises were clean and tidy and there was an infection control policy in place. Training in infection control had been undertaken for the doctor, manager, and receptionist. Infection control audits were undertaken every three months; no concerns had been identified at the last audit.

Staff had access to a toilet and appropriate hand washing facilities were provided. There was no patient toilet at the clinic. Examination gloves and alcohol hand gel were available for the doctors in the clinic room. Blood glucose kits were available for testing sugars if required and appropriate waste bins were available for use.

A waste management policy was in place. Waste exemption certificates had been applied for. The service held an ongoing contract for clinical waste removal. We saw waste had been segregated correctly.

A legionella risk assessment had been undertaken and no actions had been identified as required.

## Premises and equipment

The service was located on the second floor with no lift access. The service had recently moved into the premises which were in a good state of repair. The service was clean and tidy. The service consisted of a reception area, a consultation room and three offices two of which were not used at the time of the inspections. There was also a staff toilet. The consultation room was private and conversations could not be overheard.

The service had blinds at the windows in both the waiting area and consultation room however at the time of

inspection these were not fitted with loop cords. This had not been covered in the environmental risk assessments. We brought this to the attention of the registered manager who rectified this after the inspection.

The service had a fire risk assessment. The alarm was checked regularly and staff had completed fire training. Staff knew where the assembly points were in the event of a fire. Fire alarms were checked weekly and fire equipment had been serviced in line with recommendations.

Blood pressure monitors and weighing scales had been calibrated and there was a schedule to ensure this was completed at the correct time.

## Safe and effective use of medicines

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 and Cosmetic Clinic Middlesbrough, 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

## Are services safe?

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 staff members. Records for stock balance were completed after the end of each clinic and records were accurate.

When medicines were prescribed and given by the doctor the containers were labelled appropriately. In light of a recent incident, the doctor accompanied the service user to reception with their medicines so that staff could perform a second check. A record of supply was made in the person's records. The doctor completed a running tally, which ensured that stock could be accounted for at the end of each clinic.

# Are services effective?

(for example, treatment is effective)

## Our findings

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

### Assessment and treatment

At the first consultation, the patient completed a medical history form; this covered key pieces of information including allergies, existing medical conditions and comorbidities. During the initial consultation, the doctor reviewed this information and recorded the patient's height, current weight and blood pressure. The doctor also discussed eating patterns and habits with the patient.

We reviewed in detail 23 records and found that target weights were not set for any patients at their initial appointments and for some patients no targets were set at all. We found that health checks had taken place on the first visit however; we found that at subsequent visits health checks were not always recorded in line with the provider's policy.

Records showed that five of the 23 patients we looked at had not had a break in treatment after 13 weeks, which is recommended in the provider's policy and product literature. Three of the five patients had started treatment in January and February 2017. No breaks had been documented and no reasons why no breaks had occurred were documented. For patients returning 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 national guidance thresholds of BMI (Body Mass index), no reasons had been recorded to account for continued prescribing.

The National Slimming and Cosmetic Clinics Doctor's Manual and treatment 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/m<sup>2</sup> or 27kg/m<sup>2</sup> with Comorbid factors. From the records we reviewed, we found that this was not always followed. Five records indicated that medicines had been prescribed when the patients starting BMI was less than 30kg/m<sup>2</sup> with no comorbidities recorded and no rationale was recorded by the doctor. 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/m<sup>2</sup> or with comorbidities under 28kg/m<sup>2</sup>.

For one person over a ten-month period the persons BMI had not been documented in their notes on four occasions, on two of these occasions 56 days' supply was given, and on all occasions medicines had been supplied. No reasons for extended supply were documented; this also meant that the clinical assessments were not made on a four weekly basis as stated in the provider's policy. Using the NHS BMI calculator their BMI was found to be 23kg/m<sup>2</sup> on one occasion and on three further occasions 24.5kg/m<sup>2</sup>. On three occasions their BMI was recorded as 26kg/m<sup>2</sup> however the NHS BMI chart calculated their BMI as 24.4kg/m<sup>2</sup>. This is not in line with clinic protocol or national guidance and is not a safe practice.

### Staff training and experience

We were shown records of staff training for three of the four members of staff at the service. The registered manager had undertaken first aid training and had completed the internal training programme, which included fire training, infection control, safeguarding, data protection and health and safety. The doctor had completed both internal mandatory training and two external courses one in basic life support and the second in safeguarding.

The doctor had recently undergone revalidation process conducted by an external company.

### 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 available to be sent to the GP. Of the 23 records we looked at no patients had agreed to information being shared with their GPs.

### Consent to care and treatment

Consent was clearly documented in the patient's care record at their first visit and this was reviewed after a break in treatment for most service users. Additional information was supplied to the service user which detailed the nature of the medicines that could be prescribed and that they were unlicensed. However, one service user who had breaks in treatment recorded had not had a medical consent check since August 2013.



# Are services effective?

(for example, treatment is effective)

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

# Are services caring?

## Our findings

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

### **Respect, dignity, compassion & empathy**

We observed staff at the clinic and found them to be professional and polite. Confidentiality was maintained within the restrictions of the environment. Consultations could not be over heard and there was a system in place to ensure that all records were stored securely.

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

### **Involvement in decisions about care and treatment**

The service provided a range of information to aid patients with decision making. Comment cards indicated that patients felt listened to and supported. Decisions regarding their care were discussed and any concerns or changes were communicated and responded to during consultations.

# Are services responsive to people's needs?

(for example, to feedback?)

## Our findings

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

### Responding to and meeting patients' needs

The service completed six monthly audits of patient feedback, these were analysed by the registered manager. All comments from the last two audit cycles were positive.

To ensure that patients did not experience delays in treatment there was a system in place to closely monitor the stocks of medicines at the service.

The registered manager or reception staff met patients at reception. The waiting area was warm and welcoming with adequate seating in the waiting area. Consultations were conducted in private and the consultation room contained the appropriate equipment for the consultation. All documentation and clinic letters were available in the consultation room as well as advice regarding healthy living.

### Tackling inequity and promoting equality

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

Patient information leaflets and medicines labels were not available in large print and the service did not have a hearing loop.

Patient information leaflets and diet plans were available in other three other languages (Welsh, Punjabi, and Polish).

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 four days per week. The service is open Wednesday 10.30 – 2.30pm, Thursday 10 – 2pm Friday 9.30 – 1.30pm and Saturday 9.00 – 1pm.

### Concerns & complaints

A complaints procedure was located in the reception area. This document set out how to complain and which other services complaints could be made with. A written policy was available to guide staff. All complaints documents referred to a contact person who did not work at the service, we brought this to the attention of the registered manager who stated this would be amended after the inspection to ensure service users had the correct information. We were told that there had been no concerns or complaints raised 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

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

### 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. The clinic used the provider's policies and procedures. Staff had signed to state that they had read the policies. Access to policies was available electronically as well as via paper copies at the service.

The registered manager completed appraisals for clerical staff however; these had not been completed annually. Medical staff were not part of the appraisal process.

### Leadership, openness and transparency

The registered manager was aware of the requirements of the Duty of Candour. The manager described how complaints would be handled and how the service encouraged an open and honest environment. No concerns had been raised by or about the service in the last 12 months.

### Learning and improvement

There was a system in place to learn from significant events and incidents, which had occurred within the provider group. However, we could not be assured that the provider level information was passed effectively to the doctors, as the doctor was not aware of recent correspondence regarding safeguarding.

The registered manager described an incident that had occurred at the service and how steps had been taken both locally and more wide spread throughout the provider's services to ensure the incident did not occur again.

The service completed a series of audits, which looked at the management of medicines, dispensing sheet audit and record card audit. These audits occurred on a three monthly or six monthly basis. Actions resulting from audits were documented and outcomes could be seen to improve. However, a non-clinician completed the clinical effectiveness audit and the audit system did not identify the clinical concerns, which we saw. The doctors were not fully involved in the audit process and so information was not always shared effectively or learnt from.

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

A feedback box was available in the reception area. This was reviewed alongside a six monthly questionnaire audit. This assessed service user's views on the service as a whole.

There was a system in place to review and set an action plan following the audits however no actions had been documented as the service users had given positive feedback.

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 17 HSCA (RA) Regulations 2014 Good governance</p> <p><b>How the regulation was not being met:</b></p> <p>The registered person had not ensured that systems and processes were in place to effectively monitor and improve the quality of services being provided or that good governance arrangements were in place. In particular, employment records DBS were not up to date for all staff, Audits failed to identify risks and clinicians were not involved in audit process to drive improvement.</p> <p>This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</p>

This section is primarily information for the provider

## Enforcement actions

### Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Services in slimming clinics	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p><b>How the regulation was not being met:</b></p> <p>The registered person had not ensured that care and treatment was provided in a safe way for service users. In particular, there were unsafe prescribing practices, prescribing did not always follow clinic protocol and basic monitoring requirements were not always recorded.</p> <p>This was in breach of regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014</p>