

# Mrs Ingrid Camilleri

# Kings Private Clinic

### **Inspection report**

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### Overall summary

We carried out an announced comprehensive inspection on 1 August 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. The impact of our concerns, in terms of the effectiveness of clinical care, is minor for patients using the service.

### 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 not providing responsive care in accordance with the relevant regulations.

#### Are services well-led?

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

#### **Background**

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

Kings Private Clinic is a slimming clinic located near London Bridge. The clinic consists of a reception room and a consulting room on the second floor of 56 Borough High street. It is very close to London Bridge rail and tube station, and local bus stops. Parking in the local area is very limited and the clinic is not wheelchair accessible.

The clinic is staffed by a receptionist and a doctor. There is also a receptionist who only works on Saturdays. If for any reason, a shift is not filled by the doctor, a locum doctor is brought in. In addition, staff work closely with other staff based at the head office in Ilford. This clinic is one of four clinics that is run by the same provider organisation.

The receptionist is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like

### Summary of findings

registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 Regulations about how the clinic is run.

The clinic provides slimming advice and prescribes medicines to support weight reduction. It is a private service. It is open for walk ins or booked appointments on Tuesdays, and Saturday mornings.

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.

Patients completed CQC comment cards to tell us what they thought about the service. We received 13 completed cards and all were positive. We were told that the service was excellent, and that staff were caring and compassionate, friendly, understanding and professional.

### Our key findings were:

- The clinic appropriately refused to provide medicines to people who had high blood pressure (BP) readings.
- The feedback from patients was always positive about the care they received, the helpfulness of staff and the cleanliness of the premises.

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

• Ensure that medicines are prescribed safely to patients who fit the treatment criteria as defined in the clinic guidelines.

- · Ensure that all staff are trained in the safeguarding of children and that there is an adequate safeguarding policy. Ensure there are systems and processes in place to monitor and improve the quality of services being provided. (To include quality improvement programmes including clinical audit, medical emergency risk assessments, communication with patients' own GPs, the documentation of the maintenance and calibration of equipment and supporting policies and procedures that are appropriate to the service provided and that are up to date and understood by all staff.)
- Ensure staff receive appropriate support, training, professional development, supervison and appraisal as is necessary to enable them to carry out the duties they are employed to perform.

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:

- · Review methods to ascertain the age and identity of patients accessing the clinic services.
- · Review facilities to maintain the dignity and privacy of
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.
- Review the appropriateness of using friends and family for translation.
- Review fire safety procedures to provide assurance that people would be kept safe in an emergency.

## 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. The provider did not have effective arrangements in place to keep people protected and safeguarded from abuse. Medical equipment was not maintained appropriately. In addition, we saw evidence of prescribing that was not in line with the provider's own prescribing policy. 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). We will be following up on our concerns to ensure they have been put right by the provider.

#### Are services effective?

We found that this service was not providing effective 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 had a policy of not sharing information directly with patients' GPs. The doctor working in the clinic had undergone revalidation. Patients were provided with written information about medicines in the form of a patient information leaflet. However, the written information provided to patients using the service did not make it clear that the medicines prescribed by the doctors in the clinic were unlicensed or being used off label.

#### Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations. Patients told us that staff were caring and welcoming.

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

We found that this service was not providing responsive care in accordance with the relevant regulations. The facilities and premises were appropriate for the services being provided. We saw that staff had access to some patient information to accommodate people who did not eat meat. We saw that there was limited information available in large print format. However, medicine labels were not available in large print and there was no induction loop available for patients who experienced hearing difficulties.

#### Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

The service lacked good governance to operate effectively and had no system to assess, monitor and improve the quality of the service being provided. In addition, the provider failed to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.

The clinic had a number of policies and procedures in place to govern activity although some of these were out dated. The provider had no comprehensive assurance systems and there was no systematic programme of clinical or internal audit to monitor the quality of the service. Staff from head office provided support to staff at this clinic.



# Kings Private Clinic

**Detailed findings** 

## Background to this inspection

We carried out this inspection on 1 August 2017. Our inspection team was led by a member of the CQC medicines team, and was supported by another member of the CQC medicines team. Prior to this inspection, we gathered information from the provider, and from patient comment cards. Whilst on inspection, we interviewed staff and reviewed 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

The clinic had recently implemented a system for recording significant events. Staff were able to demonstrate their understanding of their responsibilities to raise concerns however it was staff at head office who took the lead for dealing with any incidents. There was no system for managing patient safety alerts. However, we saw evidence of one drug recall that was actioned appropriately. Staff were aware of their responsibility to comply with the requirements of the Duty of Candour. When there were unexpected or unintended safety incidents, the service gave affected people reasonable support, truthful information and a verbal and written apology.

### Reliable safety systems and processes (including safeguarding)

There was no adequate safeguarding procedure in place that informed staff of what to do or who to contact if they had a safeguarding concern. The doctor was trained in the safeguarding of vulnerable adults and children. The registered manager was recently trained in the safeguarding of vulnerable adults, but not children. Whilst both members of staff had received some training on safeguarding, the doctor was not clear on what safeguarding meant. Staff were not clear on who took the lead for safeguarding in the clinic or whether staff at head office were responsible for this.

Individual records were written in a way to keep people safe. They were accurate, complete, legible, and up to date, however they were not stored securely.

There was no system to provide assurance that the patients accessing the service were above the age of 18 years.

#### **Medical emergencies**

Whilst the clinic was not designed to deal with medical emergencies, there was no formal risk assessment detailing how emergencies would be managed. Staff had not received formal first aid training; however the doctor had completed basic life support training. If someone became unwell whilst at the clinic, there was always a doctor on duty during the clinic opening hours who could deal with this. We were told that in an emergency staff would call 999.

### **Staffing**

There were sufficient numbers of suitably trained and competent staff available at the clinic. During opening hours, the clinic was staffed by a full time receptionist (who was the registered manager), and one doctor. If a shift was not filled by the permanent doctor, locum doctors were available. Prior to a new doctor working at the clinic, he or she would shadow the permanent doctor in order to familiarise themselves with the clinic processes. Disclosure and Barring Service checks were present for all staff. References had not been obtained for all members of staff working at the clinic and there was no specific HR policy to support recruitment.

We saw that the doctor was up to date regarding their revalidation with the General Medical Council. The doctor was registered with an appropriate responsible officer.

We were told that the receptionist was able to act as a chaperone to patients that requested this. However, chaperones were rarely requested because of the nature of the service. The receptionist had not received any chaperone training.

### Monitoring health & safety and responding to risks

We saw evidence that the provider had indemnity arrangements to cover potential liabilities that may arise. The doctor had personal medical indemnity insurance.

We were told that the responsibility for fire alarm tests was with the company renting the downstairs office. Whilst we were told that the fire alarm was tested regularly, there were no records of this and staff did not practice evacuating the building. We were told that this was because the clinic was usually closed on the day that the alarm was tested.

### Infection control

The clinic had not conducted an infection control risk assessment to determine if they needed to test for Legionella at the service. (Legionellosis is the collective name given to the pneumonia-like illnesses caused by legionella bacteria.) The clinic maintained appropriate standards of cleanliness and hygiene. We observed the premises to be generally clean and tidy, however there was dust on the blinds in the consultation room. The

### Are services safe?

receptionist took responsibility for cleaning the clinic each week and kept records of this activity. We did not see any records to suggest that the blood pressure machine was cleaned regularly.

### **Premises and equipment**

We were told that clinical equipment was checked to ensure it was working properly, and that the weighing scales were calibrated. However, records were not kept to allow the provider to monitor this.

#### Safe and effective use of medicines

Records showed that Kings Private Clinic, London Bridge prescribed appetite suppressants (Diethylpropion Hydrochloride and Phentermine) 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 has 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 Kings Private Clinic 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 uses 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.

People could also purchase a herbal product (Diatus plus) to suppress appetite via the clinic's website. There was very little evidence available to support the use of this remedy.

Medicines were packed down into small quantities for sale to patients by the doctor in the presence of the registered manager. Medicines were stored securely in appropriate cupboards in the clinic. Appropriate arrangements for the storage and security of medicines keys ensured that there was an audit trail available of who had held the key. During the clinic opening hours, medicines for use were kept in the possession of the doctor. We saw evidence that staff checked medicines stock levels at the end of each working day.

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 handwritten medical record. Patients were also given written information about the products, but this information did not make it clear that the products were unlicensed.

We reviewed 11 patient records, and saw that no patient recorded as under the age of 18 was prescribed medicines for weight loss, although patients over the age of 65 had been prescribed appetite suppressants. We also noted that patients were not always given an appropriate treatment break after 12 weeks of consecutive treatment as per recommendations. One of the records we reviewed showed that the patient had received diethylpropion 75mg for 14 months without a treatment break, yet there was no improvement in weight loss. We raised this with the doctor and were told that the patient would put on weight without the medicine. However, we did not see any evidence where a treatment break resulted in an increase in the patient's weight.

### Are services effective?

(for example, treatment is effective)

### **Our findings**

#### Assessment and treatment

Prior to the consultation each person had to complete a consent and confidentiality form. The form asked people to state whether or not they suffered from a number of medical conditions.

During the initial consultation, the doctor checked the blood pressure (BP), weight and height of each patient. They also checked for contraindications to treatment such as uncontrolled hypertension, serious medical problems and co-existing mental health conditions.

We checked 11 patient records and were able to confirm that the medical history, weight, height and BP were taken at the initial visit. A body mass index (BMI) was calculated and target weights agreed and recorded. BMI, weight and BP readings were also recorded at subsequent visits.

Staff at the clinic kept records of instances when patients were refused treatment. Some of the reasons for treatment refusal were: co-existing medical conditions such as high BP and depression.

We saw a number of records where patients with a BMI lower than 30kg/m2 and those with a BMI between 27 kg/ m2 and 30 kg/m2 who did not have any comorbidities were consistently prescribed appetite suppressants. This was inappropriate and not in line with evidence based guidance. We raised this with the doctor and were told that this practice was in line with the provider's policy. We reviewed the policy (dated 30 June 2005) and it stated that: 'Patients are deemed to be suitable for medication if they have a BMI of greater than or equal to 30kg/m2 or BMI greater than or equal to 27 kg/m2 if other obesity related factors, such as diabetes, osteoarthritis, etc are present'. We raised this with the doctor who told us that the guidance was only recently sent to the service; therefore they were not yet familiar with it.

The doctor told us that if a patient had a slightly raised blood pressure, they would ask them to sit down and recheck it again after 30 minutes. If the BP normalised, they would prescribe appetite suppressants and advise the patient to visit their own GP for monitoring. The service had a blanket policy of not contacting patients' own GPs directly, despite the fact that all new patients were asked if

they would consent for information sharing with their GP. However if a BP reading was too high, the clinic would contact the patient's own GP for approval to initiate treatment with appetite suppressants.

The providers own policy made no reference as to what action should be taken for patients with borderline BP readings. Appetite suppressants should not be given to people who have high or uncontrolled BP. Therefore without appropriate referral to patients' GPs there is a risk that patients may not be given appropriate diagnosis, monitoring and treatment for hypertension.

There was no evidence of quality improvement including clinical audit to assess the quality of the service and improve patient outcomes.

### Staff training and experience

Whilst staff at the clinic were provided with the clinic policies to read and signed to say that they had done this, the policies dated June 2005 and had not been reviewed or updated. Apart from safeguarding, staff had not received any formal training from the provider. We saw that the doctor had undergone revalidation, and had attended various learning events. The registered manager had not had received an annual appraisal and learning needs had not been identified.

### **Working with other services**

As part of the consent form, people were asked whether they wanted information to be shared with their own GP. If they did not agree, they could opt out by ticking a box on the consent form. If a patient gave consent for information sharing with their own GP, the clinic would still not contact them. The only circumstance when a GP would be contacted was if the clinic felt that the patient's own GP needed to give approval for treatment. There is guidance from the General Medical Council on this. 'When an episode of care is completed, you must tell the patient's general practitioner about: changes to the patient's medicines (existing medicines changed or stopped and new medicines started, with reasons).'

#### **Consent to care and treatment**

Staff at the clinic ensured that patient consent was obtained prior to the beginning of treatment. The written information provided to patients did not make it clear to

# Are services effective?

(for example, treatment is effective)

members of the general public that the treatments being offered at the clinic were unlicensed. However, the doctor told us that patients were told verbally that treatments were unlicensed.

### Are services caring?

# **Our findings**

### Respect, dignity, compassion & empathy

Patients completed CQC comment cards to tell us what they thought about the service. We received 13 completed cards and all were positive. We were told that the service was excellent, and that staff were caring and compassionate, friendly, understanding and professional. Consultations took place in a private consultation room located next to the reception area. Whilst all consultations were conducted with the door closed, privacy was not

maintained. Conversations could be overheard in the waiting area due to poor sound proofing. However, we were told that the radio was normally on to reduce the risk of people overhearing private consultations.

#### Involvement in decisions about care and treatment

Information relating to the cost of treatment was readily available. Patients told us that they felt that they were provided with good advice. We saw that there were a variety of patient information leaflets available which included information on nutrition and exercise.

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

(for example, to feedback?)

### **Our findings**

### Responding to and meeting patients' needs

The facilities and premises were appropriate for the services being provided. The clinic was located on the second floor of the building and consisted of a reception area with seats, and a consultation room. A toilet facility was available at the clinic premises. The building was not wheelchair accessible. Where the service was unable to provide services to patients with mobility

difficulties, details of alternative services could be provided. Slimming and obesity management services were provided for adults from 18 to 60 years of age by booked or walk in appointment. We saw that staff had access to some nutritional information to accommodate people who did not eat meat.

### Tackling inequity and promoting equality

We did not see any policies that suggested that staff had an awareness of or had thought about accessibility for people with protected characteristics. (Protected characteristics are defined in the Equality Act 2010 as including: age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage and civil partnership, and pregnancy and maternity.)

We saw that there was limited information available in large print format. However, medicine labels were not available in large print and there was no induction loop available for patients who experienced hearing difficulties. Anyone accessing the service who could not speak fluent English was advised to bring a friend or relative who could translate for them. However, there was a risk that information may not be relayed accurately to people who may not understand English.

#### Access to the service

The opening hours of the clinic were as follows: Tuesdays (10am - 2pm, 3pm - 6pm) and Saturday mornings (10am - 12.30pm). Patients were always accommodated when they wanted to see a doctor. People accessing the service were able to make an appointment, or they could walk into the clinic and be seen. At busier times, there was a slight wait. Staff were available for telephone enquiries during the clinic opening hours.

#### **Concerns & complaints**

Within the clinic, there were systems for documenting incidents and complaints. The complaints procedure was available in the clinic waiting room. We were told that staff at head office dealt with complaints. Staff felt confident to raise any necessary concerns relating to suspected or actual abuse, and knew how to whistle blow.

### Are services well-led?

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

### **Our findings**

### **Governance arrangements**

We saw that there were limited systems in place that enabled the provider to assess, monitor and improve the quality and safety of the service being provided.

The clinic had a number of policies and procedures to govern activity; however staff demonstrated a lack of knowledge of their contents. In addition, most documents were dated June 2005 and had not been reviewed since.

The clinic did not have an effective approach for identifying where quality and safety was being compromised. Therefore steps were not taken in response to any issues. For example, there were no audits of clinical care, prescribing, notes, infection prevention and risks, incidents and near misses.

There was no system or process to ensure that staff who had been employed by the

service for some time had appropriate identification checks. In addition, there were no risk assessments in place to mitigate against these risks.

This clinic was one of four slimming clinics owned by the same provider. There was a registered manager in post who was supported in her role. The doctor had overall responsibility for the governance of the safe and effective use of medicines. Whilst we saw that medicines were stored safety, we noticed that patient records were not stored securely.

Staff from head office provided support to staff at this clinic. Staff were clear about who they were accountable to and felt supported in carrying out their duties. They felt that they could always go to senior staff if they had any questions or concerns. Staff could describe how they would handle any safety incidents. However the service had no system for finding out about any medical alerts.

### Leadership, openness and transparency

There were limited systems in place that enabled the provider to assess, monitor and improve the quality and safety of the service being provided. In addition, there were no system to assess compliance with policies or procedures or demonstrate what actions were taken as a result of concerns, complaints and compliments.

Staff were clear that the responsibility for managing incidents was with staff based at head office.

We did not see enough evidence to assess whether staff would be confident enough to challenge poor practice.

### **Learning and improvement**

The provider had no comprehensive assurance systems or performance measures. For example, there was no programme of audit to monitor the quality of the service. In addition, there were no systems to encourage continuous improvement.

We were told that staff attended meetings with staff based at other clinics at least annually. These meetings encouraged staff to share learning and good practice from other slimming clinics; however we did not see any records of this activity.

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

The provider had recently implemented a patient survey but had not yet analysed the results.

Staff did not feel that their views were reflected in the planning and the delivery of this service. This was because we were told the provider drove the decision making without seeking the views of the people working in the clinic.

# Requirement notices

### Action we have told the provider to take

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

Regulated activity	Regulation
Services in slimming clinics	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment
	How the regulation was not being met:
	The registered provider had not done all that was reasonably practicable to mitigate risks to the health and safety of service users receiving care and treatment. In particular:
	Medicines were not being prescribed safely to patients who fit the treatment criteria as defined in the clinic guidelines.
	A risk assessment in relation to the use or not of emergency medicines was not available.
	Consideration was given to communicating with patients' own GPs but this was not followed.
	This was in breach of regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Services in slimming clinics	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment
	How the regulation was not being met:
	The registered provider had failed to establish systems to prevent abuse. In particular:
	There was no adequate safeguarding procedure that informed staff of what to do or who to contact if they had a safeguarding concern.
	The doctor was not clear on what safeguarding meant.
	Not all staff were trained in safeguarding children.

### Requirement notices

Staff were not clear on who took the lead for safeguarding within the clinic.

This was in breach of regulation 13 (1) & (2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

### Regulated activity

### Services in slimming clinics

### Regulation

Regulation 18 HSCA (RA) Regulations 2014 Staffing

### How the regulation was not being met:

Staff had not received appropriate support, training, professional development, supervison or appraisal as is necessary to enable them to carry out the duties they are employed to perform. In particular:

There was no evidence of staff training with regards to fire safety.

There was no evidence that staff had received first aid training.

There was no evidence that staff had received any form of training updates from the provider with regards to the policies and procedures.

This was in breach of regulation 18 (2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

### **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	Regulation 17 HSCA (RA) Regulations 2014 Good governance
	How the regulation was not being met:
	There were limited or no systems or processes in place that enabled the registered person to assess, monitor and improve the quality and safety of the service being. In particular:
	There were outdated policies and procedures and staff who were unsure of the content.
	No quality improvement programme that included clinical audit.
	A lack of documentation to show the calibration of medical equipment had been carried out.
	A lack of systems to assess and monitor risks to staff and service users which may arise from the carrying on of the regulated activity.
	There was no system or process to ensure that staff who had been employed by the service for some time had appropriate identity checks.
	In addition, there were no risk assessments in place to mitigate against these risks.
	This was in breach of regulation 17 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.