

Private Medical Centre Ltd

# Private Medical Centre – Ealing

## Inspection report

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Ealing

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London

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### Overall summary

We carried out an unannounced comprehensive inspection on 20 February 2017 at the Private Medical Centre - Ealing location 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. 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 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 were unable to assess whether this service was providing caring services in accordance with the relevant regulations.

##### **Are services responsive?**

We found no sufficient evidence to rate responsive.

##### **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).

##### **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 clinic was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

Private Medical Centre Limited is an independent provider of medical services and treats both adults and children in the London Boroughs of Ealing and Acton. Services are provided primarily to Polish patients. Services are available to people on a pre-bookable appointment basis. The clinic advertises and carries out a variety of other additional services including gynaecology and obstetrics services. However following concerns identified at our inspection we imposed an urgent

# Summary of findings

condition on the provider to prevent the provision of all regulated activities in relation to the medical consultation and treatment services at both the Ealing and Acton sites.

They remain able to provide dental services which were inspected at the same time.

A copy of the full report of the dental service can be found by selecting the 'all reports' link for the Private Medical Centre on our website at [www.cqc.org.uk](http://www.cqc.org.uk).

The Ealing clinic is located on the ground floor of a rented property. The property is leased by the provider and consists of a patient waiting room & reception area, an office, a kitchen and staff room, a medical consultation room, a decontamination room, and two dental and consulting rooms which are all located on the same floor of the property.

Private Medical Centre Ltd is registered as a sole provider with the Care Quality Commission to provide the regulated activities of diagnostic and screening procedures, surgical procedures and treatment of disease, disorder or injury. We did find that the provider was providing gynaecology and obstetrics services that would meet the scope to be registered as maternity and midwifery and so the provider would need to apply to register for these when they are able to operate.

At the time of our inspection, the clinic employed three doctors. All three doctors were registered with the GMC with a licence to practise. These clinicians travelled between Poland and England to offer their services. Two of the doctors were providing specialist services in gynaecology and obstetrics and dermatology. Both doctors were not on the General Medical Council (GMC) specialist register. The third doctor was on the UK specialist register for obstetric care.

Other staff at the clinic included three receptionists and the company director. The director, who was the clinical lead, was based at the Ealing location. There was a Polish registered dentist who was registered with the General Dental Council (GDC).

The clinic was open Monday to Saturday from 8:30am to 6:30pm. We were informed that the medical doctors offering gynaecology and obstetrics attended the clinic based on demand and the family doctor was available most of the time.

The provider was not required to offer an out of hours service. Patients who required emergency medical assistance out of operating hours were requested to contact the provider via an emergency phone number and they could speak directly to them. However this telephone was held by the nominated individual who was a dentist but gave medical advice.

## Our key findings were:

- Patients were at risk of harm because systems and processes were not in place to keep them safe. Patients were being offered specialist treatment and consultation by doctors who did not have UK specialist training to do so.
- The provider had not ensured that adequate medical indemnity insurance was in place or that appropriate checks of current insurance had been carried out on all clinicians upon commencement of employment.
- Arrangements to safeguard children and vulnerable adults from abuse did not reflect relevant legislation and local requirements.
- The person with overall clinical responsibility had not completed up to date safeguarding training. No records were available to confirm that the other doctors had also received the adequate safeguarding training for their roles.
- There was no system in place for the reporting and investigation of incidents or for sharing lessons learned as a result.
- The clinic had not set up a system to ensure they received medicines alerts or other relevant information from organisations such as the MHRA.

The clinic did not keep medicines safely. We found that some medicines that required to be stored in a fridge were not stored in a fridge. The clinic did not monitor the fridge temperature to ensure that it was within the recommended temperature of between +2 degrees Celsius and +8 degree Celsius.

- The clinic held medicines and life-saving equipment for dealing with medical emergencies. However there were some medicines required for use in emergencies that had expired.
- There was not an effective system in place for obtaining written consent from patients for consultations including those that required intimate examination.

# Summary of findings

- There was no evidence that staff had received training appropriate to their roles, including update training in infection control, safeguarding and chaperoning.
- Patient outcomes were hard to identify as little or no reference was made to audits or quality improvement.
- The clinic did not have an effective process in place to ensure patients were informed of their results or that a clinical person assessed them.
- Patients who were undergoing consultation including intimate examination and ultra sounds were not offered a chaperone at the time of consultation.
- Information about services and how to complain was available and easy to understand. However complaints received were not fully investigated and no evidence of learning from these was seen.
- The clinic did not hold regular, formal clinical or team meetings.
- There was no formal process in place to ensure all members of staff received an appraisal. The clinic reported they had a responsible officer in place. We did not see how this process fed into the clinic to ensure the person with clinical responsibility had reassurances that the doctors practice was safe.
- The clinic had limited formal governance arrangements in place. The clinic did not have an effective, documented business plan in place.
- The clinic lacked a number of policies and procedures to govern activity.
- Ensure effective governance arrangements are in place to ensure patients receive safe care.
- Ensure that patient safety alerts (including MHRA) are received by the clinic, and then actioned if relevant. Put systems in place to ensure all clinicians are kept up to date with national guidance and guidelines.
- Review the process for obtaining written consent ensuring consent is recorded appropriately and patients sign these forms when consent is required.
- Review chaperone arrangements and policy in particular for gynaecology services, ensuring chaperone training is undertaken by staff who perform chaperone duties.
- Review the process for informing patients of test results including those that are urgent.

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

- Ensure that they only deliver services that staff are trained and qualified for.
- Ensure that a system is in place to ensure all clinicians have adequate valid medical indemnity insurance cover and that appropriate checks of clinicians indemnity insurance is carried out upon commencement of employment.
- Ensure there is effective clinical leadership and oversight in place

On 24 February 2017, the Commission served an urgent notice of decision to impose conditions upon the registration of this service provider in respect of two regulated activities. The following conditions were imposed:

The registered person must not provide medical consultation and treatment services (excluding dental services) under the regulated activity of treatment of disease, disorder or injury and diagnostic and screening procedures to patients without the prior written agreement of the Care Quality Commission from the following locations;

Private Medical Centre – Ealing

124 Uxbridge Road

London

W13 8QS

Private Medical Centre- Acton

1 Eastfields Road

London

W3 0AA

# 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.

- Patients were at risk of harm because systems and processes were not in place to keep them safe. There was no process in place to ensure that staff received appropriate inductions and that they had all the necessary checks before commencement of employment.
- Arrangements to safeguard children and vulnerable adults from abuse did not reflect relevant legislation and local requirements. There was no safeguarding policy in place. There were no records to indicate that doctors employed in the service and the nominated individual had completed up to date safeguarding training.
- There was not an effective system in place for the reporting and investigation of incidents or lessons learned as a result.
- Not all risks to patients were assessed and well managed.
- The clinic held medicines and life-saving equipment for dealing with medical emergencies. However some medicines required in emergencies were out of date and no records were available to confirm that all clinical and non-clinical staff had had completed appropriate training.

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### **Are services effective?**

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

- There was no formal process in place to ensure all members of staff received an appraisal.
- There was no evidence of formal supervision and support in place for all members of staff including clinical staff.
- There was very limited evidence that staff had received training appropriate to their roles, including update training in infection control, radiography, safeguarding and chaperoning.

Patient outcomes were hard to identify as little or no reference was made to audits or quality improvement.

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### **Are services caring?**

We were unable to assess whether this service was providing caring services in accordance with the relevant regulations.

- Curtains were provided in consulting rooms to maintain patients' privacy and dignity during examinations, investigations and treatments.
- A private room was available if patients wanted to discuss sensitive issues or appeared distressed.

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

We found no sufficient evidence to rate responsive.

- Information about services and how to complain was available and easy to understand. However complaints received were not fully investigated and no evidence of learning from these was seen.

The clinic was open from 8:30am until 6pm Monday to Saturday.

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

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

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# Summary of findings

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- The provider had not ensured that adequate medical indemnity insurance was in place or that appropriate checks of current insurance had been carried out on all clinicians upon commencement of employment.
  - The clinic did not hold regular, formal multi-disciplinary or team meetings, meetings that did take place were ad-hoc and were not minuted.
  - The clinic had limited formal governance arrangements in place. The clinic did not have a documented business plan in place. The clinic did not have most policies and procedures in place to govern activity.
  - The clinic did not have an effective, overarching governance framework in place to support the delivery of the strategy and good quality care. There was a lack of effective systems and processes in place for assessing and monitoring risks and the quality of the service provision.
  - There was not an effective leadership structure in place, there was a lack of day to management support in place on a daily basis and there was a lack of clinical leadership and oversight.
  - Though doctors were reported to have a current responsible officer in place. (All doctors working in the United Kingdom are required to have a responsible officer in place and required to follow a process of appraisal and revalidation to ensure their fitness to clinic). There was no evidence how this was monitored and the assurances the provider had that this was being undertaken.
  - The clinic did not have a formal system in place to collect patient feedback. We saw no evidence that patient feedback had been acted upon.
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# Private Medical Centre – Ealing

## Detailed findings

### Background to this inspection

The unannounced inspection was carried out on 20 February 2017 following concerns we had received.

Our inspection team was led by a CQC Lead Inspector and was supported by a Clinical Specialist Advisor. A dental inspector and a Dental Specialist Advisor were also present to inspect the dental services of the organisation. The teams were also supported by two Polish translators.

A copy of the full report of the dental service can be found by selecting the 'all reports' link for the Private Medical Centre on our website at [www.cqc.org.uk](http://www.cqc.org.uk).

During our visit we spoke with the reception staff, company director and the nominated individual. Reviewed the personal care or treatment records of patients and staff records.

As the inspection was unannounced the provider was not provided with CQC comment cards prior to our inspection. Due to the nature of the appointments we did not speak to any patients on the day of the inspection.

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

- During our inspection, we found that there was no system in place to enable staff or the clinic to report incidents, near misses or significant events. No incidents had been recorded at the clinic. However the nominated individual gave us an example of an incident where a patient had alleged that they had been infected during an intimate examination due to poor infection control procedures followed by the clinician. We saw no record of this incident and the nominated individual was not aware that this should have been documented and investigated as such.
- When we asked the reception staff at the clinic about the incident reporting policy they told us to speak to the nominated individual (a nominated individual is the person that organisations and companies nominate to act as a main contact with the Care Quality Commission. This person has the overall responsibility for supervising the management of the regulated activity and ensuring the quality of services provided) as they were not aware of it.
- We did not see evidence of policies which would support 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). Formal meetings did not take place; there was no evidence of formal discussion in relation to any incidents which may have been required to be reported.

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

The clinic did not have clearly defined and embedded systems, processes and clinics in place to keep patients safe and safeguarded from abuse, for example:

- Arrangements to safeguard children and vulnerable adults from abuse did not reflect relevant legislation and local requirements. We saw no safeguarding policy.

However information was available in the clinic that contained telephone numbers of whom to contact outside of the clinic if there was a need, such as the local authority responsible for investigations.

- We were unable to see evidence of safeguarding children or adults training for all members of staff. We were told that the provider, who was a dentist, was the safeguarding lead. However they had not undertaken the required safeguarding training. The nominated individual advised that the rest of non-clinical staff were going to receive training. We requested evidence of up to date safeguarding training to be provided shortly after our inspection for the doctors who were not available. We were provided with information that noted two of the doctors had received the Polish equivalent of training but not UK specific. No records were available relating to the other doctor.
- There was no system in place to alert clinical staff of any patients who were either vulnerable, had safeguarding concerns or suffered with a learning disability. The clinic did not have a register in place of vulnerable adults and children. There was no evidence of multi-disciplinary meetings taking place.
- The clinic had a chaperone policy in place. However there were no notices on display in the waiting room to advise patients that chaperones were available if required. We saw no record of patients being offered a chaperone during consultations including intimate examinations. The provider told us that patients were asked if they wanted a chaperone at the time they completed registration forms but not during consultations.
- No staff at the clinic could explain the role of a chaperone. Staff told us they had never been asked to take on the role of a chaperone. We spoke with a male doctor who offered gynaecology clinics. The term chaperone was not familiar to them.
- The clinic had a system in place for the collection of pathology samples such as blood and urine. However we saw no policy or system that ensured that was safe information flows that ensured patients were kept safe. Patients received their result by email sent by administrative staff because medical staff did not work on a daily basis. Patients did not always discuss their

# Are services safe?

result with a suitably qualified person. We were informed that patients knew to make a follow up as the result would give an indication that they required follow up.

## Medical emergencies

The clinic did not have adequate arrangements in place to respond to emergencies and major incidents.

- The clinic had a defibrillator available on the premises and oxygen with adult masks only. A first aid kit was also available.
- Some medicines for use in emergencies such as; rectal diazepam and Benzyl Penicillin had expired. The clinic had a system of monitoring medicines but it had not been noted that these had expired.
- The clinic did not have a comprehensive business continuity plan in place for major incidents such as power failure or building damage.
- No records were available to confirm that clinical staff had received adequate training in dealing with emergencies.

## Staffing

- All three doctors were registered with the General Medical Council (GMC) the medical professionals' regulatory body with a licence to practice.
- Two of the doctors provided specialist care in gynaecology & obstetrics and dermatology. However; they were not on the UK specialist register to provide this. The provider was aware of this but told us that their overseas qualifications and experience gave them the scope to deliver the specialist services.
- We were told that all doctors had a current responsible officer. (All doctors working in the United Kingdom are required to have a responsible officer in place and required to follow a process of appraisal and revalidation to ensure their fitness to clinic). However we were unable to gain any assurance that all doctors working at the clinic were following the required appraisal and revalidation processes.
- We reviewed three personnel files and found that most

## Monitoring health & safety and responding to risks

Risks to patients were not assessed and well managed.

- There were limited procedures in place for monitoring and managing risks to patients and staff safety. There was no health and safety policy available.
- All electrical equipment was checked to ensure the equipment was safe to use and clinical equipment was checked to ensure it was working properly.
- The clinic did not have a risk register in place or undertake risk assessments to monitor health and safety of the premises, staff and service users.
- No Legionella risk assessment had been carried out.

## Infection control

- We observed the premises to be clean and tidy and there were cleaning schedules in place.
- However there was no infection control protocol in place and no records to confirm that staff had received up to date training. Staff told us that a waste collection company was contracted to remove clinical waste.
- We saw that a sharps bin in the medical consultation room was not dated indicating when it had been set up. When we spoke with staff they told us that they had recently changed it though they did not know that labels were required.
- We saw no evidence that an infection control audit had been undertaken within the last 12 months.

## Premises and equipment

- Shower curtains were in place as privacy curtains however, there were no records in place to evidence when curtains were either changed or cleaned.
- Equipment checks were regularly carried out in line with the manufacturer's recommendations.

## Safe and effective use of medicines

During our inspection we looked at the systems in place for managing medicines.

- No medicines management policy was seen. The nominated individual was not sure of the existence of such a policy and could not show us the policy they worked to.
- The clinic had not signed up to receive any healthcare or medicines alert. The nominated individual was not

## Are services safe?

aware of the system they could use to access important medicines and devices alerts. The nominated individual told us that they were aware that some clinics had received alerts about “Ebola”.

- All prescriptions were issued on a private basis; however we observed that all prescription pads were not stored securely. The prescription pads were kept in a room that could be easily accessed and in a drawer that was not locked.
- The clinic did not carry out audits of medicines or prescribing.
- A Glucagon injection kit used to treat episodes of severe hypoglycaemia was not stored in a fridge that was monitored. This medicine must be stored in a fridge with a temperature range of 2–8°C. Staff told us the fridge had never been monitored.

# 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

- The clinic could not provide evidence that they assessed needs and delivered care in line with relevant and current evidence based guidance and standards.

### Monitoring and improving outcomes for patients

- There was no evidence of quality improvement including effective clinical audit. There had been no clinical audits undertaken. The provider told us they were not aware this was required. However they also felt that the individual doctors would have carried out audits in other locations they worked such as Poland.

### Staff training and experience

- The clinic did not have a comprehensive induction and on-going formal and training for staff. There was no evidence of comprehensive, written induction plans or records in personnel files for all members of staff.
- Non-clinical staff we spoke with told us they were provided with shadowing opportunities when they first joined the clinic. Some non-clinical staff told us they had received in-house mandatory training for information governance and infection control. However the provider did not keep a log of training that clinical staff had undertaken. We were told that individual doctors kept records of their training. No system was in place to provide assurance to the provider that these doctors had received the required training. Following our inspection, the provider sent us some records from the doctors of training they had undertaken in Poland and not in the UK.
- Two doctors working at the clinic were providing specialist services for which they were not licenced to deliver. These doctors were carrying out specialist consultations for dermatology and obstetrics.

- The clinic did not have a system of appraisals in place to ensure the learning needs of staff were identified. The provider told us that they were confident that the responsible officer provided adequate support to the doctors and they did not feel the need to be involved in the process.

### Working with other services

- There was no evidence of working with other organisations. The provider told us that patients were advised to inform their GPs of the treatment they were receiving and were expected to make follow ups with their own doctors. The clinic did not have a system that ensured the patients GP was informed of their attendance and treatment offered.

### Consent to care and treatment

- The clinic did not have a consent policy in place. The provider told us they worked on implied consent and consent was therefore not documented. We spoke with one doctor via telephone. They were not familiar with the concept of Gillick competence in respect of the care and treatment of children under 16. (Gillick competence is used to help assess whether a child has the maturity to make their own decisions and to understand the implications of those decisions). They told us they did not treat patients below 20 years of age and so this was not a concern for them, despite the fact that the provider was seeing patients under 16. Due to difficulties in having the interview with the doctor who was in Poland using an interpreter, we could not explore their understanding of legislation relating to the Mental Capacity Act. The provider and other non-clinical staff could not respond to questions relating to the Mental Capacity Act.
- We were told that any treatment including fees was fully explained to the patient prior to the procedure and that people then made informed decisions about their care.

Standard information about fees was detailed on the clinic website and information leaflets provided at the clinic.

# Are services caring?

## Our findings

We were unable to assess whether this service was providing caring services in accordance with the relevant regulations.

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

- We were unable to observe whether members of staff were courteous and helpful to patients and treated them with dignity and respect as there were no patients present during most of our inspection.

- Curtains were provided in consulting rooms to maintain patients' privacy and dignity during examinations, investigations and treatments.
- A private room was available if patients wanted to discuss sensitive issues or appeared distressed.
- Staff we spoke with understood the importance of confidentiality and the need for speaking with patients in private when discussing services they required.

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

- Our inspection was unannounced and no comment cards were sent prior to our inspection. On the day of the inspection no medical services were being provided and we had no patients to speak with.

# Are services responsive to people's needs?

(for example, to feedback?)

## Our findings

We found no sufficient evidence to rate responsive.

### Responding to and meeting patients' needs

- Access to the clinic was suitable for disabled persons or those with prams and pushchairs.
- The reception desk was of a lower level suitable for patients in wheelchairs.
- Staff told us that all patients attending the clinic were Polish speaking and therefore translation services were not used.
- There was a clinic leaflet which included arrangements for dealing with complaints, arrangements for respecting dignity and privacy of patients and also services available.
- Information was also available on the clinic website.
- All patients attending the clinic referred themselves for treatment; none were referred from NHS services. The clinic told us they relied on patients to refer themselves back to NHS GP services if required.

### Tackling inequity and promoting equality

- The clinic offered appointments primarily to Polish patients or anyone who requested one (and had viable finance available) and did not discriminate against any client group.

### Access to the service

- We were informed that the clinic was open from 8am until 6pm Monday to Saturday. Appointments were

available on a pre-bookable basis. Generally, patients could access the service in a timely way by making their appointment either in person or over the telephone. When treatment was urgent, patients would be seen on the same day by the family doctor but not the doctors seeing patients for dermatology or gynaecology and obstetrics.

### Concerns & complaints

The clinic had a system in place for handling complaints and concerns

- Its complaints policy and procedures were in line with recognised guidance for independent doctors in England.
- There was a designated responsible person who handled all complaints in the clinic.
- A complaints leaflet was available to help patients understand the complaints system. There was information on how to complain on the clinic website.
- We were told one complaint had been received within the last 12 months. A complaint had been received at the clinic by a patient who had undergone a cervical smear. From the explanation given by the provider, it appeared they had not dealt with it appropriately as they had no record of the response given to the patient and learning from it. The complaint should have been investigated further as a significant event in order to promote shared learning and prevent reoccurrence.

# 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.

### Vision and strategy

- The clinic did not have a vision to deliver high quality care and promote good outcomes for patients.
- No strategy and business plans were in place to reflect the values of the clinic and how these were monitored.

### Governance arrangements

- The clinic did not have an effective, overarching governance framework in place to support the delivery of safe and effective care to patients. There was a lack of effective systems and processes in place for assessing and monitoring risks and the quality of the service provision.
- The clinic did not have clear governance arrangements in place. The clinic lacked most key policies. The clinic held no clinical governance meetings, and the systems of learning, sharing and making improvements following Significant Events Analyses (SEA) were not effective.
- There was no programme of quality improvement monitoring including continuous clinical and internal audit in place to monitor quality and to make improvements.
- No risks were assessed. For example the provider had not ensured that adequate medical indemnity insurance was in place or that appropriate checks of current insurance had been carried out on all clinicians upon commencement of employment. We were unable to gain assurances that adequate medical indemnity insurance was in place. The provider was aware that one

of the doctors had been advised by the GMC to make appropriate insurance arrangements and yet they had not taken any action to stop the doctor from providing care until the indemnity insurance had been arranged.

### Leadership, openness and transparency

- There was a lack of clinical leadership and oversight. The provider of the clinic had dental experience but did not have an insight into the medical consulting part of the clinic. There was no clinical leadership structure in place. When we asked about their responsibilities in supervising the doctors that provided care at the clinic; they told us that the visiting doctors were experienced professionals from Poland and they did not have to supervise them.
- We asked the Nominated Individual (NI) about the day to day management of the clinic and we were told that the clinic manager had resigned in December 2016. We were also told that the NI was available to offer support. However from our discussions with them they could not explain the arrangements to cover the clinics as they were mainly based at the clinic in Acton.

### Learning and improvement

- We found no focus on continuous learning and improvement within the clinic.

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

- The provider told us that they received verbal feedback from patients and did not have a formal system in place to record and act on this feedback.
- The clinic did not have a formal system to gather feedback from staff and there were no formal staff meetings structures in place to encourage discussion.

## 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
Diagnostic and screening procedures Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p><b>Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Safe care and treatment</b></p> <p><b>How the regulation was not being met:</b></p> <p>The registered person did not do all that was reasonably practicable to assess, monitor, manage and mitigate risks to the health and safety of service users. For example:</p> <p>The clinic did not have systems in place to properly assess and mitigate against risks including risks associated with employing staff without full indemnity insurance cover.</p> <p>The clinic did not ensure arrangements to safeguard children and vulnerable adults from abuse reflected relevant legislation and local requirements. There were no records to confirm that clinicians and the nominated individual had completed up to date safeguarding training.</p> <p>The provider had not ensured the availability of trained chaperones at all times for patients who attended for gynaecology services.</p> <p>The provider did not ensure a system of clinical supervision for all clinical staff.</p> <p>The provider did not ensure there was an effective system in place for obtaining written consent from patients for investigative and intimate procedures.</p> <p>The provider did not have an effective process in place to ensure patients results were followed up and dealt with appropriately.</p> <p>There was no process in place for acting on and monitoring significant events, incidents and near misses.</p>

This section is primarily information for the provider

## Enforcement actions

The provider had not ensured all staff received training required to carry out their roles for example, safeguarding, chaperone, basic life support.

The provider did not have adequate systems in place to manage medicines and keep prescriptions safe.

This was in breach of regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

### Regulated activity

Diagnostic and screening procedures

Treatment of disease, disorder or injury

### Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

**Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.**

Good governance

Systems or processes must be established and operated effectively to assess, monitor and improve the quality and safety of the services provided in the carrying out of the regulated activity.

#### **How the regulation was not being met:**

The clinic had no formal governance arrangements in place and did not have a programme of regular audit or quality improvement methods to assess monitor and improve the quality and safety of the services provided.

The clinic did not have systems in place to properly assess and mitigate against risks including risks associated with employing staff without full indemnity insurance cover.

The clinic had a lack of management and clinical oversight in place on a daily basis.

This section is primarily information for the provider

## Enforcement actions

The clinic lacked key policies such as; safeguarding; medicines management; infection control and incident reporting.

All staff had not received an appraisal within the last 12 months.