

# Euro Health Service Limited

# Carmenta Life

## Inspection report

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## Overall summary

We carried out an announced comprehensive inspection on 1 November 2018 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 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.

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 service provides pregnancy and fertility services to fee-paying patients alongside other medical specialties. Carmenta Life offers a range of diagnostic and screening procedures using a range of high quality equipment and laboratory tests. This includes blood pressure, pregnancy health advice and ultrasound scans. Laboratory investigations includes a range of diagnostic and screening of blood tests and cytology samples.

The lead clinical consultant is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

As part of our inspection, we asked for Care Quality Commission comment cards to be completed by patients prior to our inspection. We received four comment cards which were positive about the level of care provided. Patients told us staff were reassuring and gave them the time to ask questions.

### **Our key findings were:**

# Summary of findings

- There was no oversight of the risks associated with the service. For example, there had been no risk assessment completed for the premises, health and safety, fire, legionella or emergency medicines.
- Staff did not receive regular appraisals and one staff member had not completed mandatory fire or infection control training.
- An infection control audit had not been completed to identify or address concerns.
- Clinical records were detailed and held securely. The service did not keep paper records.
- Staff members were knowledgeable and had the experience and skills required to carry out their roles.
- There were no practice meetings or formal communication with staff.
- The provider did not document verbal complaints received however, the provider was able to give examples of how verbal complaints had led to improved care.
- Patients were able to book appointments directly with the practitioners at a time that was convenient to them, this included at evenings and weekends.

The areas where the provider **must** make improvements as they are in breach of regulations are:

- Ensure care and treatment is provided in a safe way to patients.

The areas where the provider **should** make improvements are:

- Improve the process for recording verbal consent obtained from patients to undertake examination or treatment.
- Improve communication mechanisms with staff members.
- Improve the safeguarding policy to include a safeguarding lead for the service.
- Improve the complaints policy to include the advertising of the complaints procedure on the website, the recording of verbal complaints and recording actions taken.

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

**Professor Steve Field** CBE FRCP FFPH FRCGP Chief Inspector of General Practice

# Carmenta Life

## Detailed findings

### Background to this inspection

Carmenta Life is a service provided by Euro Health Service Limited. It is based in Chesham House, Church Lane, Berkhamsted, HP4 2AX and the service operates from the ground floor.. The provider uses several rooms for unregulated activities. The provider employs the services of self-employed practitioners to perform regulated activities from one of the rooms. These practitioners have a third-party employment contract with Carmenta Life. A well-being service also operates from the same location and the reception staff from the well-being service welcomes the patients into Carmenta Life.

The service provides a bespoke pregnancy and contraception service. The service does not have set clinic times and patients are able to book appointments with the practitioner of their choice at a time convenient to them. The service provides blood tests, fertility and contraception advice and ultrasound scans to private, fee paying patients. The service consults with approximately two patients a week.

We carried out an announced comprehensive inspection at Carmenta Life on 1 November 2018 as part of our scheduled inspection plan.

Our inspection team was led by a CQC lead inspector and included a GP specialist adviser.

The service is registered with the CQC to provide the regulated activities of treatment of disease, disorder or injury, family planning, maternity and midwifery services and diagnostic and screening procedures.

Before inspecting, we reviewed a range of information we hold about the service and asked other organisations to share what they knew. During our inspection we:

- Reviewed an anonymised sample of the personal care or treatment records of patients.
- Reviewed service policies, procedures and other relevant documentation.
- Inspected the premises and equipment used by the service.
- Reviewed CQC comment cards completed by service users.

Third party practitioners that worked at the service were not available to speak with on the day of the inspection. However, we were able to contact them via e-mail shortly after the inspection. This correspondence ascertained their understanding of their roles and responsibilities, what support they had received and the culture of the service.

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.

### Safety systems and processes

The service had systems to keep patients safeguarded from abuse. However, risks relating to infection prevention and control, fire, health and safety and legionella had not been assessed and addressed.

- The service had systems to safeguard children and vulnerable adults from abuse. Policies were regularly reviewed and were accessible to all staff. They outlined clearly who to go to for further guidance and how to report safeguarding concerns to relevant external agencies. Although the policy did not state the name of the safeguarding lead, staff in the service were clear on who this was. The local authority contact details for safeguarding was kept within the induction pack and held at reception.
- Staff were aware of the signs of abuse however, due to the small number of patients accessing the service, a safeguarding referral had never needed to be made.
- All staff received up-to-date safeguarding training appropriate to their role. They knew how to identify and report concerns. Clinical staff were trained to safeguarding children level 3.
- Staff checks were carried out at the recruitment stage and on an ongoing basis. The provider did not carry out checks of professional registration, however this was implied due to their NHS employment.
- Disclosure and Barring Service (DBS) checks were in place for all staff who were employed under a third-party agreement. (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).
- The service offered chaperones to patients for all examinations and treatment. All chaperones had a DBS check in place.
- The provider did not have an effective immunisation programme in place for all staff. Evidence of some immunisation records were provided shortly after the inspection.
- The systems to manage infection prevention and control were insufficient.
- The service did not complete infection control audits.
- We observed the treatment room was carpeted. The service ensured carpets were cleaned twice yearly and we saw evidence that this was completed.
- The service held a contract with a waste provider to manage their clinical waste and sharps. The sharps bins we saw in the clinical room were not labelled. The service regularly checked the electrical equipment in line with legislation. All equipment was regularly maintained.
- There was no formal business continuity plan in place.

### Risks to patients

There were some systems to assess, monitor and manage medical emergency situations. Due to the nature of the service, emergency situations were unlikely. Acutely unwell patients were not seen at the service.

- Staff knew what to do in a medical emergency and completed training in emergency resuscitation and basic life support annually.
- Emergency equipment and medicines were available. The service did not hold all recommended emergency medicines. The emergency medicines we checked were within their expiry dates. There was a documented risk assessment to identify which medicines were appropriate to be held by the service.
- Oxygen was available and was regularly checked and maintained.
- The service did not have a defibrillator on site and there was no formal risk assessment in place to mitigate this risk. The provider was not able to give assurance that they could adequately respond to a medical emergency at the time of our inspection. The provider intended to purchase a defibrillator following the inspection.
- Clinicians knew how to identify and manage patients that were acutely unwell however, due to the nature of the service, acutely unwell patients were not seen at the site. Patients who contacted the service with high-risk symptoms were advised to contact their local Accident and Emergency department.
- Professional indemnity insurance was in place for all practitioners.

### Information to deliver safe care and treatment

# Are services safe?

Staff had the information they needed to deliver safe care and treatment to patients.

- Individual patient records were written and managed in a way that kept patients safe. The care records we saw showed that information needed to deliver safe care and treatment was available.
- Clinical notes were held electronically and a full and thorough representation of the patient's medical condition, presenting symptoms and outcome of treatment.
- The service told us that they would share information with the patient's GP where there had been a significant clinical concern. The patient was given an electronic record of their consultation and were encouraged to share this with relevant healthcare professionals such as GP's or midwives.

The self-referral process ensured details of the patients identity and age were recorded in the clinical records.

## Safe and appropriate use of medicines

The systems for handling medicines were safe and appropriate.

- The service would only prescribe medications in very rare circumstances. This was limited to a short course of antibiotics. The practitioner would print each prescription individually to ensure there was no concerns with prescription stationary security. This would be recorded within the patient notes.
- With exception of emergency medicines, medicines and vaccinations were not held at the service.

## Track record on safety

The service did not have a good safety record and had not undertaken an assessment of infection control risks or risks associated with Legionella (Legionella is a term for a bacterium which can contaminate water systems in buildings).

- The service was unable to provide evidence of risk assessments related to fire and health and safety. There were no visible health and safety risks and the building appeared well maintained.
- The service did not conduct fire drills or ensure fire extinguishers were checked and maintained. They had worked with the property landlord to produce a fire safety policy.
- The service could not provide evidence of a legionella risk assessment and did not have a procedure in place to control the risk of legionella. However, the service had its water quality tested twice a year by an external company.
- The service was cleaned by an external cleaning agency. The service was unable to provide evidence of a cleaning schedule or assurance of what had been cleaned. The provider told us that the external company used their own cleaning supplies. During our inspection, we found cleaning chemicals in an unlocked cupboard within the patient toilets. There was no evidence of COSHH information sheets or risk assessments for these chemicals to be on-site.

## Lessons learned and improvements made

The service had systems and processes in place to learn and make improvements if things went wrong with care and treatment.

- There was a policy in place for managing incidents or significant events. However, due to the nature of the service and minimal number of patients seen in the service, there had been no occurrence of incidents or significant events.
- Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- There was a system for receiving, reviewing and acting on safety alerts including patient medicines and device safety alerts.
- The provider was aware and complied with the requirements of the duty of candour. The provider encouraged a culture of openness and honesty.

# Are services effective?

(for example, treatment is effective)

## Our findings

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

### Effective needs assessment, care and treatment

The service had systems to keep clinicians up to date with current evidence-based practice. We saw that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance supported by clear clinical pathways and protocols.

- A full assessment of the patient's medical condition was completed and recorded at the time of consultation.
- We saw no evidence of discrimination when making care and treatment decisions.
- Staff advised patients what to do if they became unwell or needed to attend a local hospital because of their symptoms.
- Relevant safety alerts were circulated to staff and the necessary action taken to ensure treatment was in line with guidelines.

### Monitoring care and treatment

The service had a programme to ensure that the effectiveness and appropriateness of the care and treatment provided was being monitored.

- The service ensured diagnosis and treatment was in line with national guidelines and service protocol.
- There was evidence of quality improvement activity, such as clinical audit being undertaken. For example, an audit was completed regarding the use of operator names being used in patient reports as patients were unsure of who to contact for follow-up advice. The audit led to a change in the electronic system to ensure that the operator name was always included in the report. A re-audit was completed to ensure the quality improvement activity had been effective.

### Effective staffing

Staff had clinical knowledge and training to do their job effectively. However, the service was unable to provide evidence of formal support and appraisal for the practitioners.

- Evidence of training was recorded for the practitioners associated with the service. However, one practitioner did not have evidence that infection control or fire safety training had been completed.
- The provider checked the training records of staff from their main employer. If this was not available, staff were encouraged to complete this through their main employer. The service did not offer training to staff.
- The provider did not offer appraisals to staff however, did not always ensure that this had been completed through their main employer.
- There was not an effective immunisation programme in place for all staff. Some immunisation records were kept, however this was incomplete and did not include all relevant immunisation history, for example chicken pox and rubella were not included.
- The service told us they provided staff with on-going support however, this was informal and not recorded. There was no record of supervision taking place for clinical staff.
- There was an appropriate induction programme for new staff.

### Coordinating care and treatment

The service had arrangements in place for working with other health professionals to ensure quality of care for the patients.

- Patients were provided with an electronic copy of their clinical records documenting the treatment that they had received, and were encouraged to share this with relevant NHS staff such as their GP or midwife.
- If the patient had given consent, the service would share concerning treatment results with the patients regular GP.

### Helping patients to live healthier lives

Staff were consistent and proactive in helping patients to have healthier pregnancies.

- Staff encouraged and supported patients to be involved in monitoring and managing their health.
- The service provided patients with bespoke maternity and pregnancy service.
- The service identified patients who may need extra support and directed them to relevant services.

# Are services effective?

(for example, treatment is effective)

- The service would signpost to the complimentary therapies practitioners, such as pregnancy massage, to assist patient's wellbeing.

## **Consent to care and treatment**

The service obtained consent to care and treatment in line with legislation and guidance.

- Clinicians understood the requirements of legislation and guidance when considering consent and decision making.
- Clinicians supported patients to make decisions by providing information about treatment options and the risks and benefits of these, as well as costs of treatments and services.
- Patients self-referred to the service and therefore gave implied consent. Verbal consent was also sought prior to any treatment or examination. However, consent to examination was not recorded formally.

# Are services caring?

## Our findings

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

### **Kindness, respect and compassion**

Staff treated patients with kindness, respect and compassion.

- The service gave patients timely support and information.
- All the four patient Care Quality Commission comment cards we received were wholly positive about the service experienced. They commented on the high levels of reassurance given by staff.

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

Staff helped patients be involved in decisions about their care:

- The service could accommodate patients who did not have English as a first language by offering a telephone translation service however, we were informed that the patient population did not often need to use this service.

- Staff communicated with patients in a way that they could understand.
- The service's website and other sources provided patients with information about the range of services available including costs. Patients were aware of the cost of treatment before they proceeded.

### **Privacy and Dignity**

The service respected and promoted patients' privacy and dignity.

- Staff recognised the importance of patients' dignity and respect.
- Reception staff were not employed by the service but had no access to confidential patient information.
- Patients' electronic care records were securely stored using a password protected system. The service was in the process of creating a more secure e-mail system that used an encryption package.
- Treatment room doors remained closed during consultations to ensure privacy.



# 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 people's needs

The service organised and delivered services to meet patients' needs.

- The facilities and premises were appropriate for the services delivered with disabled access throughout.
- The telephone translation service was available for patients who did not speak English as their first language. The provider told us he would not allow family members to translate in sensitive situations or when the patient was considered vulnerable.
- The service did not conduct any formal patient feedback activity.
- Although there was no formal system in place to collect patient feedback, the provider told us about how comments received from patients helped to shape the service provided.

### Timely access to the service

Patients could access care and treatment from the service within an acceptable timescale for their needs.

- The service had no set clinic times and patients were able to book at a time that was convenient. This included evenings and weekends.
- Patients could contact the service via telephone or e-mail. Appointments were booked directly by the practitioners.

- The service did not conduct any patient feedback activities however, the provider told us that patients were happy with the availability of appointments.
- The service used a private laboratory to process blood tests. Results were often available on the same day.
- Ultrasound appointments were 30 minutes long.

### Listening and learning from concerns and complaints

The service took complaints and concerns seriously and had some systems in place to respond to them appropriately and to improve the quality of care.

- The registered manager was responsible for dealing with complaints and the service had a complaint policy providing guidance for staff on how to handle a complaint.
- The service had received no written complaints.
- There was no log of verbal complaints made to the service. However, we were told of changes and improvements that had been made following any received. For example, the service received a verbal complaint regarding the length of time for an e-mail response to a query. The service has now created an automated acknowledgement email to reassure patients that the query has been received.
- There was no information available on the service website for patients to provide feedback and make complaints. The service told us they intended to create a link within their e-mail responses in order to collect patient feedback in the future.

# 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

### Leadership capacity and capability

Leaders had the capacity and skills to deliver high-quality clinical care to patients however, there was insufficient oversight of health and safety and risks.

- Leaders had the experience, capacity and skills to deliver the organisational strategy but had not assessed or addressed all risks associated with the delivery of the service. However, they understood the challenges and priorities of the service and would reassess service provision to address them.
- Staff told us leaders were approachable and offered swift responses to concerns or issues.

### Vision and strategy

The service had a vision and strategy to deliver high-quality, patient focussed care.

- There was a clear vision and set of values with a strategy to achieve priorities.
- The provider involved staff in the development of the strategy where appropriate.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them.
- The service monitored progress against delivery of the strategy.

### Culture

The service had a culture of providing high-quality care.

- Staff stated they felt respected, supported and valued. They were happy and proud to work in the service.
- The service focused on the needs of patients.
- Openness, honesty and transparency were key themes of systems and culture around managing incidents and complaints.
- The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.

- Staff we spoke with told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- We reviewed three staff recruitment files however, only one member of staff had evidence of an appraisal being carried out within the last year.
- There were positive relationships between staff.

### Governance arrangements

Some governance arrangements were ineffective. For example,

- There was a lack of systems to ensure effective oversight and management of key areas of risk and safety. For example, risk assessments had not been completed in relation to health and safety, fire and legionella.
- We saw evidence of an up-to-date gas and fire safety certificate with evidence of an annual smoke alarm maintenance programme.
- The service ensured that electrical equipment was tested on a regular basis. Staff were clear on their roles and accountabilities including in respect of safeguarding

### Managing risks, issues and performance

The processes for managing risks, issues and performance were insufficient.

- The processes used to identify, understand, monitor and address risks including risks to patient safety were lacking in some areas. For example, there was no effective system in place to assess risks associated with infection control.
- The service did not have a business continuity plan in place.
- The provider could not provide evidence or give assurance that all staff had received mandatory training in fire safety or infection control. All staff had received the appropriate level of training in safeguarding and basic life support.
- Service leaders had oversight of safety alerts, incidents, and complaints.
- Although there was no log of verbal complaints, the provider was able to describe in detail the concerns raised by patients and the actions taken to resolve

# Are services well-led?

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

these. For example, the service received a number of verbal complaints regarding the outcome of 4D pregnancy ultrasound scans and had developed an information sheet to explain to patients what they can expect from these scans.

- The service had received no written complaints.
- We saw evidence that clinical audit was being used to improve services.

## **Appropriate and accurate information**

The service acted on appropriate and accurate information.

- The provider met with the staff employed on a third-party basis on an ad-hoc basis however, these meetings were not documented. The provider could not provide evidence that complaints or improvements had been discussed.
- The service ensured that the patient's medical history and presenting conditions were accurately recorded onto the electronic system.
- The service submitted information or notifications to external organisations as required.
- The practice had systems in place to maintain patient confidentiality.

## **Engagement with patients, the public, staff and external partners**

The service involved patients and staff to support high-quality sustainable services.

- Patient feedback was sought through a comments box in reception, however, the provider told us this was rarely used. The provider told us that there was a culture of responding to patient comments and improving the service provided.

- The provider told us that patients' and staff views and concerns were encouraged, heard and acted on to shape services however, this was not a documented or formal process.

## **Continuous improvement and innovation**

There were some systems and processes for learning, continuous improvement and innovation.

- There was a focus on continuous learning and improvement however, we identified that some mandatory training had not been completed by some staff members
- The provider was able to tell us what improvements had been made to the service, such as increasing the information available for women having 4D scans. The provider had further plans to improve the service, such as creating an electronic feedback mechanism within the automated e-mails.
- The service was innovative in that they held only electronic records. All notes and correspondence was held electronically to enable speed of communication and response.
- The appointment system offered complete flexibility for patients to be seen at a time convenient to them. The length of appointment was longer than in other similar services or within the NHS.
- We were told that there was a rapid service to process blood tests often allowing patients to receive their blood results on the same day.

## 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
Diagnostic and screening procedures Family planning services Maternity and midwifery services Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p><b>How the regulation was not being met:</b></p> <p>This was in breach of regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</p> <p>The registered persons 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:</p> <ul style="list-style-type: none"><li>• There was no risk assessments in relation to fire, health and safety or legionella.</li><li>• The risks associated with infection control had not been assessed or addressed. An audit had not been completed.</li><li>• The provider had not ensured that all members of staff had completed mandatory infection control or fire training.</li><li>• The provider could not provide evidence of appropriate cleaning records for the premises.</li><li>• Cleaning chemicals were held on site without the appropriate risk assessments in place.</li><li>• There was no risk assessment in place in relation to which emergency medicines were held on site. There was no defibrillator held at the service and no risk assessment to mitigate this risk.</li><li>• A record of staff immunisations was not maintained.</li><li>• Not all members of staff had evidence of an appraisal within the last twelve months.</li></ul>