

# Jenna (UK) Limited

# Jenna Clinic

## Inspection report

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## Overall summary

We carried out an announced comprehensive inspection on 11 December 2017 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led? Due to concerns identified at this inspection, we also carried out an unannounced focussed inspection on 19 December 2017. We found that the clinic was not providing safe, effective or well led services, however they were providing caring and responsive services. Following this inspection, we took urgent action to place conditions on Jenna (UK) Limited to stop them providing regulated activities from the Jenna Clinic based in Peterborough. We also shared our concerns with other regulators.

The conditions placed on Jenna (UK) Limited to stop them providing regulated activities from the Jenna Clinic based in Peterborough ceased to have effect from 21 March 2018. This unannounced focussed inspection took place to ensure that sufficient changes were made in order to meet the relevant regulations.

### **Our findings were:**

#### **Are services safe?**

We found that this service was 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 well-led?**

We found that this service was 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 Jenna Clinic was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008. At the inspection on 11 December 2017, we found risks relating to good governance and safe care and treatment. Patients were at risk of harm because systems and processes were not in place to keep them safe. The systems and processes in place to ensure good governance were ineffective and did not enable the provider to assess and monitor the quality of the services and identify, assess and mitigate against risks to people using services and others. We served the provider with a letter of intent to take urgent enforcement and giving details of identified risks found during the inspection relating to breaches in regulation. The provider took immediate action and submitted an action plan and agreed to voluntarily suspend providing all services from the Peterborough location.

We carried out an unannounced focussed inspection on 19 December to ensure actions had been taken to address the risks. Following our focussed inspection (19 December 2017) we found additional concerns and risks

# Summary of findings

relating to safe care and treatment and good governance remained. We took urgent action to place conditions on Jenna (UK) Limited to stop them providing regulated activities from the Jenna Clinic based in Peterborough.

The conditions placed on Jenna (UK) Limited to stop them providing regulated activities from the Jenna Clinic based in Peterborough ceased to have effect from 21 March 2018. This unannounced focussed inspection took place to ensure that sufficient changes were made in order to meet the relevant regulations.

The clinic previously provided private GP services to Russian, Lithuanian, Polish and Ukrainian patients. However, follow the period of conditions being placed on the clinic, the provider submitted changes to their registration to stop providing private GP services. They provide ultrasound and gynaecology services, assessment for IVF and assessment for plastic surgery. This service is registered with CQC under the Health and Social Care Act 2008 in respect of some, but not all, of the services it provides. There are some exemptions from regulation by CQC which relate to particular types of service and these are set out in Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. For example, complementary therapies, including acupuncture. These types of arrangements are exempt by law from CQC regulation.

The manager of the clinic 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.

## Our key findings were:

- The scope of the service had been significantly reduced which had allowed for improved management oversight of the service.
- Openness, honesty and transparency were demonstrated when responding to the previous inspection outcome with staff.
- There were positive relationships between staff.
- Structures, processes and systems to support good governance and management were clearly set out, understood and effective.

- Staff had received up-to-date safeguarding and safety training appropriate to their role.
- There were medicines and equipment on site to treat patients in case of an emergency. We found there was a system for the checking of expiry dates of equipment.
- Prescription stationery was stored securely and staff monitored its use.
- Prescribing within the clinic was limited due to the ceasing of GP services. Staff prescribed and gave advice on medicines in line with evidence based guidance.
- Patients' health was monitored to ensure results of tests were being followed up on appropriately.
- The provider had effective systems in place to maintain a complete safety record, including a legionella risk assessment.
- There was a system for recording, acting on and learning from significant events and incidents. There was a system for receiving and acting on safety alerts.
- Records we viewed showed clinical assessment and treatment was reflective of best practice guidance.
- There was a clear plan in place for quality monitoring and improvement going forward. There was evidence of non-clinical audits.
- We saw that where patients had abnormal test results, there was a system in place to ensure this was followed up by the patient or the regular GP.
- The clinic could evidence working with local midwives as they received referrals for fertility testing.
- Consent forms were available in different languages such as Russian and Lithuanian.
- There was evidence of meetings and these were embedded in to practice every three months.
- There was a focus on continuous learning and improvement within the clinic. For example, receptionists had been trained to carry out phlebotomy.

The area where the provider **should** make improvements:

- Embed the system to ensure clinical auditing is completed to monitor quality and make improvement.

# 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 providing safe care in accordance with the relevant regulations.

- Staff had received up-to-date safeguarding and safety training appropriate to their role. Clinicians were trained to safeguarding level three.
- The clinic carried out staff checks, including checks of professional registration where relevant, on recruitment and on an ongoing basis.
- There was a system to manage infection prevention and control.
- There were medicines and equipment on site to treat patients in case of an emergency.
- We found there was a detailed system for the checking of expiry dates of equipment and medicines.
- Prescription stationery was stored securely and staff monitored its use in line with guidance.
- Prescribing within the clinic was limited due to the ceasing of GP services. Staff prescribed and gave advice on medicines and we found this was in line with evidence based guidance.
- Patients' health was monitored to ensure results of tests were being followed up on appropriately.
- The provider had effective systems in place to maintain a complete safety record, including a legionella risk assessment.
- There was a system for recording, acting on and learning from significant events and incidents. Staff understood their duty to raise concerns and report incidents and near misses.
- There was a system for receiving and acting on safety alerts.

### **Are services effective?**

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

- We saw no evidence of discrimination when making care and treatment decisions in the records we viewed.
- Records we viewed showed clinical assessment and treatment was reflective of best practice guidance.
- The clinic had completed a retrospective audit of the prescribing of antibiotics.
- There was a clear plan in place for quality monitoring and improvement going forward.
- There was evidence of non-clinical audits. For example, the clinic had run an audit on the documentation of clinical records, checking that they were signed and dated.
- We saw that when patients had abnormal test results, there was a system in place to ensure they were given to the patient or the regular GP.
- The clinic could evidence working with local midwives as they received referrals for fertility testing.
- We saw clear evidence of clinicians referring patients for contraceptive advice.
- Consent forms were also available in different languages such as Russian and Lithuanian.

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

We found that this service was providing well-led care in accordance with the relevant regulations.

- Leaders at all levels were visible and approachable.
- Openness, honesty and transparency were demonstrated when responding to the previous inspection outcome with staff.
- There were positive relationships between staff.

# Summary of findings

- Structures, processes and systems to support good governance and management were clearly set out, understood and effective.
- Leaders had established policies, procedures and activities. These were clear and comprehensive.
- There were processes to identify, understand, monitor and address current and future risks, including fire and health and safety.
- There was evidence of clinical audit impacting patient safety, care and effectiveness. There was a plan in place to complete a clinical audit programme on a continuing basis.
- There was evidence of meetings and these were embedded in to practice rota to occur every three months.
- There was a focus on continuous learning and improvement within the clinic. For example, receptionists had been trained to carry out phlebotomy.

# Jenna Clinic

## Detailed findings

### Background to this inspection

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether Jenna Clinic was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008. At the announced comprehensive inspection on 11 December 2017, we found risks relating to good governance and safe care and treatment. Patients were at risk of harm because systems and processes were not in place to keep them safe. The systems and processes in place to ensure good governance were ineffective and did not enable the provider to assess and monitor the quality of the services and identify, assess and mitigate against risks to people using services and others. We served the provider with a letter of intent to take urgent enforcement action; this letter gave details of concerns identified during the inspection relating to breaches in regulation. The provider took immediate action and submitted an action plan and agreed to voluntarily suspend services at Jenna Clinic, Peterborough.

We carried out an unannounced focussed inspection on 19 December 2017 to ensure actions had been taken to address the risks. During our focussed inspection (19 December 2017) we identified additional concerns and

risks to safe care and treatment and good governance remained. We took urgent action to place conditions on Jenna (UK) Limited to stop them providing regulated activities from the Jenna Clinic based in Peterborough.

The clinic no longer provides private GP services to patients. The clinic has continued to provide assessment for in vitro fertilisation (IVF) and assessment for plastic surgery. The clinic also provides ultrasound and gynaecology assessments, as well as complementary treatments such as acupuncture to patients of Russian, Lithuanian, Polish and Ukrainian backgrounds.

During our visit we:

- Spoke with staff, including admin staff and the registered manager.
- Reviewed a sample of the personal care or treatment records of patients.
- Looked at information the clinic used to deliver care and treatment plans.

To get to the heart of patients' experiences of care and treatment, we asked the following three questions:

- Is it safe?
- Is it effective?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

# Are services safe?

## Our findings

### Safety systems and processes

The provider had clear systems to keep patients safe and safeguarded from abuse.

- The clinic had safety policies which had been reviewed and communicated to staff. These included policies on safeguarding, complaints and chaperones. Staff were required to read these policies during their induction. The clinic had systems to safeguard children and vulnerable adults from abuse. The clinic explained that they sometimes treated patients under the age of 18 for ultrasound scans and had appropriate systems in place for checking identification of patients and parental responsibility, where appropriate. Policies outlined who to go to for further guidance. Staff spoken to were clear about their responsibilities in relation to safeguarding.
- Staff had received up-to-date safeguarding and safety training appropriate to their role. Clinicians were trained to safeguarding level three. Staff who acted as chaperones had received appropriate training for the role and had received a DBS check.
- The clinic worked with other agencies to support patients and protect them from neglect and abuse. For example, there was a system in place to record a patient's regular GP on initial assessment to discuss any concerns. The clinic reported they had communication with midwives and received referrals for fertility testing.
- The clinic carried out staff checks, including checks of professional registration where relevant, on recruitment and on an ongoing basis. Disclosure and Barring Service (DBS) checks were undertaken where required for most staff. (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). All clinicians had appropriate medical indemnity cover in place.
- There was a system to manage infection prevention and control (IPC). There was a completed audit with associated action plan. There were cleaning schedules in place all areas of the clinic. There were systems for

safely managing healthcare waste. There were spill kits available. A storage cupboard used for clinical items also contained cleaning equipment and cleaning solutions.

- A legionella risk assessment had been completed and the clinic were monitoring water temperatures as per the recommendations in the risk assessment.
- The clinic ensured that equipment was maintained according to manufacturers' instructions. Calibration and electrical testing was completed annually. This included testing of the ultrasound machine.

### Risks to patients

There were systems in place to assess, monitor and manage risks to patient safety.

- There were arrangements for planning and monitoring the number and mix of staff needed.
- There was an induction system for staff.
- Staff understood their responsibilities to manage emergencies on the premises and to recognise those in need of urgent medical attention. Clinicians had the equipment available to fully assess patients with urgent conditions such as suspected sepsis.
- There were medicines and equipment on site to treat patients in case of an emergency. This included a defibrillator and oxygen.

### Information to deliver safe care and treatment

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

- Individual care 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 to relevant staff in an accessible way. For example, the clinic had recently started using a computer system to record patient consultations.
- The clinic had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment. For example, the clinic had implemented a new patient registration form which had the name and contact details of their NHS GP.

# Are services safe?

- The practice could also evidence working with local midwives and had received referrals for fertility testing.

## Safe and appropriate use of medicines

The clinic had reliable systems for appropriate and safe handling of medicines.

- We found there was a detailed system for the checking of expiry dates of equipment and medicines. The system ensured that weekly checks of equipment were carried out. There was a system to ensure that equipment with expiry dates within a close timeframe were used first, or were disposed of.
- Prescription stationery was stored securely and staff monitored its use in line with guidance.
- Prescribing within the clinic was limited due to the ceasing of GP services. Staff prescribed and gave advice on medicines and we found this was in line with evidence based guidance. We reviewed the notes of ten patients and found that these were comprehensive. The clinic had a clear plan in place for clinical oversight of consultations. For example, the registered manager would review a sample of other clinicians' work. The registered managers' work would be externally audited.
- Patients' health was monitored to ensure results of tests were being followed up on appropriately. For example, we found that if a patient had an abnormal result from testing, there was a system in place to ensure these patients were followed up appropriately. We saw evidence of a log of patient's results that identified when the testing had been completed and the clinician completing the test, the date the test was sent, when it was received, the result and the follow up consultation with the patient.

## Track record on safety

The provider had effective systems in place to maintain a complete safety record.

- There was a fire risk assessment in place. The clinic had carried out regular fire alarm testing and had equipment including fire extinguishers and emergency lighting checked regularly.

- There was an up to date health and safety risk assessment and a poster available for clinicians and patients.
- There was a legionella risk assessment in place and there was a system to ensure regular monitoring of water temperatures.
- There were appropriate systems in place for the security and back of up clinical records kept on the computer. The provider had systems in place for the safe storage of handwritten medical records.

## Lessons learned and improvements made

The clinic learned and made improvements when things went wrong.

- There was a system for recording and acting on significant events and incidents. Staff understood their duty to raise concerns and report incidents and near misses.
- There were systems for reviewing and investigating when things went wrong. The clinic learned and shared lessons and took action to improve safety in the clinic. For example, there had been occasions where the clinic had identified ectopic pregnancies (a complication in pregnancy where the embryo grows outside the uterus). The clinic had identified these and assisted the patient to get the correct treatment. These lessons were shared with other staff.
- The clinic had completed retrospective recording and sharing of significant events to ensure that learning from past events was shared within the clinic. Significant events were discussed at the clinic meetings every three months and were a standing agenda item.
- There was a system for receiving safety alerts. The registered manager received all alerts and kept a log. Action taken was clearly written on the alert and they were sent to all staff. Due to the limited prescribing, the manager reported it was easy to identify patients on medicines and recall them if required.

# Are services effective?

(for example, treatment is effective)

## Our findings

### Effective needs assessment, care and treatment

The clinic 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.

- The clinic had completed a retrospective audit of their performance in relation to prescribing including antibiotic prescribing.
- We saw no evidence of discrimination when making care and treatment decisions in the records we viewed.
- Records we viewed showed clinical assessment and treatment was reflective of best practice guidance. The clinic could evidence regular training events attended by clinicians, including early foetal medicine training, ultrasound and gynaecological scanning courses.

### Monitoring care and treatment

The clinic was involved in quality improvement activity.

- The clinic had completed a retrospective audit of prescribing of antibiotics. The first data collection from April 2017 showed 85% compliance with local guidelines. As a result, the clinic had improved the communication of this guidance to the clinicians. The clinic completed four more data collections, with the last being in December 2017. There was an improvement to 90% compliance. The clinic had made the decision to no longer provide GP services, however this audit showed they were completing a retrospective analysis of the issues that had been raised at previous inspections to drive improvement.
- There was a clear plan in place for quality monitoring and improvement going forward. The clinic had planned audits on consultations and had liaised with an external clinician to complete some of these audits. This system was in the process of being embedded.
- There was evidence of non-clinical audits. For example, the clinic had run an audit on the documentation of clinical records, auditing whether they were signed and dated. Performance in this audit was 100% consistently.

### Effective staffing

Staff had the skills, knowledge and experience to carry out their roles.

- Up to date records of skills, qualifications and training were maintained. Staff were encouraged and given opportunities to develop. For example, staff had been encouraged to undertake phlebotomy training.
- The clinic provided staff with support. This included an induction process, appraisals and support for revalidation. Staff reported there was an 'open door' policy and that support was available when required.

### Coordinating patient care and information sharing

Staff worked together and with other health and social care professionals to deliver effective care and treatment.

- We viewed records of some patients that used the service. The clinic had a new system in place to record the patients regular GP to ensure that, where consent was gained, they could share information with them if necessary.
- We saw that where patients had abnormal test results, there was a system in place to ensure this was followed up by the patient or the regular GP. The provider informed patients that if results were abnormal they would need to follow this up. There was documented evidence of testing undertaken, the clinician who had taken it, when the testing was received and when the patient was contacted.
- The clinic could evidence working with local midwives as they received referrals for fertility testing.

### Supporting patients to live healthier lives

Staff were proactive in helping patients to live healthier lives.

- We saw evidence in clinical notes of advice relating to national priorities including dietary advice.
- We saw clear evidence of clinicians referring patients for contraceptive advice. The registered manager also ensured that contraception was fully explained to the patient and that they understood where they could gain further advice and support.

### Consent to care and treatment

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

# Are services effective?

(for example, treatment is effective)

- Clinicians understood the requirements of legislation and guidance when considering consent and decision making.
- Clinicians supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision.
- The clinic had audited consent in a set of patient notes and found they had achieved 100% for this.
- The clinic gained written consent for procedures such as ultrasound. Consent forms were also available in different languages such as Russian and Lithuanian.

# Are services well-led?

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

## Our findings

### Leadership capacity and capability

Leaders had the capacity and skills to deliver high-quality, sustainable care.

- Leaders had the capacity and skills to deliver the strategy and address risks to it. We found that due to reducing the clinical scope to ultrasound and gynaecology services only, there was now appropriate clinical oversight to ensure services were safe.
- They were knowledgeable about issues and priorities relating to the quality and future of services. For example, the clinic had been responsive to the findings of the last inspection and had implemented appropriate actions to address the areas of risk. The areas highlighted that required improvement from the last inspection had been addressed.
- Staff reported that they had been kept updated with the findings from the last inspection. There was clear evidence in meeting minutes that the issues had been discussed with the wider team.
- Leaders at all levels were visible and approachable. Staff spoken to reflected this and felt supported by the management team.
- The provider had effective systems and processes in place. Policies were available for all staff to access, and they were detailed and reflective of the clinic.

### Vision and strategy

The clinic had systems and processes to ensure visions were achievable.

- The clinic had a business plan to achieve specific priorities.
- The clinic had a clear plan to monitor progress to ensure it addressed and shortfalls that may arise.
- The clinic had redesigned the service to ensure it was safe. This included ceasing to provide GP services. There was a clear plan in place to complete audits of the work undertaken to ensure it was of high quality, though this required further embedding.

### Culture

The clinic had a culture that enabled them to deliver care.

- Staff stated they felt respected, supported and valued. Staff reported management were approachable.
- The clinic offered private services, tailored to the patient group that attended.
- Openness, honesty and transparency were demonstrated when responding to the previous inspection outcome with staff. 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 were able to raise concerns. We saw evidence of significant events being raised, and a retrospective review of events to ensure and share learning.
- There were processes for providing all staff with some of the development they need. This included appraisals.
- Clinical staff were considered valued members of the clinic team.
- There was an emphasis on the safety and well-being of all staff.
- Staff had received equality and diversity training. Staff reported they felt they were treated equally.
- There were positive relationships between staff.

### Governance arrangements

The clinic had appropriate governance arrangements to ensure safe care and treatment.

- Structures, processes and systems to support good governance and management were clearly set out, understood and effective. The clinic held three monthly meetings to discuss a range of topics relating to clinical care, updates and significant events.
- Staff were clear on their roles and accountabilities including in respect of safeguarding and infection prevention and control.
- Leaders had established policies, procedures and activities. These were clear and comprehensive. They were specific to the clinic and available for all staff.

### Managing risks, issues and performance

There were processes in place for managing risks, issues and performance.

# Are services well-led?

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

- There were processes to identify, understand, monitor and address current and future risks, including fire and health and safety. The clinic had completed a legionella risk assessment and the processes for managing infection prevention and control were effective to ensure patient safety.
- The clinic had processes to manage current and future performance. Performance of employed clinical staff had been fully reviewed, and the clinic had made the decision to cease providing GP services. Managers had a system in place for the management of safety alerts and incidents.
- There was evidence of clinical audit impacting patient safety, care and effectiveness. There was a plan in place to complete clinical audit on a continuing basis. The management team had put a system in place to monitor the decisions of the clinicians at the clinic. There was also a plan for external audit of consultations to ensure clinicians were making appropriate decisions and to review the quality of the clinical notes. Records we viewed showed best practice guidance was being followed.

## **Appropriate and accurate information**

The clinic had systems to act on appropriate and accurate information.

- There was evidence of clinical audit to drive performance and improvements to care provided.
- There was evidence of meetings and these were embedded in to practice every three months. There was a set agenda which had significant events as a standing item.

- The clinic used performance information to monitor and manage staff. Leaders could show that they acted on behaviour and performance inconsistent best practice guidance.
- The clinic had some information technology systems. All clinical records were now being completed on computer and hand written notes kept in paper form were stored in line with recognised guidance.

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

The clinic showed some involvement with patients, the public, staff and external partners to support high-quality sustainable services.

- Patients, staff and external partners' views and concerns were heard and acted on. For example, there was a complaints book in reception for patients to leave comments. The manager also attended external conferences and brought lessons from these back to the clinic for implementation.

## **Continuous improvement and innovation**

There were systems and processes for learning and continuous improvement.

- There was a focus on continuous learning and improvement within the clinic. For example, receptionists had been trained to carry out phlebotomy.
- The provider had begun to show evidence of continuous learning from safety incidents, including patient safety alerts and significant events.