Brayford Studio Limited

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Inadequate

Summary of findings

Letter from the Chief Inspector of Hospitals

We rated it as **Inadequate** overall.

We found areas of practice that required improvement:

- There was no mandatory training programme in key skills for staff, and no formal induction programme.
- There was no safeguarding policy and no written protocols available for staff to follow to help identify and manage any safeguarding concerns.
- There was no chaperone policy in place and there was no access to a suitable chaperone for intimate gynaecological scans.
- The service did not control infection risk well. There was no infection prevention and control policy in place and no standard cleaning schedule and no clear arrangements for the management, collection and disposal of clinical waste.
- There were no arrangements in place for maintenance and calibration of scanning equipment.
- There was no schedule or process for secure destruction of paper records in line with legislation. This posed a risk to the confidentiality of client information.
- There was not an effective governance framework in place to deliver good quality care. There were no written policies, processes or protocols in place to govern and monitor activity.
- The provider had an overall vision for what they wanted to achieve but no clear plans or strategy to turn it into action.
- The provider did not ensure that all staff underwent appropriate checks as required by schedule 3 of the HSCA 2008 (regulated activities) regulation 2014.
- There was no mechanism for monitoring the quality and safety of the provider's practice.
- The service had no systems in place to identify, record or manage risks and cope with both the expected and unexpected.
- There was no systematic programme of clinical and internal audit.
- Information on the provider's website advertised services that were no longer being provided; sonographers and a manager who no longer worked at the location; and did not include the provider's name.

We found good practice in relation to providing compassionate care;

- The provider and receptionist worked especially hard to make the patient experience as pleasant as possible. They recognised and responded to the holistic needs of their patients and ensured comfortable waiting areas and provided refreshments to clients who had travelled a long way.
- They provided a seating area in the ultrasound room for partners and siblings to enjoy the experience of seeing their unborn baby together.
- The receptionist provided a very warm welcome to all clients and their families and kept people informed of any delays.
- There were many thank you cards which described the overwhelmingly kind and compassionate manner women and families had received from the provider in sad situations.

Summary of findings

- The provider was extremely motivated to ensuring that women and their families enjoyed the experience and ensured that the client was satisfied with the number of images they had seen before ending the procedure and printing the images.
- The provider gave a detailed explanation of the procedure and what to expect prior to the scan and very comprehensive explanation of the images during the scan procedure.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements.

We also wrote to the provider outlining our main concerns and issued the provider with a warning notice that affected Brayford Studio Limited. Details are at the end of the report.

Actions the provider MUST take to meet the regulations;

- Ensure that persons providing chaperone services have the skills and experience to do so safely. **Regulation 12(2) (c). Safe care and treatment.**
- Ensure that measures are taken to assess, prevent and control the risk of infections, including those that are healthcare associated. **Regulation 12 (2) (h). Safe care and treatment.**
- Ensure a DBS check is completed for all staff acting in the chaperone role when recruited, or complete a risk assessment to mitigate the risk. **13(1) Safeguarding service users from abuse and improper treatment.**
- Ensure they have and implement robust procedures and processes that make sure people are protected and safeguarded from abuse and improper treatment. Ensure that chaperones used have the knowledge and skills to perform this role. **Regulation 13(1) Safeguarding service users from abuse and improper treatment**
- Ensure that staff receive safeguarding training that is relevant and at a suitable level for their role. Staff should be kept up to date and able to recognise different forms of abuse and ways they can report concerns. **Regulation 13(2) Safeguarding service users from abuse and improper treatment.**
- Ensure they have systems and processes in place to audit, monitor and improve the quality and safety of the service. The systems and processes should be continually reviewed to make sure they remain fit for purpose. **Regulation 17(2) (a) Good governance**
- Ensure they assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk from the carrying on of the regulated activity. **Regulation 17 (2) (b) Good governance.**
- Ensure records are maintained and destroyed securely with systems and processes that support the confidentiality of people using the service and not contravene the Data protection Act 1998. **Regulation 17 (2) (c) Good governance.**

Actions the provider SHOULD take to improve;

- Make arrangements for the provider's practice to be regularly assessed and appraised with regard to providing ultrasound service in the independent healthcare setting.
- Provide basic life support and emergency equipment and ensure staff are trained in basic life support.
- Consider making hand-washing facilities available within the ultrasound room.
- Consider installing washable flooring in the ultrasound room.

We issued a section 29 Warning Notice under the Health and Social Care Act 2008 ('the Act') because the quality of the care fell below what is legally required. Details can be seen at the end of this report.

Summary of findings

We told the provider they needed to make significant improvements to address the breaches.

I am placing the service into special measures.

Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

Amanda Stanford

Deputy Chief Inspector of Hospitals (Central Region)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	**Inadequate**	We rated the service as **Inadequate** overall because: • There was no mandatory training programme in key skills for staff, and no induction programme. • There was no safeguarding policy and no written protocols available for staff to be able to identify and manage any safeguarding concerns. • There was no chaperone policy in place and there was no access to a suitable chaperone for intimate gynaecological scans. • The service did not control infection risk well. There was no infection prevention and control policy in place and no standard cleaning schedule and no clear arrangements for the management, collection and disposal of clinical waste. • There was no arrangements in place for maintenance and calibration of scanning equipment. • There was no schedule or process for secure destruction of paper records in line with legislation. This posed a risk to the confidentiality of client information. • There was not an effective governance framework in place to deliver good quality care. There were no written policies, processes or protocols in place to govern and monitor activity. • The provider had an overall vision for what they wanted to achieve but no clear plans or strategy to turn it into action. • The provider did not ensure that all staff underwent appropriate checks as required by schedule 3 of the HSCA 2008 (regulated activities) regulation 2014. • There was no mechanism for monitoring the quality and safety of the provider's practice. • The service had no systems in place to identify, record or manage risks and cope with both the expected and unexpected. • There was no systematic programme of clinical and internal audit

Summary of findings

- Information on the provider's website advertised services that were no longer being provided; sonographers and a manager who no longer worked at the location; and did not include the provider's name.

Summary of findings

Contents

Inadequate

Brayford Studio

Services we looked at

Diagnostic imaging;

Summary of this inspection

Background to Brayford Studio Limited

Brayford Studio Limited is an independent ultrasound service based in Lincoln. The service offers a range of obstetric and gynaecology ultrasound scans providing both medical and diagnostic scans, 4D bonding and pregnancy reassurance scans. People generally self refer to this service. The provider referred women to hospital or other services where required.

Brayford Studio Limited has had a registered manager who is also the provider and the only sonographer. At the time of the inspection, a new receptionist had recently been appointed. There are no other staff employed there.

Facilities include three allocated parking spaces for clients, a reception area, large waiting room, an ultrasound room, and toilet facilities which are for staff, clients and visitors. There is also a small kitchen and storage facility for staff.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a CQC assistant Inspector. The inspection team was overseen by Simon Brown, Inspection Manager.

Why we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out the inspection on 22 January 2019.

How we carried out this inspection

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us. We spoke with the provider and the receptionist, patients and relatives, and looked at facilities, equipment and records. We observed two scan procedures and how staff interacted with women and their families.

Information about Brayford Studio Limited

The service is registered to provide the following regulated activities:

- Screening and diagnostic procedures.

During the inspection, we looked at the facilities, including the ultrasound room, the waiting room and reception area. We spoke with the registered provider, who is also the sonographer, and the receptionist. We spoke with three clients and their families. During our inspection, we reviewed three sets of patient records.

Summary of this inspection

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service had been inspected two times, and the most recent inspection took place in March 2013 which found that the service was meeting all standards of quality and safety it was inspected against.

Activity:

The provider conducted approximately 500 scans each year. All were self-funded.

Track record on safety (October 2017 to October 2018):

Records were not available for the following;

- Number of never events
- Number of clinical incidents
- Number of serious injuries
- Number of complaints

Services accredited by a national body:

- There were no services provided that were accredited by a national body.

Services provided at the hospital under service level agreement:

- There were no services provided under a service level agreement

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Inadequate

We rated safe as **Inadequate** because:

- There was no mandatory training for staff, and no provision made for the newly recruited receptionist to undertake an induction programme.
- There was no safeguarding policy and no written protocols available for staff to be able to identify and manage any safeguarding concerns.
- There was no chaperone policy in place and there was no access to a suitable chaperone for intimate gynaecological scans.
- The service did not control infection risk well. There was no infection prevention and control policy in place and no standard cleaning schedule. However, the premises appeared generally clean throughout.
- There were no clear arrangements for the management, collection and disposal of clinical waste.
- There were no arrangements in place for maintenance and calibration of scanning equipment.
- There were no schedules or processes for secure destruction of paper records in line with legislation. This posed a risk to the confidentiality of client information.

However:

- In situations where the provider needed to break bad news, this was done immediately and sensitively.
- Where there were unexpected or significant findings during the scan procedure for pregnant women, the provider liaised directly with the local hospital where urgent care was required.
- The provider sent a copy of the scan report to client by email around two weeks after the scan. A printed summary was provided for the client along with digital images on the same day to take home.
- The provider had purchased new ultrasound equipment which had been recently installed, although not in use at the time of our inspection.

Are services effective?

Are services effective?

We do not currently rate effective in diagnostic imaging services.

Our findings were:

Summary of this inspection

- The provider did not routinely monitor the effectiveness of the service they delivered or compared their results with those of other local services to learn from them.
- The provider did not routinely collect information about patient outcomes.
- The provider did not conduct any audits of practice.
- The provider accessed NICE guidelines electronically to inform their practice, and attended courses twice a year to keep up to date with changes to ultrasound practice.
- Where clients were referred onto the hospital due to any anomaly detected, the provider asked the client to inform him of the outcome.
- The provider sent images from scans that had detected Downs syndrome to a clinician at the local NHS hospital so that the images could be assessed and feedback provided on the quality of the image.
- The provider attended courses twice each year to keep up to date with changes, however, they had not had their sonographer practice observed or assessed in the independent healthcare setting since completing their qualification in 2002.
- The provider did not routinely communicate with GP's, but had direct links with the midwifery centre at a local hospital to make immediate referrals for clients where a serious anomaly had been detected.

Are services caring?

Good

Are services caring?

We rated caring as **Good** because:

- Staff ensured women and people who accompanied them were treated with kindness and compassion.
- The receptionist was very welcoming when people arrived for their appointment, and took time to interact with people using the service and those who accompanied them.
- Where a heart beat could not be detected, the provider gave clients the option of receiving images of the baby as a keepsake and charges were waived.
- Women were mostly treated with dignity and respect. However, the location of the toilet in the reception area meant that women who were undergoing a procedure had to walk through the reception area in a gown or wrapped in a sheet.
- Women and people who accompanied them were provided with emotional support when they needed it.
- The provider had a number of cards from people who used the service previously, which were overwhelmingly complimentary.

Summary of this inspection

- The provider informed us that if there was any concern identified from the scan, women were immediately referred to the hospital.
- For a gender scan or an early reassurance scan women were provided with a booklet, which had contact details on for concerns or issues.
- The provider communicated with women and those accompanying them throughout their scan to provide comprehensive information.

Are services responsive?

Good

We rated responsive as **Good** because:

- The service planned and provided services in a way that met the needs of local people.
- The environment had comfortable seating, a separate waiting room, a toilet and children's toys were available. Refreshments including bottled water was provided.
- Information was available in leaflet form and on the website.
- Flexible appointment times were available which included evening and Saturday appointments.
- The service provided a specialist gynaecological scanning service that was not widely available.
- The service took account of patients' individual needs. Enough time was allocated for women to ask questions.
- The woman's partner and other members of the family including their other children were encouraged to join in the experience. Provision was made for them to observe the baby scan in the ultrasound room.

Are services well-led?

Inadequate

We rated well-led as **Inadequate** because:

- We were not assured that there were effective governance systems in place to ensure the regulated activities were carried on in accordance with the regulations. This meant there was a risk the health, welfare and safety of people who used the service might not be protected.
- There was not an effective governance framework in place to deliver good quality care. There were no written policies, processes or protocols in place to govern and monitor activity.
- The provider had an overall vision for what they wanted to achieve but no clear plans or strategy to turn it into action.
- The provider did not ensure that all staff underwent appropriate checks as required by schedule 3 of the HSCA 2008 (regulated activities) regulation 2014.

Summary of this inspection

- There was no policy for the storage, security and destruction of records. There was no schedule or process for secure destruction of records in line with legislation. There was a risk of unauthorised access to these records. This posed a risk to the confidentiality of client information
- There were arrangements with third party providers for some activities. However, arrangements were informal and were not supported by an agreed process or protocol.
- There was no mechanism for monitoring the quality and safety of the provider's practice.
- The service had no systems in place to identify, record or manage risks and cope with both the expected and unexpected.
- There was no systematic programme of clinical and internal audit
- Information on the provider's website advertised services that were no longer being provided; sonographers and a manager who no longer worked at the location; and did not include the provider's name.

However:

- The provider had completed the relevant qualification to conduct ultrasound scans.
- The provider was visible and approachable to staff and clients.
- Although there was no formal written vision, values or strategy, staff shared a set of values which was around ensuring the best possible experience for women and their families.
- Staff said they felt supported, valued and respected.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Inadequate	N/A	Good	Good	Inadequate	Inadequate
Overall	Inadequate	N/A	Good	Good	Inadequate	Inadequate

Inadequate

Diagnostic imaging

Safe	Inadequate
Effective	
Caring	Good
Responsive	Good
Well-led	Inadequate

Are diagnostic imaging services safe?

Inadequate

We rated safe as **inadequate.**

Mandatory training

- There was no mandatory training programme in key skills for staff at Brayford Studio Limited. The provider had previously accessed mandatory training through their position as a consultant gynaecologist and at the time of our inspection was undertaking a full suite of training modules online. However, no provision has been made for the newly recruited receptionist to undertake mandatory training.
- The provider told us that they attended annual training courses to keep up to date with any changes to practice in ultrasound scanning. Records of attendance were not available at the location on the day we inspected.
- New staff received a verbal induction and explanation about their role and how to manage all aspects of their work, including the appointment system, managing payments, and caring for clients and their families in the waiting areas. The newly appointed receptionist was experienced in dealing with members of the public but had not held a position in healthcare.

Safeguarding

- Staff did not fully understand how to protect patients from abuse and we were not assured that the service worked well with other agencies to do so. Not all staff had received training on how to recognise and report abuse.
- The service did not accept women under the age of 18 years. However, the provider did not routinely ask for identification for young women who may be under 18 years. We were told that careful questioning during the initial process would highlight whether a young person was under 18 years. In situations where the provider suspected that a young woman was under 18 years, they would refuse to provide a service in this instance.
- It is the duty of healthcare organisations to ensure that all health staff have access to appropriate safeguarding training to ensure staff understand the clinical aspects of child welfare and information sharing. The Safeguarding children and young people: roles and competences for health care staff intercollegiate document 2014, sets out the requirements related to roles and competencies of staff for safeguarding vulnerable children and young people. Level 2 training is required for all non-clinical and clinical staff that had any contact with children, young people and/or parents/carers.
- The provider informed us they had completed adults and children's safeguarding training as a consultant gynaecologist, however, there were no records of this kept at the location. We saw electronic evidence of safeguarding training which was booked for the provider to complete online.
- At the time of our inspection, there was no provision made for the receptionist to undertake safeguarding training, and no risk assessment made to mitigate this risk. However, the provider told us that they would consider making this available. Although services were not provided for clients under 18 years, training is necessary for non-clinical staff because clients attended with children.

- We did not see a safeguarding policy at the location and no written protocols available for staff to be able to identify and manage any safeguarding concerns.
- The provider knew to refer any safeguarding concerns to the local authority, and told us that the receptionist would inform the provider of any concerns they may have in the first instance.
- Brayford Studio Limited did not have a chaperone policy in place and there was no access to a chaperone for intimate gynaecological scans. The provider encouraged clients to bring a partner or friend to act as a chaperone, and if there was no partner or friend available, then the receptionist would act as a chaperone. A chaperone is usually a healthcare professional who have knowledge of the chaperone role and familiar with the procedures involved in performing a routine intimate examination. We were not assured that the provider or the receptionist understood the role and remit of the chaperone role. However, we noted that the name of the person acting as chaperone was recorded in the client's record. The provider also informed us that they would not conduct a gynaecological scan for any client who refused a chaperone.

Cleanliness, infection control and hygiene

- The service did not control infection risk well. There was no infection prevention and control policy in place and no standard cleaning schedule.
- The environment was generally clean; however, the ultrasound room was cluttered. We also noted there were corded window blinds in use in the waiting room where children waited. This provided a potential ligature risk for children.
- Standards of cleanliness were maintained in the reception and waiting areas every day by the receptionist and there was a cleaner who attended weekly. We noted that the waiting areas, kitchen and toilet were clean and free from dust, however there was visible dust on the top of the ultrasound machine.
- The ultrasound equipment and couch were cleaned at the start of each ultrasound session. We observed the equipment and couch being cleaned between each patient with antiseptic wipes. The provider showed us the process for cleaning the trans vaginal probe. A disposable sheath was used on the probe for each patient. Non- latex sheaths were available for patients with a latex allergy. At the end of the scan the sheath was removed and disposed of and the probe was cleaned with a high level disinfectant wipe. Clinical waste such as sheaths and gloves were disposed of in a waste bin in the ultrasound room, however, the arrangements for collection of clinical waste were unclear. We also noted a sharps box was stored in the kitchen which contained used sharps but was not dated or signed. The provider told us that this was not in use and would be removed from the premises that day. There was an informal arrangement with a midwife to attend the location to take blood samples for Down's Syndrome when required. The midwife provided the necessary equipment, disposal of clinical waste from the procedure, and transport of the blood sample.
- General cleaning equipment was stored in the kitchen area and toilet cleaning equipment in the toilet area. Standard cleaning wipes and probe disinfectant wipes were kept in the ultrasound room. Carpets were vacuumed weekly. The room in which the scans were performed was carpeted, which did not promote easy cleaning and infection prevention and control.
- Hand-washing facilities were available in the kitchen and toilet areas but these were
- There had been no hand hygiene or cleaning audits conducted during the previous 12 months.

Environment and equipment

- The service had suitable premises. The waiting area and reception area was comfortable and pleasant with sufficient seating for people waiting. There were toys available for young children. The door to the ultrasound room was kept closed during consultations and examinations, however, conversations could be heard by people in the reception area.
- The equipment was not entirely suitable. We did not see any first aid or emergency equipment at the premises and there was no risk assessment made to mitigate risk of emergency or collapse.
- The provider had purchased new ultrasound equipment which had been recently installed. It was

not in use at the time of our inspection. The provider was planning to meet with the product representative for a demonstration of the product and any other relevant information.

- The previous ultrasound equipment was still in use at the time of our inspection. There were no service records or maintenance contract available on site, however, we saw that the machine had last been serviced in October 2016. We are unable to say whether this was in line with the manufacturer's instructions.
- The provider told us that the new machine came with a guarantee and that a plan would be agreed for ongoing maintenance.
- We saw that a small stock of disposable gloves and ultrasound probe covers were available in the ultrasound room, which included latex-free products for clients who had a latex allergy.

Assessing and responding to patient risk

- Clients who presented at the clinic were generally well. There was no escalation policy for women who appeared unwell or displaying medical symptoms, and no risk assessment to mitigate this risk. However, the provider advised clients to speak with their GP if they had concerns.
- Where there were unexpected or significant findings during the scan procedure for pregnant women, the provider liaised directly with the local hospital where urgent care was required, for example; if the baby's heart beat was not detected during the scan, and for any other potential concern, the patient was provided with a letter outlining the scan findings to take to the hospital or care provider. Women were advised to continue with their NHS scans as part of the maternity pathway.
- Women who attended for a gynaecological scan were advised to discuss the scan findings with their GP or gynaecologist. However, there was no process in place to escalate abnormal findings. For example; if cancer was suspected.
- There was no basic life support equipment on site to use in an emergency if a person collapsed or became very unwell, and no risk assessment made to mitigate the risk of not having this.

Staffing

- There was one sonographer and one receptionist who worked part time hours which were flexed around the needs of the service.
- There was no formal induction policy for new staff, however, we were told that a full explanation of every aspect of the role was provided during the first few days and weeks in the role, and that the provider was very supportive and approachable.
- We were told that there was no lone working at the clinic. The provider took annual leave and days off at the same time as reception staff, and if the receptionist was unable to attend due to sickness, then no scans would be conducted during that time.

Records

- Staff kept detailed records of clients' care. Records were clear, up-to-date and easily available to all staff providing the service.
- All client records were paper records which were stored in a locked cabinet in the reception area. Clients were required to complete a scan request form on arrival which included details of their pregnancy or gynaecological condition. The form also included the name of the person they had brought to act as a chaperone and the client signed to indicate they had consented to the scan and agreed with the terms and conditions of the service provided. The provider used the form to record additional information during the consultation and scan procedure and stored the record indefinitely. However, there was no schedule or process for secure destruction of records in line with legislation. This posed a risk to the confidentiality of client information.
- Where a blood test was performed, the provider received the result electronically and attached a printed copy of the result to the client's record.
- All scan images detailed patient identity, examination type, date and time and were stored digitally on the hard drive of the ultrasound scan equipment for future reference.

Diagnostic imaging

- The provider sent a copy of the scan report to client by email around two weeks after the scan. A printed summary was provided for the client along with digital images on the same day to take home.
- It was the client's responsibility to share the scan report with their GP or midwife. Where concerns were identified, the provider shared the findings of the scan directly with the health professional once a verbal referral had been made.

Medicines

- There were no medicines stored or used at the clinic.

Incidents

- The service had not recorded any patient safety incidents. When things went wrong, staff apologised and gave clients honest information and offered a refund. However, there was no incident management policy in use and no record of incidents at the clinic. However, there were a small number of events that had occurred that would have been relevant to record and manage as an incident. For example; some clients who had left the premises without paying, and an incident where an item of personal property was stolen from the premises. Although there was no record of learning from these events, the provider had made changes to the way they worked to mitigate this risk in the future.
- The provider was aware of the duty of candour and informed clients about any problems incurred. For example; when there was a technical problem with the printing facility, the provider was unable to issue a client with suitable images and so invited them back for a further scan free of charge once the printing issue had been resolved.
- In situations where the provider needed to break bad news, this was done immediately and sensitively. Where a heartbeat could not be detected, the provider gave clients the option of receiving images of the baby as a keepsake and charges were waived.

Are diagnostic imaging services effective?

We do not currently rate effective in diagnostic imaging services.

Evidence-based care and treatment

- The service provided care and treatment based on national guidance and evidence of its effectiveness. However, there was a lack of policies and procedures to support their use.
- The provider told us that they accessed National Institute for health and care excellence (NICE) guidelines electronically to inform their practice, and attended courses twice a year to keep up to date with changes to ultrasound practice. However, we did not see any documentary evidence to support this.
- There was no evidence of use of the 'pause and check' system prior to conducting scans. Pause and check is a set of checks developed by the Society and College of Radiographers (SCoR) and the British Medical Ultrasound Society (BMUS) which need to be made when any ultrasound examination is undertaken.
- Technology was used to deliver effective care. For example; where anomalies were detected, relevant images were sent directly to the clinician providing ongoing care.

Nutrition and hydration

- There was no drinks machine where people could purchase refreshments, however, refreshments including bottled water were provided as required.

Patient outcomes

- The provider did not routinely monitor the effectiveness of the service they delivered or compared their results with those of other local services to learn from them.
- The provider did not routinely collect information about patient outcomes.
- Where clients were referred due to any anomaly detected, the provider asked the client to inform them of the outcome.
- The provider monitored an aspect of their practice and described how they sent images from scans that had detected Down's syndrome to a clinician at an NHS hospital so that the images could be assessed and feedback provided on the quality of the image.
- The provider did not conduct any audits of practice.

Inadequate

Diagnostic imaging

Competent staff

- The provider made sure staff were competent for their roles once they had been recruited by working alongside them to provide explanation and guidance. However, there was no formal induction process or appraisal process to monitor staff's work performance and there were no supervision meetings with them to provide support and monitor the effectiveness of the service.
- The provider was the sonographer and had completed a training course to provide ultrasound services in 2002. They held a certificate of competence with The Standing Joint Committee of The Royal College of Obstetricians and Gynaecology and The Royal College of Radiologists.
- The sonographer attended courses twice each year to keep up to date with changes, however, had not had their sonographer practice observed or assessed in the independent healthcare setting. The provider had received an appraisal within the last year for their previous work as a gynaecologist. However, there were no plans in place for this aspect of their clinical practice to be assessed.
- The provider told us that there was a regular turnover of reception staff due to the limited number of hours they were required to work and the requirement to be extremely flexible with their work hours. There were no recruitment files available for us on the day of our inspection and no formal induction policy or process in place, and no records of performance management or appraisal process.
- There were no training records for reception staff available on the day of our inspection. We saw that the provider had registered to complete a number of mandatory e-learning modules with a local medical agency.

Multidisciplinary working

- The provider did not routinely communicate with GP's, but had direct links with the midwifery centre at a local hospital to make immediate referrals for clients where a serious anomaly had been detected.
- There were no clear links in place with local safeguarding specialists.

Consent and Mental Capacity Act

- Women were fully informed about the nature of the examination at the time of attendance. This enabled the person to give their informed consent freely and voluntarily, which was recorded on the record.
- For baby sexing scans, the provider also checked again during the scan prior to informing the client of the sex of the baby. Women were advised that there was a possibility of an error in sexing scans.
- Clients were informed of the benefits and risks of using the service at the time of consultation.
- We did not see evidence of the provider having attended training for conducting mental capacity act assessments.

Are diagnostic imaging services caring?

Good

We rated caring as **good.**

Compassionate care

- Staff cared for clients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff ensured women and people who accompanied them were treated with kindness and compassionate care. We observed this when people were greeted in the reception area, whilst they waited to be called through, during their appointment and as they left the service.
- The receptionist was very welcoming when people arrived for their appointment, time was taken to interact with people using the service and those who accompanied them. We spoke with one woman, who informed us the receptionist helped them relax before their scan. We observed staff reassure woman and people who accompanied them.
- Women were mostly treated with dignity and respect. The provider left the ultrasound room to allow women to change, then knocked before entering the room once they were ready. The ultrasound room had

frosted glass on the door to enable privacy. However, we observed one woman exiting the scanning room through the reception to use the toilet facilities, with a sheet wrapped around them.

- There was no lock on the inside of the door to prevent someone entering uninvited, however, the receptionist knew to ensure no one entered during a procedure. Conversations taking place in the ultrasound room could be partially overheard from the reception area.
- Staff demonstrated they understood women's needs and were non-judgemental towards women and people who accompanied them.

Emotional support

- Women and people who accompanied them were provided with emotional support when they needed it. We observed staff reassuring women, and providing further information to decrease their emotional stress.
- The provider had many cards from people who used the service previously, one in particular thanked the provider who supported them in a difficult time when a heartbeat was not detected. The cards we looked at described women being cared for by the provider, during an emotional time.
- The provider informed us that if there was any concern identified from the scan, women were immediately referred to the hospital.
- For a gender scan or an early reassurance scan women were provided with a booklet, which had contact details on for concerns or issues.

Understanding and involvement of patients and those close to them

- Staff involved clients and those close to them in decisions about their care and treatment**.**
- The provider consistently communicated with women and those accompanying them throughout their scan. During a gender reveal scan, we observed the provider repeatedly ask if they wanted to know the gender of the baby before it was revealed. The provider also ensured women received very detailed information, and provided them with the best possible pictures to take home.
- The provider had installed a large television screen in the ultrasound room to project the scan images so that clients and their families could enjoy seeing the new baby together. The provider interacted with the partner and siblings as well as the woman to help them feel involved in the experience.
- We observed women express their views with staff, and one woman we spoke with described actively being involved in decisions made about their care.
- Discussions about cost were appropriate, as women stated they were informed about the process before hand. Women paid a deposit when they booked their scan, and then paid the balance on arrival once they had completed their form.

Are diagnostic imaging services responsive?

Good

We rated responsive as **good.**

Service delivery to meet the needs of local people

- The service planned and provided services in a way that met the needs of local people. The environment had comfortable seating, a separate waiting room, a toilet and children's toys were available.
- Information was available in leaflet form and on the website.
- Flexible appointment times were available which included evening and Saturday appointments.
- The service also provided a trans-labial ultrasound scanning service. This was a specific gynaecological scanning service to meet the needs of women throughout the country who had undergone surgical treatment for a urinary stress incontinence problem during the 1980s and 1990s whereby a mesh implant had resulted in complications later in life. The provider told us that there was just one other service in the country where this was available for this specific problem.

Meeting people's individual needs

- The service took account of patients' individual needs. Enough time was allocated for women to ask questions. The woman's partner and other members of the family including their other children were encouraged to join in the experience. Provision was made for them to observe the baby scan in the ultrasound room.
- There was no evidence of equality and diversity training for staff.
- There was no provision for accessing translation services if required.

Access and flow

- People could access scans in a timely way and at a time to suit them.
- Appointments could be made online through the provider's website or by telephone. Clients were offered a choice of appointments.
- We saw that most women were seen quickly after their arrival time, however, where one scan procedure took longer than expected, we noted that other clients were kept waiting more than 30 minutes after their appointment time. The receptionist kept the clients informed of any delays and offered refreshments.
- Clients received a verbal explanation of the scan findings throughout the scan procedure. They were provided with scan images and a report summary on the day. For gynaecological scans, clients received a report summary and images on a CD to take away with them. A full report was sent to clients by email around two weeks after the scan. Where concerns were detected, a report and images was issued to the ongoing care-giver immediately with the client's consent.
- If a scan needed to be cancelled or postponed, this was rebooked as soon as possible.

Learning from complaints and concerns

- The service received very few complaints but treated these seriously. For example; if a client was dissatisfied with the outcome, a refund was offered.
- We did not see information displayed about how to complain. The provider told us that they resolved any dissatisfaction very quickly.

Are diagnostic imaging services well-led?

Inadequate

We rated well-led as **inadequate.**

Leadership

- The provider of the service did not demonstrate they had the right skills and abilities to run a service providing high-quality sustainable care.
- They had the skills, knowledge, and experience to conduct ultrasound scans but had not established
- The provider was approachable and supportive to staff.

Vision and strategy

- The provider had a vision for what they wanted to achieve but no clear plans or strategy to turn it into action.
- Although there was no formal written vision, values or strategy, staff shared a set of values which was around ensuring the best possible experience for women and their families.

Culture

- Staff said they felt supported, valued and respected.
- There was a culture of openness and honesty. The provider told us that they were always gave honest factual information to clients in a sensitive manner.
- There were no formal processes in place to the ensure the provider met the requirements of the duty of candour, however, they were aware of the requirement to inform clients if something went wrong.

Governance

- There was not an effective governance framework in place to deliver good quality care. There were no written policies, processes or protocols in place to govern and monitor activity.
- The provider did not ensure that all staff underwent appropriate checks as required by schedule 3 of the HSCA 2008 (regulated activities) regulation 2014. For example; DBS checks

Inadequate

Diagnostic imaging

- There were arrangements with third party providers for some activities. For example; a midwife attended on occasions to take blood samples; maintenance of equipment on an ad hoc basis; weekly cleaning of the premises; and quality assessment of scans following detection of Down syndrome. However, arrangements were informal and were not supported by an agreed process or protocol.
- There was no mechanism for monitoring the quality and safety of the provider's practice.

Managing risks, issues and performance

- The service had no systems in place to identify, record or manage risks and cope with both the expected and unexpected.
- There was no systematic programme of clinical and internal audit.
- Staff were instructed about how to manage situations but were not made aware of any formal policies and procedures.

Managing information

- The service did not collect, analyse, or manage information well to support all its activities.
- The ultrasound machine stored images and reports which could be printed on request. All patient records were paper records.
- There was no policy for the storage, security and destruction of records. We saw patient records that had been stored in a filing cabinet for a number of years. The records were stored in a locked cabinet in the reception area. There was no schedule or process for secure destruction of records in line with legislation. There was a risk of unauthorised access to these records. This posed a risk to the confidentiality of client information
- Although there was no confidentiality policy in place, the receptionist had been instructed about keeping patient details confidential and knew to place patient records face down.
- Women were provided with a statement that included terms and conditions of the service and the amount and method of payment as part of the patient record.
- Advertising was mainly through the service website which included prices of scans and packages. However, the information on the website was out of date as it advertised a large number of services that were no longer being provided. It also identified that other sonographers worked at the location and there was a photograph of a midwife manager who no longer worked at the location. The provider's name and photograph was not included in the website information, even though their qualifications were listed there.

Engagement

- The service engaged well with clients and their families during consultation.
- The provider had engaged and involved the newly recruited receptionist in decisions about refurbishing the waiting room and had listened to their ideas.
- People's views and experiences were gathered through feedback and comments left on the website and through thank you cards sent to the provider. There was a large number of photographs of babies in the waiting room which satisfied clients had sent in.

Learning, continuous improvement and innovation

- There were no systems and processes for learning continuous improvement and innovation.
- The provider had purchased new up to date ultrasound equipment which would further improve the quality of the images provided to clients and enable more accurate diagnosis of gynaecological conditions.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Ensure that persons providing care to service users have the qualifications, skills and experience to do so safely.
- Ensure there is a process for the provider's practice to be regularly assessed and appraised with regard to providing ultrasound service in the independent healthcare setting.
- Ensure a DBS check is completed for all staff acting in the chaperone role when recruited, or complete a risk assessment to mitigate the risk.
- Ensure that they assess the risk of, and prevent, detect and control the spread of infections, including those that are healthcare related.
- Ensure they have and implement robust procedures and processes that make sure people are protected and safeguarded from abuse and improper treatment. Ensure that chaperones used have the knowledge and skills to perform this role.
- Ensure that staff receive safeguarding training that is relevant and at a suitable level for their role. Staff should be kept up to date and able to recognise different forms of abuse and ways they can report concerns.
- Ensure they have systems and processes in place to audit, monitor and improve the quality and safety of the service. The systems and processes should be continually reviewed to make sure they remain fit for purpose.
- Ensure they assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk from the carrying on of the regulated activity.
- Ensure records are maintained and destroyed securely with systems and processes that support the confidentiality of people using the service and not contravene the Data Protection Act 1998.

Action the provider SHOULD take to improve

- The provider should ensure that corded blinds used in the waiting areas comply with safety requirements.
- The provider should ensure there is a schedule for maintenance and calibration of the ultrasound equipment in line with manufacturers recommendations.
- The provider should consider a washable floor surface in the ultrasound room and reducing the amount of clutter to enable more effective cleaning.
- The provider should update the company website to reflect the current services offered and to remove details of staff who no longer work there.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **Regulation 12 (2)(c)(h)**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment **Regulation 13 (1)(2)**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Regulation 17(2) (a)(b)(c)**

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment Warning notice issued under Section 29 of the HSCA

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance Warning notice issued under Section 29 of the HSCA