

Baby It's You Limited

Quality Report

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Date of inspection visit: 24 June 2019
Date of publication: 29/08/2019

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

Are services safe?

Are services responsive?

Are services well-led?

Overall summary

Baby It's You Limited is operated by Baby It's You Limited. The service is a single speciality independent healthcare provider offering 3D, 4D and early pregnancy scans to self-funding people who use the services.

Following a comprehensive inspection in February 2019, the provider was issued with a suspension notice and a warning notice. The suspension lasted for two months and a further site visit was carried out on 1 April 2019 to assess whether the provider had addressed the urgent and immediate concerns which had resulted in the imposition of the suspension notice. The provider was issued with a warning notice, which all related to Regulation 17: Good governance.

The provider was issued with a warning notice because:

- There were no policies and procedures in place to support staff to monitor, assess and record risks in relation to health and safety for both staff and service users.
- There was no privacy and dignity policy in place. There was no lock on the scan room door and the privacy curtain could not be closed.
- There was no consent and mental capacity policy in place to enable services users to make an informed decision about their scan and potential risks to their pregnancy.
- There was no complaints policy, information or leaflets in place, there was no signage in place to advise service users how to make a complaint.

Summary of findings

- There was no infection protection and control policy in place which included cleaning schedules and audits to monitor compliance with the policy. The premises were visibly dirty during the inspection.
- There was no risk policy in place and risk assessments were not completed for environmental and clinical factors.
- There was no data management policy in place to protect service user's personal information.
- There was no policy for the training of staff, appraisals and supervision, whistleblowing, recruitment and incidents.
- There were no governance arrangements in place to assure the provider that clinical practice was evidence based and in line with national guidance.
- There were no audits to monitor and review practice.
- There was no evidence or record of staff meetings to monitor and improve the quality of the service.
- The provider did not consider risk or hold a risk register.

Following issue of the warning notice, the provider sent information and evidence to demonstrate how they were meeting the regulation. We carried out a review of this evidence to ensure the provider had taken action to comply with the regulations. We found that there had been improvements made; however, there was still work to do in some areas.

We found the following improvements had been made:

- The provider had a privacy and dignity policy. During a site visit to check improvements had been made to enable the suspension to be lifted, we observed a lock had been bought for the scanning room door and the curtains could be fully closed.

- During the site visit, we observed the premises to be visibly clean.
- The provider had information for service users on how to make a complaint that was to be displayed in the clinic.
- Recruitment and staff training processes were in place.

However:

- Although new policies had been written for privacy and dignity, consent and mental capacity, complaints, infection prevention and control, risk, data management, staff training and development, assessing and managing risk, whistleblowing, recruitment, emergency referral process and governance, some of them referenced old CQC guidance and referred to other services. Further improvements therefore needed to be made to the policies.
- The provider had carried out a workplace risk assessment, but this only identified one risk. It was not clear how regular review of the risk would be evidenced. The provider could not identify any other risks to the service.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and to help the service improve. We also issued the provider with one requirement notice. Details are at the end of the report.

Ann Ford

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Summary of each main service

We found that the provider had made some improvements since the issue of the warning notice. However, there were still improvements to be made with regards to policies and risk management.

Summary of findings

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Summary of this inspection

Background to Baby It's You Limited

Baby It's You Limited is operated by Baby It's You Limited. It is a single speciality independent healthcare provider, which opened in Doncaster in 2013. The service primarily serves South Yorkshire. It also accepts women from outside this area.

The service has had a registered manager in post since 2013.

The service is registered for the regulated activities:

- Diagnostic and screening procedures.

An inspection of the service was carried out in February 2019 and the service was suspended for a period of two months. The service was rated as inadequate and served with a warning notice in relation to Regulation 17: Good governance.

Our inspection team

A desktop review was undertaken to assess the information and evidence provided in response to the warning notice. A site visit had been done previously to check improvements had been made to ensure the suspension notice could be lifted.

Information about Baby It's You Limited

Baby It's You Limited offers 3D and 4D pregnancy scans, sexing and early pregnancy imaging services. The service employs one sonographer, an office manager and three reception/ production technician staff.

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?

- Premises were visibly clean during a site visit.
- The provider had produced an infection prevention and control policies. However, some of these policies were not relevant to the services provided and referred to services provided within the home.
- Clinical guidance documents had been produced, which gave guidance for staff who identified any foetal anomalies.
- Although the provider had produced a document for assessing and managing risks for service users, this referred to assessments that the service would not undertake, such as falls assessments and skin assessments.

Are services responsive?

- Complaints information was available in the clinic.
- The provider had produced a complaints policy. However, this referred people who used the service to the local government ombudsman if they were not happy with the complaint response. The local government ombudsman would not be the correct organisation for people who used this service to contact.

Are services well-led?

- Following receipt of the warning notice, the provider had produced various policies. However, a number of these policies referenced old CQC guidance and information that was not relevant to their type of service. There was therefore more work needed to produce relevant policies.
- More work was needed on a risk register as the provider had only identified one risk to the service, which had been captured in a workplace risk assessment.

Diagnostic imaging

Safe

Responsive

Well-led

Are diagnostic imaging services safe?

Cleanliness, infection control and hygiene

- At the inspection in February 2019, the premises were visibly dirty. During a follow up site visit, the premises appeared visibly clean.
- At the inspection in February 2019, there were no infection prevention and control policies or cleaning schedules. Following receipt of the warning notice, the provider produced infection prevention and control policies. However, these included policies that would not be relevant to the service, such as invasive devices and aseptic technique policies, along with general infection prevention policies. All policies referred to providing services in the home, which the service did not do.

Assessing and responding to patient risk

- At our inspection in February 2019, the service had no risk assessment policy or any guidance for staff around potential risks. We did not see any evidence of robust risk identification, escalation or management process.
- During a follow up site visit, we saw that clinical guidance documents had been produced, which included actions for staff to take in response to a range of foetal anomalies and contact telephone numbers for NHS services.
- Evidence provided in response the warning notice included a document entitled 'Assessing and managing risks for service users'. However, this referred to the service conducting falls assessments and skin assessments, which would not normally be routinely done by this type of service.

Are diagnostic imaging services responsive?

Learning from complaints and concerns

- At the inspection in February 2019, we found the provider did not have a robust system to enable individuals to manage and investigate complaints. There was no clear guidance for people who used the service to raise a complaint.
- At a follow up site visit, we saw complaints information, which would be available for patients. We saw complaints responses sent to patients, which we had not seen during the inspection in February 2019.
- Following the warning notice, the provider produced a complaints policy. However, this did not meet the needs of people using the service. For example, the complaints policy advised people who used the service to contact the local government ombudsman if they were not happy with the complaint response. The local government ombudsman is the final stage for complaints about councils, adult social care providers and some other organisations providing local public services, therefore it would not be relevant for service users of a baby scanning service.

Are diagnostic imaging services well-led?

Governance

- At our inspection in February 2019, we found there was no effective governance framework to support the delivery of high quality patient care. The service had no policies or procedures, including policies to protect service user's privacy and dignity, policies and procedures in relation to mental capacity and consent, policies for whistleblowing or policies for staff training and development. There were no audits to monitor and review practice.

Diagnostic imaging

- Following receipt of the warning notice, the provider produced various policies, including a mental capacity act policy, staff training and development policy, data management policy, whistleblowing policy and a privacy and dignity policy. However, a number of these policies contained information that would not be relevant to the service, such as advanced directives and living wills in the mental capacity act policy and references to NHS and social care staff in the whistleblowing policy. The staff training and development policy and the data protection policy contained references to old CQC guidance.
- Following receipt of the warning notice, the provider sent an example of an infection prevention and

control audit that would be undertaken. However, there has been insufficient time to check whether these audits have been completed regularly and this will be followed up at subsequent inspections.

Managing risks, issues and performance

- At the inspection in February 2019, the provider did not have a risk register for the service and had not completed risk assessments for any aspect of the service or working environment.
- Following receipt of the warning notice, the provider produced a workplace risk assessment. However, this only identified one risk referring to slips and trips and did not contain a section for re-evaluation of the risk. There was therefore a risk that there would be no ongoing assessment or monitoring of the risk identified.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

Action the provider MUST take to meet the regulations:

- The provider must ensure governance systems and processes are introduced and operated effectively to ensure the service is assessed and monitored and any risks mitigated. Regulation 17(1)(2)(a)(b)
- The provider must ensure policies are further developed to accurately reflect their service and ensure they do not contain out of date or irrelevant guidance. Regulation 17(1)(2)(a)
- The provider must continually evaluate and seek to improve their governance and auditing practice. Regulation 17(1)(2)(a)

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	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>Regulation 17 HSCA 2008 (Regulated Activities) Regulations 2014 Good governance</p> <p>The provider did not effectively identify and monitor risks.</p> <p>The provider had not fully developed policies relevant to the service.</p> <p>The provider did not undertake regular audits.</p>