

# The Well - One Limited

# Well-One Clinic

## Inspection report

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## Overall summary

We carried out an announced comprehensive inspection on 7 March 2018 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

### **Our findings were:**

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

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

#### **Are services effective?**

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

#### **Are services caring?**

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

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

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

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

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

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory

functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

Well-One clinic is an Independent Health clinic. The clinic provides general practice, consultation and treatment without accommodation. The provider offers services across a range of areas but in particular in relation to Lyme disease and chronic fatigue.

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. At Well One Clinic a service was provided called RIFE treatment which is short wave therapy delivered by a machine. This was built for the clinic by a PhD scientist following research into the various types of RIFE machines. This service is registered with CQC under the Health and Social Care Act 2008 in respect of the treatment of disease, disorder or injury by, or under the supervision of, a medical practitioner, including the prescribing of medicines. At Well One Clinic the RIFE treatment that is provided is exempt by law from CQC regulation. Therefore we were not able to inspect the RIFE treatment element of the service.

# Summary of findings

Dr Beryl Beynon 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.

We obtained feedback from patients through 16 completed comment cards and speaking with two patients during the inspection. All the feedback was very positive and patients commented that staff offered excellent care and were supportive and responsive to questions and that they had confidence in the service provided. Patients told us they had no difficulties in arranging a convenient appointment and that staff put them at ease and listened to their concerns.

## Our key findings were:

- There was an open and transparent approach to safety and a system in place for reporting and recording incidents. However we found that the systems were not always followed, we saw examples of incidents that had not been reported and investigated.
- Arrangements for the management of medicines at the service did not always keep patients safe. Patients were not informed if a medicine they were prescribed was being used outside of its licence and when patients were prescribed medicines that required monitoring this was not always undertaken.
- Patients reported they were involved in their care and decisions about their treatment.
- Information about services was available and easy to understand.

- All consultation rooms were organised and equipped, with good light and ventilation.
- Clinical staff maintained the necessary skills and competence to support the needs of patients. Staff were not up to date with all required training.
- Staff were aware of current clinical guidelines.
- Staff were kind and caring and put patients at their ease.
- The provider was aware of the requirements of the Duty of Candour.
- Systems and processes were in place for managing governance in the service. However these were not fully implemented and followed.

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

- Ensure care and treatment is provided in a safe way to patients in respect of the management of medicines
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care

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

There were areas where the provider could make improvements and should:

- Review arrangements for the provision of medicines and equipment for use in a medical emergency.
- Review the process for confirming parental responsibility when children attend the clinic.
- Review policies to check they are relevant to the service.

# Summary of findings

## The five questions we ask about services and what we found

We always ask the following five questions of services.

### **Are services safe?**

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

The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of this occurring in the future is low once it has been put right. We have told the provider to take action (see full details of this action in the Requirement Notices section at the end of this report).

- Staff received training in safeguarding and knew how to recognise the signs of abuse and how to report concerns.
- There were systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. However these were not always implemented and followed.
- The staffing levels were appropriate for the provision of care and treatment.
- Premises and equipment were clean and properly maintained.
- Arrangements for the management of medicines at the clinic did not always keep patients safe.

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### **Are services effective?**

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

- The provider was aware of published research and current guidance and they subscribed to a number of medical journals to enable them to remain up to date. We found that the clinic was providing effective care however this was not always in line with current guidelines.
- Patients received a comprehensive assessment of their health needs which included their medical history and
- Staff who were registered with a professional body such as the General Medical Council (GMC) had opportunities for continuing professional development (CPD) and were meeting the requirements of their professional registration. The Doctor had completed their revalidation in 2016.
- Staff were knowledgeable about how to ensure patients had sufficient information and the mental capacity to give informed consent.
- Staff we spoke with were aware of the impact of patients' and their family's general health and wellbeing and were proactive in providing information and support.

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### **Are services caring?**

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

- We saw evidence that patients were cared for and supported and could contact staff anytime for advice.
- Feedback from patients through completed comment cards and discussion were very positive about their experiences at the service. Patients were happy with the care they received and felt fully involved in making decisions about their treatment.
- Patients also commented that the staff were committed to their work and displayed empathy, friendliness and professionalism towards them. Patients were treated with dignity and respect.

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

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

- The clinics' appointment system met patients' needs and patients told us they could get an appointment quickly if required.

# Summary of findings

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- The clinic took patients views seriously and valued comments and compliments from patients.
  - There was a complaints process in place and information on the process was available in the reception area.
  - All areas in the clinic were accessible including the waiting area, consultation rooms, the communal meeting room and toilet.
  - Information on fees was available on the service website.
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## **Are services well-led?**

We found that this service was not providing well-led care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Requirement Notices section at the end of this report).

We found areas where improvements should be made relating to well led. This was because some policies did not fully reflect the service.

- Review policies to check they are relevant to the service.

The service had some arrangements to ensure the smooth running of the service.

- Policies and procedures were in place to support the safe running of the service.
  - There was a clearly defined structure and staff felt supported and appreciated.
  - The practice team kept complete patient care records which were clearly written and stored securely.
  - The practice monitored clinical and non-clinical areas of their work to help them improve and learn. This included infection control monitoring and asking for and listening to the views of patients and staff.
  - Systems and processes were in place for managing governance in the service. However these were not always fully implemented and followed. We found there were gaps in training and no clinical audit had been undertaken to monitor the quality of care and treatment.
  - The culture within the service was open and transparent.
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# Well-One Clinic

## Detailed findings

### Background to this inspection

Well One Clinic Jacobs Well Yard, Swinemoor Lane, Beverley, HU17 0JX is an independent provider of medical services. The provider offers services across a range of areas but in particular in relation to Lyme disease, chronic fatigue and psychological therapies. The service has a website where people can access information, [www.welloneclinic.org.uk](http://www.welloneclinic.org.uk). Services are available to people on a pre-bookable appointment basis and there is an open door support session on a Wednesday afternoon. The service is based in a single storey building and consists of a reception and waiting area, consultation rooms and a communal meeting room.

Well One Clinic provides a fee charging service consisting of consultations and treatment particularly in relation to the management of Lyme disease, chronic fatigue and psychological therapies.

The clinic team consists of one GP, an administrator and four volunteer administration staff. During the inspection we spoke with the GP, the administrator and two of the volunteer administration staff. We looked at practice policies and procedures and other records about how the service is managed.

The clinic is open 9am to 5pm, Monday and Thursday, 9am to 12.30pm on Tuesday, 9am to 4pm on Wednesday and 9am to 3pm on Friday.

The inspection took place on 7 March 2018 and was led by a CQC inspector who had access to advice from a GP Specialist Advisor. The team also included a CQC Medicines Inspector.

Prior to the inspection we reviewed information provided by the Provider. We informed the Clinical Commissioning Group CCG and Healthwatch that we were inspecting the service; the CCG did not share any concerns about the service. We did not receive any information of concern from Healthwatch.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

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

# Are services safe?

## Our findings

There were areas where the provider could make improvements and should:

- Review arrangements and undertake a risk assessment for the provision of medicines and equipment for use in a medical emergency.

### Safety systems and processes

The service had clearly defined and embedded systems, processes and practices in place to keep patients safe and safeguarded from abuse.

- Arrangements were in place to safeguard children and vulnerable adults from abuse which reflected relevant legislation and local requirements.
- Safeguarding policies and contact information was accessible to all staff. The policies clearly outlined who to contact for further guidance if staff had concerns about a patient's welfare.
- There was a lead member of staff in place for managing safeguarding concerns and guiding staff. Staff demonstrated they understood their responsibilities and we were told they had received training relevant to their role. We confirmed the doctor had completed training in safeguarding vulnerable adults and safeguarding children level three. The doctor told us they had also joined a group for volunteer organisations to keep up to date with safeguarding issues.
- The practice had a whistleblowing policy in place. Staff told us that they felt confident that they could raise concerns about colleagues without fear of recriminations.
- There was a chaperone policy and the patient treatment record informed them that they could request a chaperone.
- All staff had been employed in the service for a number of years. We reviewed two personnel files one for employed staff and one for a volunteer. We found that appropriate recruitment checks had been undertaken prior to employment. For example, proof of identification, references and qualifications. We saw evidence that the appropriate checks through the Disclosure and Barring Service (DBS) had been undertaken in line with the provider's policy.

- The Doctor was registered with the General Medical Council (GMC) and they had undergone revalidation in 2015, records we looked at confirmed this.
- The clinic had current employer's liability insurance and the doctors medical indemnity insurance was up to date.

### Monitoring and responding to risks

There were procedures in place for monitoring and managing risks to patient and staff safety.

- The provider had undertaken risk assessments and audits for significant risks, for example fire and infection control. The practice's health and safety policies and risk assessments were up to date and reviewed regularly.
- Fire safety systems were maintained annually. Evacuation instructions were displayed on the premises and staff were knowledgeable about their role in the event of a fire.
- There were arrangements in place to meet the Control of Substances Hazardous to Health 2002 (COSHH) regulations.
- The provider had systems in place for building maintenance and repair to provide a safe environment for patients and staff.
- All electrical equipment was checked to ensure the equipment was safe to use and clinical equipment was checked to ensure it was working properly.
- Infection prevention and control (IPC) policies and procedures were in place and covered blood-borne virus transmission, sharps injuries, hand hygiene and segregation and disposal of clinical waste.
- The practice maintained appropriate standards of cleanliness and hygiene. We looked around the premises during the inspection and found the treatment rooms and other areas were visibly clean and hygienic. We looked at the treatment rooms where patients were examined and treated. All rooms and equipment appeared clean, uncluttered and well-lit with good ventilation.
- Arrangements were in place for cleaning the premises and for the disposal of clinical waste.
- The latest IPC audit showed the practice was meeting the required standards.

# Are services safe?

## Information to deliver safe care and treatment

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

- The care records we saw showed that information needed to deliver safe care and treatment was available to staff.
- The practice had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment.
- Paper records were held for patients and were stored securely. Other records were kept on computers which were password protected.
- The doctor made referrals to other services when required.

## Safe and appropriate use of medicines

We checked the arrangements for the management of medicines at the clinic and found these did not always keep patients safe.

- The clinic had a medicines policy in place, which was last reviewed in February 2018. However, the policy did not relate to the service being provided, for example it referred to a medical director and lead nurse, neither of whom were employed at the clinic. Staff responded appropriately to national patient safety alerts and medicines recalls, and we saw records of the action taken in response to these.
- We checked how medicines were ordered, stored and supplied to patients. Administrative staff produced dispensing labels and kept records of medicines which had been supplied. However, staff had received no formal training for this role.
- Patients completed a medical history form before being seen by the doctor, which included details about any known allergies, their medical history and any medicines they were taking. Written consent was obtained before treatment was provided in accordance with the Mental Capacity Act 2005.
- We reviewed medical records for five people in detail. In one case, the patient had been prescribed a medicine which was not licensed for the treatment of Lyme disease. The manufacturer recommends extra

monitoring and blood tests before and during treatment with this medicine. However, there was no record in the medical notes that these tests had been carried out. In addition, the doctor had not recorded their rationale for prescribing the medicine outside of its licensed indication, and there was no record that this had been discussed with the patient.

- We checked the arrangements for dealing with medical emergencies. The medicines management policy stated medicines for a clinical emergency should be readily accessible and kept in a tamper-evident container. The clinic held adrenaline (a medicine used to treat severe allergic reactions), however this was not in a tamper-evident container and there were no other emergency medicines available. There was no oxygen available, and on the day of our inspection, the defibrillator was not in working order. Staff could not provide evidence that a risk assessment had been carried out covering the choice and availability of emergency medicines and equipment.

## Lessons learned and improvements made

When there were unexpected or unintended safety incidents.

- The provider was aware of the requirements of the Duty of Candour.
- The provider encouraged a culture of openness and honesty. The service had systems in place for knowing about notifiable safety incidents
- They kept written records of any accidents or incidents. We saw evidence that when non clinical accidents had occurred these were recorded and action taken to minimise the risk of recurrence.
- There were systems in place for reviewing and investigating when things went wrong. However we found that these were not always followed, for example, we found that some of the medication dispensing labels contained errors or omissions, for example they stated the wrong quantity or information was missing which was needed to support patients to take their medicines safely. The clinic had not recognised these as incidents. They told us there had been no significant patient safety events in the last year.



# Are services effective?

(for example, treatment is effective)

## Our findings

### Effective needs assessment, care and treatment

We saw that the provider was aware of published research and current guidance and they subscribed to a number of medical journals to enable them to remain up to date.

- The majority of patients attended the clinic for treatment for Lyme disease (a bacterial infection which is spread by ticks). The doctor at the clinic was aware of national guidance for treating this disease; however the treatments they offered were not in line with current guidance.
- Patients' treatment needs were assessed and treatment plans were drawn up with risk assessment in place where needed. The assessment took account of allergies, lifestyle, existing medication, previous diagnoses and the presenting problem/s. The provider encouraged each patient to bring a past medical history with them and explained that many of the patients had a detailed understanding of their own condition. They told us that information from patients was used to help reach a decision about suggested treatment. Feedback from patients confirmed this.
- We saw evidence that the provider had consulted with other specialists to provide a service which considered patients' holistic needs. We saw that plans were kept under review to ensure they took account of changing needs.

### Monitoring care and treatment

- The clinic had not undertaken any form of clinical audit or quality improvement activity, which meant they could not demonstrate the effectiveness of the treatments on offer. However feedback from patients showed all patients were satisfied with the care and treatment they had received. All the patients we received feedback from said they had noticed an improvement in their symptoms and condition.
- The clinic continuously monitored patients and adapted their treatment plans when required.

### Effective staffing

Staff had the skills, knowledge and experience to deliver effective care and treatment.

- We confirmed clinical staff completed the continuous professional development required for their registration with the General Medical Council.
- We found clinical staff had the skills, knowledge and experience to deliver effective care and treatment. They had access to appropriate training to meet these learning needs and to cover the scope of their work.
- During our inspection, we observed that there were gaps in some areas of training for some staff members, for example, safeguarding and infection control. The service informed us after the inspection that awareness raising sessions had been held for staff on safeguarding children and adults and infection control. We were told basic life support training was completed in 2014 for staff and volunteers; however there was no evidence available to confirm what training had taken place.
- We found no formal appraisal had been undertaken as of yet in the service, however staff told us that they felt supported by the doctor and they were always available to discuss any issues or concerns.

### Coordinating patient care and information sharing

The information needed to plan and deliver care and treatment was available to staff in a timely and accessible way through the patient records.

- The service shared relevant information with the patient's permission with other services, for example, when referring patients to other services or informing the patient's own GP of any matters. We saw examples of letters which had been sent to GPs and hospital consultants, which included sufficient detail of the consultation and treatment patients had received.
- Staff worked with patients to advise and sign post patients to other services where required for their on-going care and treatment.

### Supporting patients to live healthier lives

- Staff ensured that patients were given advice with regards to smoking cessation, drugs and alcohol and travel advice to minimise risk and ensure patient safety.
- There was a range of information available for patients on health promotion and healthy lifestyles, including smoking cessation, cancer, alcohol and mental health issues.



# Are services effective?

(for example, treatment is effective)

## **Consent to care and treatment**

Staff sought patients' consent to care and treatment in line with legislation and guidance.

- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005.
- The provider told us that they always sought patient's consent before giving treatment and we saw examples

of this. The patients we spoke with told us that the provider explained anything new at each consultation and that they felt clear about the treatment they consented to.

- Information about fees was transparent and available on the website.
- Details of the next of kin were recorded when children attended the clinic. However no identification checks were completed to confirm the adult with the child had parental responsibility.

# Are services caring?

## Our findings

### Kindness, respect and compassion

We reviewed feedback that stated members of staff were caring and very supportive to patients.

- The provider explained to us how they ensured information about patients using the service was kept confidential. The service had paper records for all patients which were held securely.
- Staff demonstrated to us their knowledge of data protection and how to maintain confidentiality.
- All of the feedback we received was very positive about the service experienced. Patients said they felt the service offered excellent care and staff listened and offered care and treatment at the right time.

### Involvement in decisions about care and treatment

- We saw a good range of information available on the website. Feedback from patients indicated they felt listened to and supported by staff and had sufficient time during their consultations to make informed decisions.
- Staff told us that a patient's medical status was discussed with them in respect of decisions about the care and treatment they received. We saw these discussions were always documented.

- We looked at examples of written records and found they explained the treatment required. This allowed patients to consider the options, risks, benefits and costs before making a decision to proceed. However we found that patients had not been informed when a medicine was being used outside of its licensed indication.
- Patients were given information about the cost of treatment when they contacted the clinic. Details of fees were also displayed on the clinic website.

### Privacy and Dignity

Staff treated people with dignity and respect.

- Treatment rooms were private and protected patients' privacy and dignity during consultations. Consultation room doors were closed during consultations and conversations taking place in these rooms could not be overheard.
- Patients said staff treated them with dignity and respect. Patients were very satisfied with the care provided by the service.
- Staff we spoke with were aware of the importance of protecting patient confidentiality and reassurance.

# Are services responsive to people's needs?

(for example, to feedback?)

## Our findings

### Responding to and meeting people's needs

- As part of our inspection we reviewed the clinical area and we found the facilities were appropriate for the services that were planned and delivered. The waiting area and treatment rooms were comfortable and welcoming for patients. The treatment and consultation areas were well designed and well equipped.
- The provider offered a service to meet the needs of their patients. Staff explained how they scheduled enough time to assess and undertake patients' care and treatment needs.
- Staff told us that the programme they offered to patients was designed to educate and empower patients in order to give them ownership of their own health.

### Timely access to the service

- The service displayed its contact details and opening times on the website.
- Patients could access care and treatment in a timely way and the programme met their needs. Patients told us appointments were available the same day and next day if needed.

### Listening and learning from concerns and complaints

- There was a complaints policy which explained how the clinic handled formal and informal complaints from patients. The service had not received any complaints but we were told that all complaints would be discussed, analysed and lessons shared with the staff team.
- Information for patients about how to make a complaint was available in the waiting area.

# Are services well-led?

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

## Our findings

There were areas where the provider could make improvements and should:

- Review policies to check they are relevant to the service.

### Leadership capacity and capability;

- There was a clear leadership structure in place and staff felt supported by the doctor. Staff told us the doctor was approachable and always took the time to listen to them. The team had a cohesive working relationship. Issues were discussed on a daily basis as and when they arose.

### Vision and strategy

- Staff shared the same vision and values and these were outlined on the clinic's website.
- Staff told us that the service was a small, friendly family service and that they all strived to successfully meet the needs and expectations of the patients. Feedback from patients supported this view.

### Culture

- Staff stated they felt respected, supported and valued. They were proud to work in the clinic.
- The clinic focused on the needs of patients.
- Staff we spoke with told us they were able to raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- The Doctor was aware of the requirements of the Duty of Candour (the duty of candour is where the health provider must always be open and transparent when mistakes occur). They encouraged a culture of openness and honesty and there was an incident reporting policy in place.

### Governance arrangements

The Doctor had overall responsibility for the management and day to day running of the service and clinical leadership of the clinic. However we found there were gaps in the governance arrangements for the clinic.

- Staff knew the management arrangements and their roles and responsibilities.

- The practice had policies, procedures and risk assessments to support the management of the service and to protect patients and staff. These included arrangements to monitor the quality of the service and make improvements. The information in some policies did not always reflect the clinic.
- The service told us they had not had any significant events or incidents in the past 12 months. Staff told us how if they occurred these would be discussed, dealt with appropriately and how they would document learning from any errors that occurred. However we found that the incident reporting policy was not followed. For example, we found issues regarding dispensing labels containing errors or omissions that had not been reported as near misses or incidents. The practice had not followed its incident reporting policy to recognise, investigate and implement measures to prevent a recurrence.
- We found no formal staff appraisals had been undertaken as of yet in the service, however the team told us they felt well supported, could ask for advice or raise any issues or concerns at any time.
- The Doctor told us the service was supportive of training and professional development, and we saw evidence to confirm this, for example the administrator had completed information governance courses. However we observed there were gaps in some areas of training for staff members, for example, safeguarding and infection control. The service informed us after the inspection that awareness raising sessions had been held for staff on safeguarding children and adults and infection control. Basic life support training was completed in 2014 for staff and volunteers; however there was no evidence available to confirm this training had taken place.
- A programme of audits was planned to ensure the service regularly monitored the environment and infection control. However there was no evidence that clinical audit was undertaken to monitor the quality of care and treatment provided.
- Information governance arrangements were in place and staff were aware of the importance of these in protecting patients' personal information.

### 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 was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The practice had processes to manage current and future performance. There was oversight of MHRA alerts, incidents, and complaints.
- The practice had plans in place for managing major incidents.
- We reviewed a patient feedback questionnaire that had been completed for the Doctor's appraisal in 2016. Results were very positive about the care, treatment and service provided.
- Patients were asked for feedback on their care and treatment at every contact.
- The Doctor engaged with the public and other partners, for example other voluntary organisations in the area.

## **Appropriate and accurate information**

- All patients had a consultation whereby medical history and assessment of need was obtained. We saw that the results of consultations were documented in patient records. Staff had access to patient information when required, including information from other healthcare professionals involved in the patients' care.

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

- The practice used a comments book to obtain patients' views about the service.

## **Continuous improvement and innovation**

- The Doctor told us that they were continually striving to provide a service that would meet patient's needs and had been involved in research into Lyme's disease. In January 2018 with other groups from around the country the Registered Manager had attended the All Party Parliamentary Group (APPG) on Lymes Disease. This was a round table discussion where each of the groups talked about the issues relating to Lyme's disease which would inform the enquiry that the APPG was undertaking.

## Requirement notices

### Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Maternity and midwifery services Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Care and treatment must be provided in a safe way for service users</p> <p><b>How the regulation was not being met</b></p> <p>There was no proper and safe management of medicines. In particular:</p> <ul style="list-style-type: none"><li>• staff involved in the dispensing of medicines had not completed appropriate training.</li><li>• rationale was not recorded in patient records and discussed with patients when medicines were administered outside the terms of their product license.</li><li>• appropriate monitoring was not carried out when some specific medicines were prescribed.</li></ul> <p>This was in breach of Regulation 12(1) of the Health and Social Care Act (Regulated Activities) Regulations 2014.</p>
Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Maternity and midwifery services Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p><b>How the regulation was not being met:</b></p> <p>The registered person had systems or processes in place that operated ineffectively in that they failed to enable the registered person to assess, monitor and improve the quality and safety of the services being provided. In particular:</p> <ul style="list-style-type: none"><li>• The incident reporting process was not always followed and staff did not always recognise report and investigate incidents.</li></ul>

## Requirement notices

- Clinical audits were not undertaken to monitor and improve the quality of services.

The registered person had systems or processes in place that operated ineffectively in that they failed to enable the registered person to maintain securely such records as are necessary to be kept in relation to persons employed in the carrying on of the regulated activity or activities. In particular:

- There was no evidence of training that staff had undertaken or records of supervision and support provided.

This was in breach of Regulation 17(1) of the Health and Social Care Act (Regulated Activities) Regulations 2014.