ABC Clinic Limited

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Inspection report

Wealden House
Lewes Road
East Grinstead
RH19 3TB
West Sussex
Tel: 01342 324 861
Website: www.keesmedical.co.uk

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Overall summary

We carried out an announced comprehensive inspection on 3 November 2017 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 services in accordance with the relevant regulations

Are services effective?

We found that this service was not providing effective services 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 services in accordance with the relevant regulations.

Background

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.

ABC Clinic Limited provides private independent doctor services to people who reside in the UK and overseas. Services include diagnostic and screening or referral to specialist screening services. The provider consists of one clinician, a practice manager and personal assistant. The service has approximately 500 active clients on their list.

Dr Josef Kees 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.

Services are provided from the following locations:

Lewes RoadEast GrinsteadRH19 3TBWest SussexUnited Kingdom

And

Summary of findings

The provider also has use of rooms to provide consultations at :

10 Harley StreetLondonW1G 9PF

The practice is open Monday to Friday 8.30am until 6.00pm. Consultations are usually provided on Thursdays at Harley Street and no clinician is available at the East Grinstead service on that day.

We did not visit the Harley street location as part of this inspection.

Nineteen people provided feedback about the service. This included feedback through Care Quality Commission comment cards and face to face interviews.

Our key findings were:

- Patients were at risk of harm because systems and processes were not in place in a way to keep them safe. For example, risk assessments were not in place and action had not been taken to mitigate the risks. For example there was no health and safety risk assessment.
- Safeguarding policies were not in place and safeguarding training was not undertaken.
- There was no infection control system, the policy was more than seven years out of date for review and an infection control audit had not been undertaken. There were no cleaning schedules and staff had not received infection control training.
- The practice did not have emergency medicines in place or a rationale for why they were not available on site.
- Recruitment processes were in place, however staff recruited in the two months prior to the inspection did not have satisfactory information about conduct in previous work prior to commencing work. The practice had no system to ensure staff roles were risk assessed and if required a DBS check undertaken.
- There was no evidence of quality improvement initiatives including clinical audit.
- The service learning needs of staff were not identified through a system of appraisals, meetings and reviews of practice development needs. Systems were yet to be established to allow staff access to appropriate training to meet their learning needs and to cover the scope of their work.
- Patient records did not always demonstrate that information was shared when appropriate.
- The practice had only one policy and procedure to govern activity; this was not sufficient to address all aspects of the service and had not been reviewed since 2009.
- Patients said they felt the practice offered an excellent service and staff were helpful, caring and treated them with dignity and respect.
- Patients told us that it was very straightforward to make an appointment and they could arrange these around their other commitments.

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

- Ensure that there is an accessible health and safety policy and that risk assessments are carried out and acted upon. Including for fire safety, infection control and management of legionella.
- Ensure that all staff attend fire safety training, that regular fire drills are carried out and where necessary, improvements in practice are demonstrated as a result.
- Review and update all practice policies, ensuring that policies are accessible to all staff.
- Ensure that infection control protocols are up to date, that there is an identified and trained infection control lead within the practice, that annual infection control audits are undertaken and that all staff attend infection control training.
- Ensure recruitment arrangements include all necessary employment checks for all staff and that these are undertaken before employment commences.
- Ensure that clinical audits are undertaken, demonstrating improvements and that there is evidence of shared learning as a result.

Summary of findings

- Ensure a risk assessment is carried out for all roles within the practice to identify which roles should be subject to a DBS (Disclosure and Barring Service) check.
- Introduce a system that ensures all staff have training appropriate to their role and an annual appraisal.
- Ensure safeguarding policies are in place for children and adults and staff receive appropriate training.
- Ensure all patient records are complete and contain the information required to demonstrate that advice had been given to patients and where appropriate documented proof that referrals have been made. Records must also include evidence that the patient's GP has been informed of any treatment or a clear rationale why this has not been undertaken.

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 the service's complaint policy and procedures in relation to the steps a complainant can take if still dissatisfied with the response from the provider.
- Review the access arrangements for patients with limited mobility and reflect the outcome in an access statement and policy.

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 services in accordance with the relevant regulations.

We have told the provider to take action (see full details of this action in the Requirement Notices/Enforcement section at the end of this report).

- Patients were at risk of harm because systems and processes were not in place in a way to keep them safe. For example, risk assessments were not in place and action had not been taken to mitigate the risks.
- Safeguarding policies were not in place and safeguarding training was not undertaken.
- There was no infection control system, the policy was more than seven years out of date for review and an infection control audit had not been undertaken. There were no cleaning schedules and staff had not received infection control training.
- The practice did not have emergency medicines in place or a risk assessment for why they were not available on site.
- Recruitment processes were in place, however staff recruited in the two months prior to the inspection did not have satisfactory information about conduct in previous work prior to commencing work. The practice had no system to ensure staff roles were risk assessed and if required a DBS check undertaken.

Are services effective?
We found that this service was not providing effective 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/Enforcement section at the end of this report).

- There was no evidence of quality improvement initiatives including clinical audit.
- The service learning needs of staff were not identified through a system of appraisals, meetings and reviews of practice development needs. Systems were yet to be established to allow staff access to appropriate training to meet their learning needs.
- Patient records did not always demonstrate that information was shared with the patients GP when appropriate.

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

- Patients said they felt the practice offered an excellent service and staff were helpful, caring and treated them with dignity and respect.

Are services responsive to people's needs?
We found that this service was providing responsive care in accordance with the relevant regulations.

- Patients told us that it was very straightforward to make an appointment and they could arrange these around their other commitments.

We found areas where improvements should be made relating to the provision of responsive services. This was because:

Summary of findings

- The complaint policy and procedures were not in line with recognised guidance. Information contained in the procedure was out of date.
- Services were delivered from a building that could present difficulties for patients with limited mobility as all entrances are accessed via steps. This was not reflected in an access statement and policy.

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/Enforcement section at the end of this report).

- The practice had one policy and procedure to govern activity, but this was out of date and not sufficient to address all aspects of the service. There was no evidence that this document had been reviewed since 2009.
- Risk management processes were insufficient and the lack of systems to address health and safety concerns placed patients at risk.

ABC Clinic Limited

Detailed findings

Background to this inspection

The inspection was led by a CQC inspector and a GP specialist advisor.

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

Safety systems and processes

- The provider told us that they did not provide services to children however when we reviewed this with the clinician we were told that occasionally a child had been treated in the service and parents had brought their children to the service. Whilst the service had contact information for the adult and child support teams they did not have policies covering adult and child safeguarding and staff had not received safeguarding training.
- We were told that all staff acted as chaperones for the doctor. Staff who acted as chaperones had not been trained for the role and had not received a Disclosure and Barring Service (DBS) check. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable). We noted that this had not been risk assessed.
- The service uses a number of rooms within a shared listed building. Whilst the landlord was responsible for the maintenance and safety of the overall building there was no evidence that the provider had sought assurances about the safety of the building. For example, the last gas safety certificate on file was 2008. There was no evidence of a fire safety assessment or test and no evidence that the risk of legionella had been assessed. (Legionella is a term for a particular bacterium which can contaminate water systems in buildings).
- We observed the premises to be clean and tidy. However the service had not conducted any form of infection control audit or maintained records of cleaning schedules to demonstrate cleaning systems kept patients safe. Staff had not received training in infection control
- We saw evidence that electrical equipment had undergone electrical safety testing. Medical devices had been serviced and calibrated regularly.
- The provider's recruitment process did not keep patients safe. For example, we examined the record of a new employee and found that recruitment checks were not in place. With the exception of the individual's CV there was no information about conduct in previous work, proof of identity or a DBS check prior to commencing their employment.

Risks to patients

- We found that the service did not have a policy or system in place to record significant events or complaints received. The provider confirmed that they had not had any of these events and therefore there were no opportunities for any learning from such incidents and events.
- We saw evidence of professional medical indemnity insurance as part of the provider's public liability insurance. We noted that this expired in October 2017. We were told that this had been renewed and they were waiting for the new policy and certificate to be sent. The provider was given an opportunity to submit this following the inspection. The provider submitted evidence that this had been renewed.
- Resuscitation equipment was available at the service. For example, an automatic electrical defibulator (AED) and oxygen were in place and the AED had been serviced and calibrated. However, the pads used for the AED were out of date since 2010.
- The service had no emergency medicines held on the premises. For example, the practice policy made reference to medicines being available to treat emergency situations and adverse reactions. We found that medicines used to treat anaphylaxis were not available. The service had no risk assessment, or rationale, for the provision and use of emergency medicines.

Information to deliver safe care and treatment

- Before providing consultations and treatment the provider verified the identity of the patient by checking photo identity documents. For example passports and driving licences.
- Individual care records were not always written and managed in a way that kept patients safe. The care records we saw showed that information needed to deliver safe care and treatment was not always well documented. For example, the records did not always contain evidence of the advice given to patients at consultations and were difficult to follow. The provider told us they recognised a need to improve their record keeping and they had appointed a medical secretary to

improve record keeping. We saw an improvement in more recent records with clearly documented consultations and evidence of referral to other practitioners.

- We were told that patient records were mainly held as paper records. These were stored securely. The provider also received correspondence including test results electronically on a laptop. These are transported between the practice and other locations including the individual's home. We were told that the laptop is fitted with encryption software. Some records were not available as they were stored at the clinician's private residence. There was no risk assessment in place for the security of records held off site.

Safe and appropriate use of medicines

- The provider used specialised treatment regimens for patients that are made under a manufacturers specials licence. Medicines made in this way are referred to as 'specials' and are unlicensed. The Care Quality Commission (CQC) does not regulate the manufacture of these medicines. The MHRA guidance states that unlicensed medicines may only be supplied against valid special clinical needs of an individual patient. The General Medical Council's prescribing guidance specifies that unlicensed medicines may be necessary where there is no suitable licensed medicine. At ABC Clinic Limited we found that patients were treated with unlicensed medicine. Treating patients with unlicensed medicine is higher risk than treating patients with licensed medicine, because unlicensed medicine may not have been assessed for safety, quality and efficacy. The CQC does not inspect or regulate the manufacture of unlicensed medicine, this was not checked.
- The practice kept prescription stationery securely and monitored its use. The service had printed prescription pads which were numbered. We saw evidence that the doctor made a note of the prescription pad number in the patient's notes when one was issued.
- The systems for managing medicines, including medical gases, and equipment minimised risks. Medicines were secured. Medicines requiring refrigeration were appropriately stored and fridge temperatures monitored.
- We saw evidence of consent from patients in the form of letters of authorisation to carry out treatments.

Track record on safety

- There were few risk assessments in relation to safety issues.
- We noted that the service had arrangements in place to receive and comply with patient safety alerts, recalls and rapid response reports issued through the Medicines and Healthcare products Regulatory Authority (MHRA) were reviewed by clinical staff. We were told that due to a change in the email contact address alerts had not been received since 2016. This meant that more recent alerts had not been received or actioned. This was rectified by the service during our inspection and a new email address was registered with MHRA.

Lessons learned and improvements made

- We were told that the provider had not had any significant events, incidents or accidents. Therefore we had no information to assess if the provider learned from such events.
- The provider was aware of the requirements of the Duty of Candour. The provider told us they encouraged a culture of openness and honesty. Whilst this was reflected in a limited policy statement the service had no systems in place for knowing about notifiable safety incidents. The service policy referred to out of date notifiable incidents as set out by a predecessor regulator.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

The clinician was aware of how to access relevant and current evidence based guidance and standards. For example the National Institute for Health and Care Excellence (NICE) best practice guidelines.

There was evidence of an assessment to establish individual needs and preferences on nine of the ten patients records we reviewed

Monitoring care and treatment

- There was no evidence of quality improvement initiatives including clinical audit. The provider had not undertaken any audits of the care and treatment interventions provided to patients.

Effective staffing

- The practice did not have an induction programme for newly appointed staff. The provider could not demonstrate that staff received training and guidance in such topics as safeguarding, infection prevention and control, fire safety, health and safety and information goverance.
- The learning needs of staff were not identified through a system of appraisals, meetings and reviews of practice development needs. Systems were yet established to allow staff access to appropriate training to meet their learning needs and to cover the scope of their work. The clinician had undergone revalidation.

Coordinating patient care and information sharing

It was not evident from a review of patient records that the information needed to plan and deliver care and treatment was always available to relevant staff in a timely and accessible way. For example, the practice's patient record system did not always demonstrate that information was shared with other professionals involved in the care and treatment of the individual.

Records of referral were available for some records but not for all including evidence of communication with the patient's own GP. One patient told us that the clinician had regular contact and discussion with their consultant.

Supporting patients to live healthier lives

- The practice identified patients who may be in need of extra support and encourages them to discuss this with their general practitioner.

Consent to care and treatment

- Staff understood the relevant consent and decision-making requirements of legislation and guidance. However training had not been undertaken in areas such as the Mental Capacity Act 2005 and the provider did not demonstrate an understanding of this legislation.
- We saw evidence of consent from patients in the form of letters of authorisation to carry out treatments. We were told that the clinician also sought verbal consent however they did not regularly record this in the patient care notes. We also noted that consent to share information was not routinely sought. For example, the practice's patient record system did not always demonstrate that patients had agreed to share their treatment information with other appropriate clinicians including the patient's registered GP.

Are services caring?

Our findings

Kindness, respect and compassion

All of the 18 patient Care Quality Commission comment cards we received were positive about the service experienced. Patients said they felt the practice offered an excellent service and staff were helpful, caring and treated them with dignity and respect. A patient we spoke with shared the same level of satisfaction with the service. They told us that their experiences had always been positive, supportive and caring.

Involvement in decisions about care and treatment

Feedback received through comment cards and interviews demonstrated that patients felt fully informed and consulted on their care and treatment. For example,

- Patients told us they felt involved in decision making about the care and treatment they received. Options for treatment were explained and discussed. They had time to consider the treatments offered and were not rushed into making decisions.
- Patient feedback from the comment cards we received was positive and stated that staff were caring and professional.

Privacy and Dignity

Staff recognised the importance of patient's dignity and respect. Privacy screens were available in the consultation room. We observed that consultations took place behind closed doors and staff knocked when they needed to enter.

A patient we spoke with confirmed that staff took steps to maintain their privacy and dignity at all times.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The practice organised and delivered services to meet patients' needs. It took account of patient needs and preferences.

- The practice understood the needs of its population and tailored services in response to those needs. For example offering opening hours and advanced booking of appointments to suit the circumstances of the patient.
- The facilities and premises were appropriate for the services delivered and the current patient population. However, services were delivered from a building that would present difficulties for some patients with limited mobility as all entrances were accessed via steps. The provider told us that they did not see any patients with mobility issues at the time of the inspection and access issues would be explained to the individual and alternative services recommended.

Timely access to the service

Patients were able to access care and treatment from the practice within an acceptable timescale for their needs.

- Patients had timely access to initial assessment, test results, diagnosis and treatment.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- The appointment system was easy to use.
- Patients told us that it was very straightforward to make an appointment and they could arrange these around their other commitments. They told us that they rarely had to wait and any changes to appointments were agreed in advance.

Listening and learning from concerns and complaints

The practice told us they took complaints and concerns seriously and would respond to them appropriately to improve the quality of care.

- Information about how to make a complaint or raise concerns was available. Staff we spoke with told us they would treat patients who made complaints compassionately.
- The complaint policy and procedures were not in line with recognised guidance. The information we saw was out of date and made reference to organisations that no longer existed. For example, it made reference to the Healthcare Commission as a contact if the complainant dissatisfied with the response from the provider.
- We were told that no complaints were received in the last year. We were unable to review complaints to determine that they were satisfactorily handled in a timely way. Consequently we could not assess if the practice learned lessons from individual concerns and complaints and also from analysis of trends.

Are services well-led?

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

Our findings

Leadership capacity and capability;

- The provider consists of one clinician and we were told by staff that they were approachable. We were told that they worked closely with their small team.
- The concerns identified at this inspection meant that the provider could not demonstrate capacity to provide well-led services.

Vision and strategy

- There was a documented vision and set of values. However, the practice did not have a strategy and supporting business plans to achieve priorities. For example, the provider told us that they were looking for potential expansion of their services however this was not supported with any formal plan.
- Staff were aware of and understood the vision, values and their role in achieving them.

Culture

- The provider was aware of, and had statements, within their policy to ensure compliance with the requirements of the duty of candour. The practice policy made reference to investigating and responding to concerns however, there were limited systems to assist staff with managing incidents including a lack of training.
- The member of staff we spoke with told us they felt able to raise concerns and had confidence that these would be addressed.
- The staff member we spoke with stated they felt respected, supported and valued. However there were no processes for providing all staff with the development they need. This included induction, appraisal and career development conversations. The staff member had only recently started with the provider and therefore had not had an appraisal.
- The practice could not demonstrate that it actively promoted equality and diversity as there was no programme to ensure staff received equality and diversity training.

Governance arrangements

The clinician, who is also the registered manager, was identified as being the accountable person to support good governance and management.

- Structures, processes and systems did not support good governance
- Staff were not clear on their roles and accountabilities in respect of safeguarding and infection prevention and control.
- The provider had not established proper policies, procedures and activities to ensure safety.

Managing risks, issues and performance

- There was no effective, process to identify, understand, monitor and address current and future risks including risks to patient safety. For example, the system to monitor and respond to MRHA alerts was not in place at the time of our inspection. Health and safety risks had not been fully assessed or mitigated including legionella and infection control.
- The practice did not have effective processes to manage current and future performance. For example, clinical staff could not demonstrate that they had completed any audits of their consultations, prescribing and referral decisions.
- There was no evidence of any action to change practice to improve quality based on audit or quality improvement initiatives.
- The practice had no plans in place or had trained staff for major incidents.

Appropriate and accurate information

The practice could not demonstrate it acted on appropriate and accurate information.

- The limited record keeping, lack of risk assessment and monitoring records meant that quality and operational information was not available to ensure and improve performance.
- There were limited arrangements to safeguard the confidentiality of patient identifiable data, records and data management systems.
- The practice had not established a programme of audit to assess the performance and outcomes of clinical interventions.

Engagement with patients, the public, staff and external partners

- The practice has only recently appointed a staff member and therefore there was limited opportunity to demonstrate staff engagement with the service. We

Are services well-led?

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

were told that the provider and staff member have regular informal meetings to discuss improvements to the running of the service. However these have not been recorded.

- We noted that there were no systems in place to obtain the views of people.

Continuous improvement and innovation

There were no systems and processes for learning, continuous improvement and innovation.

- The lack of significant events, incidents and complaints meant it was not possible for the practice to demonstrate they made use of internal and external reviews of incidents and complaints to make improvements.
- However the practice did not have an up to date system in place to review such events should they occur.

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 Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment • The provider had not ensured safeguarding policies were in place for children and adults and staff had received appropriate training. • Risk assessments and DBS checks were not completed for staff designated as chaperones. This was in breach of regulation 13.1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing • The provider did not ensure that staff received appropriate support, training, professional development, supervision and appraisal. • The required training for each role had not been identified. • Staff had not received an induction and regular training relevant to the requirements of their role. • An annual appraisal plan and personal development plan was not in place to support staff. This was in breach of regulation 18.1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed

This section is primarily information for the provider

Requirement notices

The provider had not ensured staff recruitment files contained the information as set out in regulation.

This was in breach of regulation 19 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

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 Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • The provider had not ensured an infection control system was in place to access and mitigate any risks of infection. • The provider had not ensured that all staff attend fire safety training, or that regular fire drills were carried out. • The provider had not ensured emergency medicines were in place or put in place rationale for why they are not available on site. • The provider had not ensured staff with unsupervised access to patients had undertaken a risk assessment and received a DBS check. This was in breach of regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The practice could not demonstrate that they had an adequate governance system in place to manage the assessing, monitoring and mitigation of risks relating to the health, safety and welfare of service users and others who may be at risk. • The provider had not ensured a programme of quality improvement such as a regular programme of clinical audit to review clinical intervention against national and local guidelines and established best practice.

This section is primarily information for the provider

Enforcement actions

- The provider had not ensured records were complete and accurate. Not all patient records contained the information required to demonstrate that advice had been given to patients and where appropriate documented proof that referrals had been made. Records did not include evidence that the patients GP has been informed of any treatment or include a clear rationale why this has not been undertaken.

This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.