Hightree Medical Limited

Hightree Clinic

Inspection report

Hightree House,
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East Sussex,
TN22 5QL
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Overall summary

We carried out an announced comprehensive inspection of Hightree Clinic on 9 October 2018 under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This was the providers first comprehensive inspection. We found the service was not providing safe, effective, responsive or well-led care in accordance with the relevant regulations. We issued two warning notices requiring the provider to achieve compliance with the regulations set out in those warning notices. A warning notice was issued against Regulation 12 (Safe care and treatment) and Regulation 17 (Good governance). We also issued two requirement notices for Regulation 18 (Staffing) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and Regulation 19 (Fees) of the CQC (Registration) Regulations 2009.

This inspection was a focused inspection carried out on 23 January 2019 to confirm whether the provider was compliant with the warning notices issued, following the inspection on 9 October 2018. This report only covers our findings in relation to the requirements set out in the warning notices.

Our findings were:

At this inspection we found that although improvements had been made, the requirements of the two warning notices had not all been met.

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 not providing effective care in accordance with the relevant regulations.

Are services responsive?

We found that this service was not 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.

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 regulated activities and services and these are set out in Schedule 1 and Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Hightree Clinic is an independent doctor service. They provide consultation, treatment and prescribing services

Summary of findings

for conventional and complementary medicine, with an aim to improve and/or sustain patients' overall quality of life. The clinic offers consultation and treatment only to patients over the age of 18.

Hightree Clinic provides a range of complementary therapies, for example medical acupuncture and osteopathy, which are not within CQC scope of registration. Therefore, we did not inspect or report on these services.

The lead GP is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Our key findings were:

- The service had reviewed and improved some systems and processes at the clinic, but not all requirements had been completed. They had developed an action plan to make sure the concerns identified at our last inspection would be addressed. We saw all actions were planned for completion by March 2019.
- The processes to identify, understand, monitor and address current and future risks including risks to patient safety were not always complete or clearly set out. This included the recording and oversight of safety alerts, significant events and complaints, the systems for monitoring patients' health and the management of patient records.
- Although the recording of patients' information, consultations and treatment had been improved, the standard of the files we reviewed was inconsistent and they did not always contain information we would expect to see.
- We saw that the provider had started a process to review and update their policies and procedures to ensure they contained relevant and up to date information. This was not yet complete.
- A variety of risk assessments had been completed in relation to safety issues, including for fire and health and safety. However, an action plan was not in place to ensure required improvements were completed.
- Staff told us the morale had improved at the clinic and they felt more supported. They were aware that improvements were still required and they felt encouraged to be involved in the process.

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

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

We have told the provider to take action (you can see full details of the action and regulations not being met in the Enforcement Actions section at the end of this report).

Professor Steve Field CBE FRCP FFPH FRCGP Chief Inspector of General Practice

Hightree Clinic

Detailed findings

Background to this inspection

Hightree Clinic is an independent doctor service. They provide consultation, treatment and prescribing services using conventional and complementary medicine. The clinic aims to address the physical, nutritional and well-being needs of patients in order to improve their health and aid recovery. The clinic offers comprehensive health diagnostics and assessments, for example screening tests for a wide spectrum of infections, deficiencies and hormone imbalances. Services include intravenous treatments for nutritional deficiencies, oxygen therapy (such as medical ozone), local and whole-body hyperthermia. They also offer treatments for musculoskeletal disorders, including joint injections.

The clinic address is:

Hightree House,

Eastbourne Road,

Uckfield,

East Sussex,

TN22 5QL

The clinic is open between 9am to 5pm on a Monday, Tuesday, Thursday and Friday.

Registered services are provided by one GP and a healthcare worker (in training). The registered manager had also employed a consultancy agency to assist with improving and streamlining their governance arrangements. The agency also provided reception support.

We carried out an announced comprehensive inspection at Hightree Clinic on 23 January 2019. Our inspection team was led by a CQC lead inspector who was accompanied by a CQC National Clinical Advisor - Online and Independent Health, a CQC Pharmacist Specialist and a Practice Manager Specialist Advisor.

Information was gathered from the provider and reviewed before the inspection.

During our visit we:

- Spoke with a range of staff, including the lead GP, the healthcare worker and one member of the consultancy agency.
- Made observations of the internal and external areas of the main premises.
- Looked at information the clinic used to deliver care and treatment plans.
- Reviewed documentation relating to the clinic including policies and procedures.

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 formed the framework for the areas we looked at during the inspection.

Are services safe?

Our findings

At our previous inspection we found that this service was not providing safe care in accordance with the relevant regulations. We issued a warning notice in response to these concerns:

- There was no fire risk assessment and no evidence of fire drills.
- Not all staff had received appropriate infection control training and there were no cleaning logs for equipment used. There was no completed infection control audit or legionella risk assessment.
- Consultation notes were not always clear, comprehensive and legible. Not all records contained information we would expect to see about the consultation and treatment plan.
- The provider could not demonstrate that they always prescribed, administered and supplied medicines to patients in line with legal requirements.
- The provider did not always follow or work to national guidance, such as NICE (National Institute for Health, Care and Excellence). They did not evidence the guidance used or a written rationale for the approach when it was not to national guidance.
- There was no evidence of how safety alerts received would be recorded, actioned or shared with staff.
- Not all staff demonstrated an understanding of significant events.

We carried out this inspection to follow up on these concerns on 23 January 2019 and found although the clinic had made improvements, not all requirements of the warning notice had been met.

Safety systems and processes

The service had some systems to keep people safe.

- The clinic maintained appropriate standards of cleanliness and hygiene. We observed the premises to be clean and tidy. The lead GP was the infection prevention and control (IPC) lead. Infection control had been addressed by a health and safety risk assessment completed by an external body in December 2018. We saw actions that were in progress, however there was no action plan to ensure required improvements were completed. The provider had not conducted any infection control audits. We saw they were recording daily spot checks of cleanliness throughout the clinic, but there was no log of cleaning for the equipment used at the clinic. All sharps bins were sited safely and labelled in line with guidance. There was evidence of staff training for infection control, except for agency (administrative) staff. The provider was asked to send evidence of their training but this was not received. Following our inspection, the provider sent us evidence of their weekly cleaning rota template. This did not include equipment used at the clinic.
- The provider had employed a business consultant in January 2019 providing health and safety and employment support. We saw that a comprehensive health and safety assessment had been completed by an external body, which included COSHH (Control of Substances Hazardous to Health Regulations 2002) and Legionella (Legionella is a term for a particular bacterium which can contaminate water systems in buildings). Actions had been identified which were planned or in process and the provider could describe priorities, however there was no documented action plan for this. For example, actions recorded as medium risk in the Legionella risk assessment included insulation to the mains water supply and a drain valve to be fitted. We saw documentary evidence of water temperature testing and flushing of water outlets to minimise risk of Legionella. However, the two forms used to record temperature did not consistently describe the accepted range and action to take if the temperature was outside of these ranges. We saw that the hot water temperature did not reach the accepted minimum on 14 January 2019, but staff we spoke with could not describe any action taken.

Information to deliver safe care and treatment

Staff did not always have the information they needed to deliver safe care and treatment to patients.

- We found that the provider had improved the systems and processes for the recording of patient details, consultation and treatment. Patients were asked to complete a registration form and update their details with information on clinical history including medicines taken and known allergies. Each set of clinical notes now contained a registration page, health risk assessment and terms of conditions for each patient.

The provider told us that they had started a process to ensure consultation summaries were typed up electronically after consultation. We saw evidence of this.

- However, the medical records we reviewed were not consistently clear, comprehensive and legible. They did not always contain information we would expect to see including; the date of consultation, whether the consultation was face to face or by telephone, the working diagnosis or clinical impression, investigations provided or arranged, a completed treatment plan, and follow up arrangements (where clinically appropriate). We also found that consultation summaries were not always completed in a timely manner, including one patient seen the week prior to our inspection and the notes had not yet been written up.
- We reviewed six clinical records for patients seen since our last inspection. Five out of six records had the patients' own GP details recorded, but only one had record of whether there was consent to share information with the GP. None of the records detailed whether the consultation was face to face or a telephone consultation. Out of six records, four had handwritten consultation notes that were undated and four did not have a documented treatment plan. This meant that information to deliver safe care and treatment was not always available to relevant staff in an accessible way.

Safe and appropriate use of medicines

The service had some systems for appropriate and safe handling of medicines.

- At our last inspection we identified weaknesses with the safe and effective use of medicines. Since the last inspection improvements had been made. Medicines were purchased from a licensed pharmaceutical wholesaler and stored securely at the service within their recommended temperature ranges.
- The provider did not always follow or work to national guidance, such as NICE (National Institute for Health, Care and Excellence). The provider told us that any treatment offered would be fully discussed with the patients, including the benefits, risks, potential side effects and if the medicine was not licensed in the UK. Following our inspection, the provider sent us seven published papers to support the treatments offered. These papers explained the rationales for high dose intravenous vitamin C, the combination of vitamins B, C, minerals and trace elements as an injection and the chelation of heavy metals. These papers described groups of individual patient case studies, small scale clinical trials and narrative reviews of other published papers. These sources were not nationally approved or recognised guidance.
- We reviewed three documents relating to treatment provided and saw these had improved; with details of the medicines administered, the dose and batch numbers. The patient's blood pressure and pulse were recorded before and after the administration of medicines. Although these were stored in each patient's medical file, they did not have the patient name recorded on the document and were not always signed by the clinician administering the medicine. Additionally, it was not clear if the medicines were administered individually, or mixed together prior to administration.
- We saw three issued prescriptions that were for high risk medicines and reviewed the set of clinical notes for this patient. There was no record in the patient's clinical notes or recorded rationale and no evidence of communication with patient's own GP regarding these prescriptions. Following our inspection, the provider has sent us evidence of a letter sent to the patients' GP with a copy of prescriptions issued.

Track record on safety

The service did not always have a good safety record.

- The provider demonstrated that comprehensive risk assessments had been carried out in relation to safety issues. The practice had conducted a fire risk assessment by an external body in December 2018 and had completed fire drills. We saw evidence of this.
- We found the provider was not receiving all relevant external safety events as well as patient safety alerts, recalls and rapid response reports issued through the Medicines and Healthcare products Regulatory Authority (MHRA). We saw that the provider was receiving a limited selection of safety alerts. There was no documentary evidence of whether action was required, any action that had been taken or any learning as a result. The meeting minutes we reviewed did not evidence any discussion on safety alerts. When asked, the provider was not aware of a patient safety alert issued 18 December 2018 relating to pulse oximeters.

Are services safe?

Lessons learned and improvements made

The service had systems in place to learn and make improvements when things went wrong, but these were not all well implemented.

- The provider had started to update their systems for recording, acting on, analysing and learning from significant events. A template had been created to record incidents, but this focused on injury/illness/property damage. There was no significant event policy. The provider told us they planned to discuss any events in a monthly staff meeting. We were told there had not been any significant events or unexpected or unintended safety incidents. However, during our inspection we were provided with detail of an incident constituting a significant event that had not been thoroughly recorded, investigated and disseminated to all appropriate staff. Staff told us this had been discussed at the clinic, however there was no evidence of this discussion or any other significant event in the minutes of meetings we reviewed.

Are services effective?

(for example, treatment is effective)

Our findings

We found that this service was not providing effective care in accordance with the relevant regulations. We issued a warning notice in response to these concerns:

- Care plans were not consistently completed for each patient.
- There was limited evidence of quality improvement activity.
- Not all staff had received Mental Capacity Act 2005 training appropriate to their role.

We carried out this inspection to follow up on these concerns on 23 January 2019 and found although the clinic had made improvements, not all requirements of the warning notice had been met.

Effective needs assessment, care and treatment

The lead GP told us they assessed needs and delivered care and treatment, in line with relevant standards and guidance.

- We saw that the clinic had developed a health risk assessment used for care planning, and had requested each patient to update their details. This included information such as known allergies, current medication being taken, medical history. We reviewed six clinical records and saw this had been completed and recorded in each file. The clinic told us they scanned this document into their electronic database. We cross checked five records and saw that the risk assessment had not been recorded on the database.

Monitoring care and treatment

There was limited evidence of quality improvement activity to review the effectiveness and appropriateness of the care provided.

- There was a lack of documentary evidence to demonstrate that clinical audits leading to quality improvement were planned or had been completed. The provider told us they were in the process of planning a programme of clinical audits appropriate to services and care, including prescribing.

Consent to care and treatment

The service obtained consent to care and treatment.

- All staff, including the lead GP, had completed Mental Capacity Act 2005 training. Clinicians demonstrated an understanding of the requirements of legislation and guidance when considering consent and decision making.
- We were told that patients were provided with all the information they required to make decisions about their treatment prior to treatment commencing. The clinic had revised their Terms and Conditions, which had been in place since January 2019. They told us that each patient was asked to read and sign the document. We saw evidence of completed Terms and Conditions in the patient files we reviewed.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was not providing responsive services in accordance with the relevant regulations. We issued warning notices in response to these concerns:

- The provider did not have clear systems and processes to ensure that complaints were always thoroughly recorded, acted on, analysed and appropriately stored.

We carried out this inspection to follow up on these concerns on 23 January 2019 and found although the clinic had made improvements, not all requirements of the warning notice had been met.

Listening and learning from concerns and complaints

The service told us they took complaints and concerns seriously and would respond to them appropriately to improve the quality of care. However, we found that the systems and processes for investigating, acting on and responding to complaints were still not clear.

- The provider told us they had not received any verbal or written complaints since our last inspection. Staff told us they would treat patients who made complaints compassionately.
- We were told that the lead GP was the responsible person for complaints. We were told the complaints policy had not yet been updated and we saw the policy in place was undated. Therefore, it was not possible to determine when the policy had last been reviewed. There was no patient information on how to complain and there was no reference to complaints in the clinic Terms and Conditions. Staff we spoke with could not describe the complaints procedure. Following our inspection, the provider demonstrated they took immediate action and have sent us a new complaints policy that details their complaints procedure.
- The provider told us they intended to learn lessons from individual concerns and complaints. The provider planned to implement a tracker to log complaints and for analysis of trends, but this had not yet been completed.

Are services well-led?

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

Our findings

We found that this service was not providing well-led care in accordance with the relevant regulations. We issued warning notices in response to these concerns:

- Policies and procedures were not all specific to the clinic, regularly reviewed and containing up to date information.
- The processes to identify, understand, monitor and address current and future risks including risks to patient safety were not always clear or well implemented.

We carried out this inspection to follow up on these concerns on 23 January 2019 and found although the clinic had made improvements, not all requirements of the warning notice had been met.

Governance arrangements

The responsibilities, roles and systems of accountability to support good governance and management had been improved.

- Following our last inspection in October 2018, the provider developed an action plan to address our concerns. We saw this included the concern, necessary action, personnel required and the evidence that will be available. Each concern was given a priority rating and time for completion. Many of these actions were due for immediate completion. We also saw actions that were not due for completion until after this inspection, either by 31 January 2019 or by 1 March 2019. This was after the date for compliance for both warning notices, which was 3 January 2019.
- We saw that the provider had started a process to review and update their policies and procedures to ensure they contained relevant and up to date information. We were told there were numerous policies to be updated and streamlined but they had not yet had capacity to complete this work. The provider told us there had been staff changes since our last inspection and they were currently advertising for a new practice manager. They told us that the ongoing oversight of policy review would be included in their role.

Managing risks, issues and performance

We found that the processes to identify, understand, monitor and address current and future risks, including risks to patient safety had been improved but were not always sufficient.

- The provider demonstrated that comprehensive risk assessments had been carried out in relation to safety issues, including for fire and health and safety. However, a documented action plan was not in place to ensure required improvements were completed.
- There were processes for managing risks, issues and performance, however these were not always clear or well implemented. This included the recording and oversight of safety alerts, significant events and complaints, the systems for monitoring patients' health and the management of patient records. Although the recording of patient information, consultations and treatment had been improved, the standard of the files we reviewed was inconsistent and they did not always contain information we would expect to see about the consultation and treatment plan.
- There was no evidence of a quality improvement programme or continuous clinical and internal audit in place to monitor quality and to drive improvements.

Culture

- Staff we spoke with told us the morale at the clinic had improved significantly since our last inspection. They told us they felt more supported and the provider had taken steps to improve organisation and communication within the clinic. Staff were aware that improvements were still required. They told us they felt encouraged to be involved in the process.

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 How the regulation was not being met: • The provider was unable to demonstrate accurate, complete, contemporaneous and legible records of service users in respect of care and treatment provided to the service user and decisions taken in relation to the care and treatment provided. • The registered person did not do all that was reasonably practicable to assess, monitor, manage and mitigate risks to the health and safety of service users. The provider could not demonstrate that they were ensuring patients' health was always monitored in relation to the use of medicines and then being followed up appropriately. • The provider was unable to demonstrate effective systems and processes to ensure the safe management of medicines. • The provider was unable to demonstrate effective systems or processes to assess the risk of, and prevent, detect and control the spread of, infections, including those that are health care associated. 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 How the regulation was not being met:

This section is primarily information for the provider

Enforcement actions

- The provider was unable that service policies were comprehensive, up to date and contained relevant information.
- The provider was unable to demonstrate that systems and processes were implemented effectively to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activities. This included risk assessments about the health, safety and welfare of people using their service to make required adjustments.
- The provider was unable to demonstrate systems and processes were in place to ensure significant events, complaints and safety alerts were always thoroughly recorded, acted on, analysed and appropriately stored.
- The provider was unable to demonstrate a programme of quality improvement activity to review the effectiveness and appropriateness of the care provided. The provider did not demonstrate clinical audits to monitor the quality of prescribing.

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