The Medical Cannabis Clinic

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Requires Improvement
Are services safe?	Requires Improvement
Are services effective?	Requires Improvement
Are services well-led?	Inadequate

Overall summary

We carried out an announced comprehensive inspection at The Medical Cannabis Clinic on 1 & 9 March 2022 (Previous inspection May 2021 rated Good). Following this inspection it is rated as Requires Improvement overall.

We looked at three key questions and they are rated as:

Are services safe? – Requires improvement

Are services effective? – Requires improvement

Are services well-led? – Inadequate

We carried out this announced focused inspection of The Medical Cannabis Clinic under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions and to follow up on breaches of regulation we identified in a compliance review in May 2021 and to follow up on information of concern that we had received. At the inspection carried out in May 2021 we found they were not operating effective systems and processes to ensure good governance in accordance with the fundamental standards of care, in particular:

- Some policies did not provide clear guidance to clinical staff such as the medicines management and the prescribing policy in relation to how consent is obtained and what information is given to patients about unlicensed drug use.
- There was no formal recruitment and selection process for clinical staff and no skills assessment process for managerial staff.
- The provider did not have a formal system for carrying out clinical audits and quality improvement.
- Patients were not provided with clear information about external factors that may delay receipt of their medication

At this focused inspection on 1 & 9 March 2022 we looked at the domains of Safe, Effective and Well-led. We found that although some improvements had been made, we found further concerns and served Warning Notices on the provider in relation to breaches of Regulations 12 (Safe Care & Treatment) and Regulation 17 (Good Governance)

We based our judgement of the quality of care at this service on a combination of:

- what we found when we inspected
- information from our ongoing monitoring of data about services and
- information from the provider, patients, the public and other organisations

The Medical Cannabis Clinic provides medical treatment for patients focused around the use of Cannabis Based Products for Medicinal Use (CBPMs) by experienced medical staff working within the government guidelines.

At the time of our inspection the provider was in the process of recruiting a registered manager and the head of operations was undertaking these duties. 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 did not speak directly with patients during the inspection.

Our key findings were:

Overall summary

- The provider had systems in place to protect people from avoidable harm and abuse.
- All staff we spoke with felt valued by the leaders and said there was a high level of staff support and engagement.
- Individual care records did not always indicate what the patient was being treated for.
- There were no details of discussion in Multi Disciplinary Team (MDT) meetings to demonstrate robustness of decision making.
- The provider did not have effective processes in place to assess the competencies of all staff they employed in order to plan appropriate training and development.
- The policies relating to medicines and prescribing of cannabis based medicinal products did not cover important operational aspects of the service and were not always followed.
- We found there was a lack of transparency with patients as regards pharmacy choice.
- Clinical outcomes audits did not contain sufficient details about patient outcomes to provide an adequate evaluation of the treatments prescribed.
- Patients could access care and treatment from the service within an appropriate timescale for their needs.
- There was a commitment and appetite to work with external partners to share learning and make the service as accessible as possible.
- A nurse led aftercare support service had been launched to provide additional support to patients managing chronic pain. This has had some positive feedback from patients.

The areas where the provider **must** make improvements as they are in breach of regulations are:

- 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.

Dr Rosie Benneyworth BM BS BMedSci MRCGP
Chief Inspector of Primary Medical Services and Integrated Care

Our inspection team

Our inspection team was led by a CQC lead inspector**.** The team included a CQC specialist adviser, a second inspector and two members of the CQC medicines team.

Background to The Medical Cannabis Clinic

The MC Clinic Ltd provides medical treatment for patients focused around the use of cannabis-based products for medicinal use (CBPMs) by medical staff working within government guidelines. The service is located at 10 Harley Street, London, W1G 9PF. The building entrance lobby is accessed via steps from the pavement. Wheelchair access is via a ramp at the front of the building. The service has access to two consultation rooms and a waiting area for patients. However, at the time our inspection most consultations were taking place online due to Covid–19.

The opening hours are 9am to 6pm with patients' appointments between 9.30am and 5pm. Patients can also book appointments for evenings and weekends. The medical team comprises of nine consultants who specialise in Psychiatry, Pain and Neurology. There is also a managing director, head of operations, clinic nurse advisor and nine patient services coordinators.

The service treats a range of conditions including pain, psychiatric conditions, neurological conditions, gastroenterological, cancer and palliative care.

How we inspected this service

We reviewed information sent to us by the provider remotely prior to attending the site to reduce the time spent on site in line with our Covid- 19 inspecting guidance. We spoke with the managing director, clinical director, registered manager, one of the consultants, head of operations and administrative staff. We looked at records related to patient assessments and the provision of care and treatment. We also reviewed documentation related to the management of the service. We reviewed patient feedback provided to a third party.

To get to the heart of patients' experiences of care and treatment, we asked the following three questions:

- Is it safe?
- Is it effective?
- Is it well-led?

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

Requires Improvement

Are services safe?

We rated safe as Requires improvement because:

- The provider was unable to evidence that all consulting doctors had satisfactorily completed an induction.
- Individual care records did not always indicate what the patient was being treated for.
- We noted prescriptions from another service had been used on occasions to obtain medicines from their pharmacy.
- We found records where CBPMs had been prescribed for longer than the Department of Health guidance which states that certain controlled drugs, such as CBPMs, should not normally be prescribed for more than 30 days unless there is a specific reason to do so. Where this happens, the reason (s) should be documented in the notes. There were no records of these reason(s) within the notes we reviewed.
- Where a prescribing error had occurred, this was not reported as an incident.

Safety systems and processes

The service had clear systems to keep people safe and safeguarded from abuse.

- The landlord for the building conducted safety risk assessments. They had appropriate safety policies, which were regularly reviewed and communicated to staff. They outlined clearly who to go to for further guidance. Staff received safety information from the service as part of their induction and refresher training. The service had systems to safeguard children and vulnerable adults from abuse.
- At the time of our inspection the provider was not treating children. However, they planned to start doing so once they had recruited paediatric clinicians, therefore they had systems in place to assure that an adult accompanying a child had parental authority.
- The service worked with other agencies to support patients and protect them from neglect and abuse. Staff took steps to protect patients from abuse, neglect, harassment, discrimination and breaches of their dignity and respect.
- The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. Disclosure and Barring Service (DBS) checks were undertaken where required. (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).
- Staff received up-to-date safeguarding and safety training appropriate to their role. All staff were trained to level 3. They knew how to identify and report concerns.
- The landlord for the building had an effective system to manage infection prevention and control, which had been updated to reflect the changes needed following Covid-19. The landlords had carried out Legionella testing and were following the identified actions.

Risks to patients

There were systems to assess, monitor and manage risks to patient safety.

- At the time of our inspection, due to Covid-19, consultations were being carried out online. The doctors told us they conducted consultations in private in order to maintain patient confidentiality. All consultants used an encrypted, password secure laptop to log into the operating system, which was a secure programme.
- There were arrangements for planning and monitoring the number and mix of staff needed.
- There was an induction system for all staff tailored to their role. However, the provider was unable to evidence that all consulting doctors had satisfactorily completed an induction.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. For example, we saw there were occasions where consultants had stopped the consultation to ask for further medical assessments before any treatment would be considered.
- There were appropriate indemnity arrangements in place.

Requires Improvement

Are services safe?

Information to deliver safe care and treatment

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

- Individual care records did not always indicate what the patient was being treated for. We noted that on some records the reason why the CBPM had been prescribed was not clearly stated in the patient's records.
- The service had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment.
- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading.

Safe and appropriate use of medicines

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

- The service kept prescription stationery securely, however we found they did not always monitor that all staff were using the appropriate prescriptions. We noted prescriptions from an NHS service had been used on occasions to obtain medicines from their pharmacy. Following the inspection, the provider sent information to confirm that they had recently raised this issue with the consultant involved and were planning to introduce an audit to ensure oversight of this issue.
- The provider told us they carried out regular audits to ensure safe prescribing was taking place, however we found records where CBPMs had been prescribed for longer than the Department of Health guidance which states that certain controlled drugs, such as CBPMs, should not normally be prescribed for more than 30 days treatment at a time without documented reasons for doing so. There was no rationale for this recorded in the patients notes.
- The service only prescribed cannabis-based products for medicinal use (CBPMs) which is a Schedule 2 controlled drug (medicines that have the highest level of control due to their risk of misuse and dependence). Clinicians prescribed cannabis-based medicines to patients and gave advice on how to administer them in line with legal requirements and current national guidance.
- Cannabis based medicines are currently unlicensed medicines. Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy. Therefore, they must be prescribed and supplied in line with the Medicines and Healthcare products Regulatory Agency (MHRA) guidance for the prescribing and supply of unlicensed medicines. Additional written information to guide the patient when and how to use these medicines safely was supplied with the medicine.
- They had effective protocols for verifying the identity of patients including children.

Track record on safety and incidents

The service had a good safety record.

- There were some risk assessments in relation to safety issues.
- The service had some systems for monitoring and reviewing activity. They had implemented a call monitoring system since our last inspection which helped them understand how many calls they were getting, how long people were waiting to be answered and how many calls were not answered.

Lessons learned and improvements made

The service learned and made improvements when things went wrong.

- There was a system for recording and acting on significant events.

Requires Improvement

Are services safe?

- The provider was aware of and complied with 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.

When there were unexpected or unintended safety incidents:

- They kept written records of verbal interactions as well as written correspondence.
- The service acted on and learned from external safety events as well as patient and medicine safety alerts. The service had an effective mechanism in place to disseminate alerts to all members of the team including sessional and agency staff.

Requires Improvement

Are services effective?

We rated effective as Requires Improvement because:

- Consent for communicating with GPs was missing on occasions and no summary care records for others.
- Consultation notes did not always indicate what the patient was being prescribed CBPMs for.
- There were no details of discussions undertaken in MDT meetings to demonstrate robustness of decision making.
- Records of how patient outcomes were monitored were sometimes poor, documented only as 'Better' but CBPMs continued to be prescribed.
- We found in cases where 'unmet clinical need' was not confirmed in the consultation records
- There was no formal process in place for recruiting, inducting and monitoring doctors

Effective needs assessment, care and treatment

The provider had systems to keep clinicians up to date with current evidence-based practice. However, clinicians did not always assess needs and deliver care and treatment in line with current legislation, standards and guidance (relevant to their service)

- Cannabis-based products for medicinal use (CBPMs) was legalised in the UK on 1 November 2018, but the regulations around its use and supply remain strict and should be in line with relevant and current evidence-based guidance and standards such as the Medical Cannabis Clinicians Society and National Institute for Health and Care Excellence (NICE) best practice guidelines. We were told that before patients were prescribed a CBPM, the provider would have to be satisfied that they had an 'unmet clinical need and that patients would have to have tried at least two different treatments for their condition prior to being accepted by the clinic. However, we found cases where 'unmet clinical need' was not confirmed in the consultation records. The provider informed us that they would have been discussed and noted in MDT meetings.
- We noted that not all patient records that we reviewed contained clear information about the care and treatment provided including the rational. Consultation notes did not always indicate what the patient was being treated for.
- Clinicians did not always obtain enough information from the patients and their NHS GP to confirm a diagnosis. Consent for communicating with a patient's GP was missing on occasion and there was no summary care records on the system.
- Individual consultants would recommend specific medication, however patients should only receive their prescriptions once initial prescribing decisions had been ratified at the twice weekly MDT meetings attended by consultants. However, we found the notes to these meetings did not contain enough details of the discussions that took place to demonstrate robustness of decision making or any ratification provided by second specialists in regard to prescribing Cannabis Based Products for Medicinal Use (CBPMs).
- The provider had implemented a new nurse aftercare support service since our last inspection where nurses would contact patients on a weekly basis to discuss wellbeing, which has had some positive feedback.
- We saw no evidence of discrimination when making care and treatment decisions.
- Patients had to attend follow up consultations to obtain repeat prescriptions.

Monitoring care and treatment

The service engaged in some quality improvement activity.

- The service used information about care and treatment to make improvements. The service carried out quarterly medical records audits although this was not always effective as they had not identified the concerns we found. They also completed monthly patient's outcome reports. The patient outcomes report was based on information gathered during follow up appointments and noted whether patients were either feeling 'better', 'the same' or 'worse'.

Requires Improvement

Are services effective?

- The service had only been operating for just over a year and had not developed a system for carrying out clinical audits which could assist in demonstrating quality improvement.

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles.

- All staff were appropriately qualified. However, whilst the provider had a recruitment and induction policy in place, we found they were not always effective. The provider did not provide any evidence to confirm that all clinical staff had been recruited and inducted in line with their policies. Further, there was no evidence to show the provider had assessed and understood the learning needs of their clinicians and management staff at the time of recruitment. Following the inspection, the provider sent evidence to demonstrate that clinicians had one to one meeting with senior managers.
- Relevant professionals (medical and nursing) were registered with the General Medical Council (GMC) and the Nursing Midwifery Council (NMC) and were up to date with revalidation.
- We saw that all staff had completed generic mandatory training such as Safeguarding, Health and Safety, GDPR and Mental Capacity Act. Clinicians were required to provide copies of training certificates to confirm they were up to date with the training.

Coordinating patient care and information sharing

Staff worked together, and worked well with other organisations, to deliver effective care and treatment.

- Before providing treatment, doctors at the service tried to ensure they had adequate knowledge of the patient's health, any relevant test results and their medication history.
- All patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service.
- Care and treatment for patients in vulnerable circumstances was coordinated with other services. For example, mental health services.
- The provider told us they carried out monthly audits to ensure patients had not been given an appointment for consultation, until consent had been given to obtain a medical diagnosis and history from patients' NHS GPs. However, these audits were not always effective as we found that a consent form was missing in one out of twelve records we reviewed.

Supporting patients to live healthier lives

Staff were consistent and proactive in empowering patients and supporting them to manage their own health and maximise their independence.

- Where appropriate, staff gave patients advice so they could self-care.
- Risk factors were identified, highlighted to patients and where appropriate highlighted to their usual care provider for additional support. For example, patients and their GPs were made aware of the dangers of not using the CBPMs in the manner prescribed and the legal consequences.
- Where patients needs could not be met by the service, staff redirected them to the appropriate service for their needs.

Consent to care and treatment

The service obtained consent to care and treatment in line with legislation and guidance.

Requires Improvement

Are services effective?

- Staff understood the requirements of legislation and guidance when considering consent and decision making.
- Staff supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision.

Inadequate

Are services well-led?

We rated well-led as Inadequate because:

- The provider did not have effective processes in place to assess the competencies of all staff they employed in order to plan appropriate training and development.
- We found a record where no ID had been uploaded to a patient's record in line with good guidance.
- The policies relating to medicines and prescribing of cannabis based medicinal products (CBPMs) did not cover important operational aspects of the service.
- The provider was not following their prescribing policy and had prescribed CBPMs for longer than 30-day period in line with good guidance and their own policy, and there was no rationale for this recorded in patients notes, and no MDT review undertaken.
- We found there was a lack of transparency with patients as regards pharmacy choice.
- Clinical outcomes audits did not contain sufficient details about patient outcomes to provide an adequate evaluation of the treatments prescribed.
- 'Unmet clinical need' was not always confirmed in the consultation records in line with the clinics policy.

Leadership capacity and capability;

Leaders had the capacity and skills to deliver high-quality, sustainable care.

- Leaders at all levels were visible and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.
- The provider did not have effective processes in place to assess the competencies of all staff they employed in order to plan appropriate training and development.

Vision and strategy

The service had a vision and credible strategy to deliver high quality care and promote good outcomes for patients.

- There was a clear vision and set of values. The service had a realistic strategy and supporting business plans to achieve priorities.
- The service developed its vision, values and strategy jointly with staff.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them.

Culture

The service had a culture of sustainable care.

- Staff felt respected, supported and valued. They were proud to work for the service.
- The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour. However, we found there was a lack of transparency with patients as regards pharmacy choice. We were told that patients could take their prescriptions to any pharmacy of their choice, but the clinic could not produce any evidence to confirm this was the case.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were processes for providing some staff with appraisals and career development conversations.
- There was a strong emphasis on the safety and well-being of all staff.
- The service actively promoted equality and diversity. Staff had received equality and diversity training. Staff felt they were treated equally.

Inadequate

Are services well-led?

- There were positive relationships between staff and teams.

Governance arrangements

There were some systems of accountability to support good governance and management.

- Staff were clear on their roles and accountabilities
- Leaders had established some policies, procedures and activities to ensure safety and assured themselves that they were operating as intended. We asked for policies relating to medicines and prescribing of cannabis based medicinal products. The policies provided did not cover certain operational aspects of the service, such as; treatment inclusion and exclusion criteria, considerations required to demonstrate unmet clinical need, how risks of misuse should be managed, considerations required for paediatric prescribing, how controlled stationery should be managed, additional considerations required for remote prescribing.
- We were told that before patients were onboarded and/or allocated an appointment with a consultant identity checks were carried out and one form of picture ID would be uploaded to patients' records. However, we found one record, from the sample of twelve that we looked at where this was not the case.
- We found clinicians did not always follow the policies as we found cases where 'unmet clinical need' was not confirmed in the consultation records and this was not in line with the Medicines Management policy. Further, we also found records where CBPMs had been prescribed for longer than this period stated in the clinics Prescribing Policy with no rationale for this recorded in patients notes.

Managing risks, issues and performance

There were some processes for managing risks, issues and performance.

- The provider held twice weekly MDT meetings where all proposed treatment was discussed and agreed. This meeting was attended by all consultants. However, we found the meeting notes did not contain enough information for clinicians not in attendance to understand why particulars decision had been made to ensure consistent learning.
- The service used performance information which was reported and monitored.
- The service submitted data or notifications to external organisations as required.
- There were robust arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.
- There was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The service had processes to manage current and future performance. Leaders had oversight of safety alerts, incidents, and complaints.
- The provider had not completed clinical audits which supported quality improvement, however there was some evidence of action to change services to improve quality as they had introduced a new call monitoring system and completed monthly patient outcome audits. However, the clinics audit on clinical outcomes did not contain sufficient details about patient outcomes to provide an adequate evaluation of the treatments prescribed.
- The provider had plans in place and had trained staff for major incidents.

Appropriate and accurate information

The service acted on appropriate and accurate information.

- Quality and operational information was used to ensure and improve performance. Performance information was combined with the views of patients.
- Quality and sustainability were discussed in relevant meetings where all staff had sufficient access to information.

Inadequate

Are services well-led?

Engagement with patients, the public, staff and external partners

The service involved patients, the public, staff and external partners to support high-quality sustainable services.

- The service encouraged and heard views and concerns from the public, patients, staff and external partners and acted on them to shape services and culture. The provider also responded to all the negative comments they received.
- Staff could describe to us the systems in place to give feedback. They told us they had daily and weekly meetings where they were invited to give feedback and could also provide feedback anonymously.
- The service was transparent, collaborative and open with stakeholders about performance.

Continuous improvement and innovation

There was some evidence of systems and processes for learning, continuous improvement and innovation.

- There was a focus on continuous learning and improvement. Clinicians were expected to complete a CPD accredited course, however this was not monitored.
- The service made use of internal and external reviews of incidents and complaints. The new nurse support team would contact patients when they received a complaint and ensure it was addressed in line with their Complaints policy. Learning was shared and used to make improvements.
- Leaders and managers encouraged staff to take time out to review individual and team objectives, processes and performance.
- There were systems to support improvement and innovation work. The provider was taking part in a research project which aimed to provide evidence on the effectiveness and tolerability of medical cannabis.

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.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • We found the notes to the MDT meetings did not contain enough details of the discussions that took place to demonstrate robustness of the decision making or any ratification provided by second specialists in regard to prescribing Cannabis Based Products for Medicinal Use(CBPMs). • We found two out of the five patients we reviewed had not had their first prescriptions referred to the MDT for assessment and ratification. This was not in line with the policy. • Consultation notes did not always indicate what the patient was being treated for. We found two records where the reason why the CBPM had been prescribed was not clearly stated in the patient's records. This was not in line with good practice guidance. • We found in three cases 'unmet clinical need' was not confirmed in the consultation records. This was not in line with the policy. • We found there was one record where there was no evidence of consent being given and one where there were no GP summary care records. This was not in line with your policy and put these patients at risk of harm. • We found that some records did not contain adequate details about how patients were being monitored for both safety and the effectiveness of the treatments prescribed. • We found one example where a patient had been issued a follow up prescription but there was no consultation record at all. We also found a record for another patient which did not include details or rationale as to why prescribing had been initiated for them given that one of the medical conditions they were experiencing was an exclusion criteria. This put the patient at risk of harm. • Schedule 2 CBPMs should not normally be prescribed for more than 30 days treatment at a time. We found

This section is primarily information for the provider

Enforcement actions

three records where CBPMs had been prescribed for longer than this period with no rationale for this recorded in the patients notes, and no MDT review undertaken. This was not in line with the providers own policies, which puts patients at risk.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider did not have a system in place demonstrating a consistent review process for clinical recording, review and oversight as we found: • We found there was no ID uploaded for a patient who had been prescribed a CBPM. This practice does not align the General Medical Council's "Good practice in prescribing and managing medicines and devices" guidance. • We found there was a lack of transparency with patients as regards pharmacy choice and the provider could not provide any evidence to confirm this information was provided to patients. • The medicines and prescribing of cannabis based medicinal products policies. did not cover important operational aspects of the service, such as; treatment inclusion and exclusion criteria, considerations required to demonstrate unmet clinical need, how risks of misuse should be managed, considerations required for paediatric prescribing, how controlled stationery should be managed, additional considerations required for remote prescribing and how the Multi- Disciplinary Team (MDT) should operate, and what records need to be maintained in relation to this. • The providers audit on clinical outcomes did not contain sufficient details about patient outcomes to provide an adequate evaluation of the treatments prescribed.