Privategp.com Ltd (Private General Practice Services)

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	Inadequate
Are services safe?	Inadequate
Are services effective?	Inadequate
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Inadequate

Overall summary

This service is rated as Inadequate overall**.** At our previous inspection in March 2016, independent health services were not awarded a rating, but the service was found to be compliant in all of the key questions.

The key questions from our inspection in October 2021 are rated as:

Are services safe? – Inadequate

Are services effective? – Inadequate

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Inadequate

We carried out an announced comprehensive inspection at PrivateGP.com Ltd on 12 October 2021 as all independent health services now require a rated inspection. We also wanted to review the governance arrangements to support the prescribing of medical cannabis, as a new service which had been introduced by the provider in May 2021.

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 general exemptions from regulation by CQC which relate to particular types of service and these are set out in Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Therefore, at PrivateGP.com Ltd, we were only able to inspect the services which fall under the scope of CQC registration and the regulated activities.

The lead GP, who is also the Chief Executive Officer (CEO) and Medical Director, 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:

- We found concerns relating to the provision of safe care and treatment. This included some aspects of medicines management; systems to review and comply with good standards of infection control; a lack of robust recruitment procedures; and the oversight of health and safety supported by risk assessments to mitigate any areas of concern.
- We found concerns relating to the provision of effective services. This included the absence of an established programme of quality improvement and clinical audit to demonstrate the efficacy of patient outcomes; the processes for obtaining appropriate patient consent; limited communication with the patient's registered NHS GP; and ensuring that clinicians worked within the scope of their competencies.
- We found that the service was caring and compassionate with patients and we observed a range of positive comments received from patients.
- We found that the service was responsive and flexible to patients' needs.
- We found that the service did not have sufficient governance or assurance processes in place, supported by effective leadership.

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

Overall summary

- 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.
- Ensure 'fit and proper' persons are employed by operating robust recruitment procedures, including undertaking any relevant checks and having a procedure for ongoing monitoring of staff to make sure they are adequately trained and work within the scope of their role.
- Ensure that care and treatment of service users is only be provided with the consent of the relevant person.

(Please see the specific details on action required at the end of this report).

We issued the provider with three warning notices following our inspection, highlighting where improvements must be made.

The areas where the provider **should** make improvements are:

- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.
- Improve access to the premises for service users who have a disability.
- Undertake a review of the complaints procedure to provide assurance this is adhered to in line with guidance.

I am placing this service in special measures. Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate for any key question or overall, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve.

The service will be kept under review and if needed could be escalated to urgent enforcement action. Where necessary, another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to remove this location or cancel the provider's registration.

Special measures will give people who use the service the reassurance that the care they get should improve.

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, supported by a second CQC inspector**.** The team included a GP specialist adviser, a pharmacist specialist adviser and a nurse specialist adviser.

Background to Privategp.com Ltd (Private General Practice Services)

PrivateGP.com Ltd is registered with the CQC to provide services from Beech House, 3 Knighton Grange Road, Stoneygate, Leicester. LE2 2LF. The service has a website at www.privategp.com

PrivateGP.com Ltd provides an alternative means for patients to receive medical consultation, examination, diagnosis and treatment by general practitioners and medical and clinical specialists. It is an independent provider which offers a wide range of specialist services including functional medicine, integrated therapies, sexual health, immunisations and vaccinations, the prescribing of medical cannabis, bioidentical hormone replacement therapy, nutritional medicine including intravenous vitamin therapy, mental health services, a multi-disciplinary service for autism, occupational health, cryotherapy, and aesthetic procedures.

The service is delivered from a private residence. There is a reception and administrative office on the ground floor, with consulting rooms on the first and second floors. There is limited parking on site but street parking is available very close to the practice.

The service is registered to provide the regulated activities of diagnostic and screening procedures, family planning, maternity and midwifery services, treatment of disease, disorder or injury, and services in slimming clinics.

The service is available to any person and does not require a clinical referral. Whilst most patients will be from the Leicester area, the service sees people from other parts of the country.

The service is delivered by two GPs, one of whom is the medical director and the Chief Executive Officer, assisted by a practice nurse. Operational management is provided by a commercial manager, with a support team of five administrative/reception staff. A number of clinicians, including medical and other clinical specialists and complimentary therapists, provide clinics both on and off site for patients on a contracted basis.

The opening hours are 8.30am – 5pm from Monday to Thursday, and 8.30am – 4.30pm on a Friday. Patients can access face-to-face, telephone and online consultations. Home visits can be arranged when this is deemed necessary.

Both GPs are members of the Independent Doctors Federation (IDF) which is a designated body with its own Responsible Officer. This organisation provide the GPs with a regular appraisal and support with revalidation.

How we inspected this service

Throughout the pandemic CQC has continued to regulate and respond to risk. However, taking into account the circumstances arising as a result of the pandemic, and in order to reduce risk, we have conducted our inspections differently.

This inspection was carried out in a way which enabled us to reduce the amount of time on site. This was with consent from the provider and in line with all data protection and information governance requirements.

This included:

- Conducting interviews using video conferencing.
- Requesting evidence from the provider to be submitted electronically.
- A shorter site visit which included a review of patients' notes and adherence to infection control standards.

To get to the heart of patients' experiences of care and treatment, we 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?

Inadequate

Are services safe?

We rated safe as Inadequate because:

- The provider was not ensuring the proper and safe management of medicines.
- The provider was not assessing the risk of, and preventing, detecting and controlling the spread of infection.
- The provider was not effectively assessing the risks to the health and safety of patients and doing what was reasonably practicable to mitigate any such risks.
- The provider was not ensuring that persons providing care or treatment to patients always had the qualifications, competence, skills and experience to do so safely.

Safety systems and processes

The service did not have clear systems to keep people safe and safeguarded from abuse.

- The service had developed some systems to safeguard children and vulnerable persons from abuse. There were policies available for child and adult safeguarding which were accessible to staff, and they outlined clearly who to go to for further guidance. However, the child and adult safeguarding policies provided limited information for staff. For example, training requirements were vague and had not been updated in line with Intercollegiate guidance. We observed that non-clinical staff had completed child safeguarding training level one, rather than the required level two training. There was no reference to how a safeguarding concern may be identified by staff, and issues such as domestic violence and modern slavery were not included in the policies. The provider had developed separate guidance on Female Genital Mutilation (FGM) in recognition of the families who may try and access their service for vaccinations to travel abroad for this procedure. The safeguarding policies contained some inaccuracies in terms of how any safeguarding allegations received against staff would be handled. For example, the policies correctly stated any such allegations against staff members would be reported to the Local Authority, but also that the incident would be managed through the practice complaints policy and procedure and the disciplinary procedure. Any such allegations would be investigated by the Local Authority and not dealt with internally. There was no reference to informing the CQC through the notifications system in the policy in relation to safeguarding allegations made against staff.
- The service demonstrated an awareness of the vulnerability of some of their patients, although they were reliant on families informing them of any ongoing safeguarding concerns. We were informed of a potential child safeguarding concern which the service followed up with the patient's NHS GP and their school, and achieved a good outcome for the patient.
- We were informed how the service had worked with other agencies to support patients and protect them from neglect and abuse. The lead GP had attended and contributed to multi-agency safeguarding meetings.
- We reviewed personnel files for four staff working at the service. The provider had carried out most of the required pre-employment checks at the time of recruitment, but some gaps were identified. This included verified evidence of qualifications, a record of interview notes, legible photographic identity, and absent references in some records. Therefore, we could not be assured that these members of staff had gone through an effective recruitment and selection process.
- Disclosure and Barring Service (DBS) checks were not undertaken on appointment, and we saw DBS certificates that had been obtained by previous employers were used. (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). Whilst the provider had accepted the DBS certificates from previous employers, there was no record to confirm that the appropriateness for this had been considered, and there was no procedure for updating these at specified time intervals. When issues had been identified through the DBS process, we found that the service had not undertaken a risk assessment, or had a documented process to mitigate this.
- The service was not adhering to infection prevention and control standards. The lead GP was the designated infection control lead. The practice infection control policy was limited in detail and did not always reflect how the practice

operated. For example, there was reference to an autoclave, although staff told us that there was no autoclave on site. We were provided with a copy of an infection control audit undertaken on 28 April 2021. This audit only incorporated the three clinical consulting rooms and not the remainder of the building used or accessed by staff and patients. The audit was very basic and did not provide a sufficient assessment of the premises and environment to demonstrate the practice met infection control standards. We did not see any involvement from the designated infection control lead in the audit. Our discussions with staff demonstrated a lack of awareness with regards to infection control compliance.

- We observed that two of the three clinical rooms were carpeted. We asked for, but were not provided with evidence that there was a schedule in place for the deep-cleaning of these carpets, or future plan for replacement with vinyl floor coverings. We were informed that the carpeted rooms were used for consultations, taking bloods, and occasional smears or coil removal.In the third clinical room, although there was a vinyl floor covering, we observed gaps in the floor covering and other environmental risk factors which created an infection control risk.
- There had been no environmental risk assessment to consider the safety and appropriateness of the furnishings, such as fabric coverings in clinical areas (including chairs and a privacy screen), or the fixtures in the room. These issues had not been identified as part of the infection control audit undertaken internally. The cleaning schedules did not incorporate cleaning for any of these items. The cleaning schedules completed by the contracted cleaners had been completed but it was unclear which tasks had been undertaken. There was no oversight of this process by the service. We were informed that cleaners attended for four days each week although we were informed that patients attended the practice on all five weekdays. We were informed that the cleaners attended for two hours to undertake the cleaning and tasks such as tests for Legionella, and we were informed that clinicians were responsible for cleaning surfaces and equipment in their own rooms, and general cleaning of the area and equipment in-between consultations. However, we found evidence that this was not always happening.
- We observed three clinical waste sharp bins in one of the clinical rooms, and saw that the management of clinical waste sharp bins did not follow best practice and there was no oversight of this.
- Staff we spoke with were not aware of the practice arrangements for clinical waste disposal and were unaware of where clinical waste bags were stored. The practice waste contract and pre-acceptance waste audit were not available on the day of the inspection, nor were waste consignment notes. The last consignment notes available were dated 23 October 2020. The provider was not aware that these documents were not available.
- We saw that an operational protocol including the use of personal protective equipment, social distancing and enhanced cleaning arrangements between consultations had been developed to follow during the pandemic. A hand washing audit had been completed in April 2021.
- The premises had been risk assessed for Legionella, and we saw that a programme of water testing was in place and records were kept to verify this.
- The provider ensured that equipment was safe, and that it was maintained according to manufacturers' instructions. We saw evidence that all medical equipment had been calibrated in the last 12 months and all electrical equipment had been subject to portable appliance testing (PAT). PAT is the term used to describe the examination of electrical appliances and equipment to ensure they are safe to use.
- The provider carried out environmental and safety risk assessments, including fire and health and safety checks. However, we did not find these provided assurance that these assessments were adequate in identifying and managing areas of risk. A fire risk assessment dated January 2021 had been undertaken internally. We observed that the assessment did not incorporate or consider mitigation of key risk areas. For example, there was no fire alarm or emergency lighting in situ, and there were no signs in place to highlight fire exits, or escape routes. There was no information about fire assembly points on display. Patient consultations took place on the second and third floor. We requested a risk assessment for what would happen in the event of a fire with regards evacuation but none was available. The internal fire risk assessment concluded that there were no significant hazards in the workplace. However, at the end of the report there were two comments "Long-term – look to replace the electrical wiring in the

cellar. Long-term - to possibly formalise the smoke alarm system by upgrading house alarm and combining the two". There was no evidence that this had been looked into further, and no action plan with updated information was available. The risk assessment had not included potential sources of ignition including the oxygen cylinder. There had been a recent fire drill on site.

- Health and safety assessments had not identified issues such as the storage of the oxygen cylinder. Whilst a sign said 'oxygen' on the entrance door to the room, there was nothing placed on the cupboard to indicate that oxygen was stored within it. We asked for a risk assessment for storage of the oxygen cylinder but this was not provided.

Risks to patients

There were not effective systems to assess, monitor and manage risks to patient safety.

- There were arrangements for planning and monitoring the number and mix of staff needed.
- There was an effective induction system tailored to their role.
- The service did not use locum staff.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. Staff knew how to identify and manage patients with severe infections, for example sepsis. Not all staff had completed training in sepsis at the time of the inspection.
- We were told that when there were changes to services or staff the service assessed and monitored the impact on safety. However, we identified some concerns with a new service introduced in May 2021 to prescribe medical cannabis, these are explained in the medicines section of this report.
- There were appropriate indemnity arrangements in place.
- There were suitable medicines and equipment to deal with medical emergencies which were stored appropriately and checked regularly. Some items recommended in national guidance were not kept, but there was an appropriate risk assessment to inform this decision. However, we observed that the cupboard where the emergency equipment was kept had no signage to indicate this. We were told that staff knew where they were located but it was unclear if any of the visiting contracted clinicians had been made aware of this. Therefore, there was a risk that patients may not be treated in a timely manner if they had a medical emergency.

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 were not always written and managed in a way that kept patients safe. For example, we saw that some notes for a patient had not been added onto their record contemporaneously in a timely manner. Some handwritten notes from June 2021, had not been included and were produced later on the day of the inspection. We received confirmation that these had been documented in the patient's record following our inspection.
- The service did not have clear systems for sharing information with other agencies to enable them to deliver safe care and treatment. For example, patients' registered GPs were not routinely contacted following treatment. This would be potentially important, for example, for GPs to be aware of any unlicensed medicines that were prescribed, and may influence their own clinical decision making.
- 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. Minutes from a recent staff meeting indicated that patient information awaiting archiving/shredding was being stored in the garage. On the day of the inspection, we were able to enter the garage by an unlocked door at the main entrance meaning patient information was not appropriately secured.
- Clinicians made appropriate and timely referrals in line with protocols and up to date evidence-based guidance.

Safe and appropriate use of medicines

Inadequate

Are services safe?

The service did not have reliable systems for appropriate and safe handling of medicines.

- The systems and arrangements for managing medicines, including vaccines, controlled drugs, emergency medicines and equipment did not always minimise risks. For example, the controlled drug cabinet was not securely attached to the wall and we found some out of date equipment.
- Patient Group Directions (medicines which can be given without a prescription for specific groups of people) had expired in January 2021. These can only be extended in exceptional circumstances and we were unable to determine how the service could justify this as a rationale for not having them reviewed and updated.
- The service kept prescription stationery securely and monitored its use.
- The service did not carry out regular medicines audit to ensure prescribing was in line with best practice guidelines for safe prescribing. For example, people were prescribed antimicrobials for inflammatory disorders, and the service did not monitor their use.
- The service prescribed medicinal cannabis - a schedule 2 controlled drug. Controlled drugs are medicines which requires additional controls due to their risk of misuse and dependence.

The initial consultation and prescribing of medicinal cannabis was carried out by a specialist consultant. The decision to prescribe would then need to be peer reviewed by another specialist consultant before the prescription was written. We could not see evidence of this discussion when we checked the electronic record of one patient who had been prescribed medicinal cannabis.

The policy also stated that the information must be shared with the person's regular GP, however there was some confusion as to which clinician would be responsible for this and we did not see evidence that this had taken place. The second prescription of this medicine was written by the GP at the service under a shared care agreement. However, this was against their policy which stated that the first two prescriptions should be written by the specialist consultant.

The service did not have robust policies in place for prescribing of medicinal cannabis and had ambiguous information on which people would be considered for treatment and which specific medical conditions could be treated.

Processes were not in place for accurately checking patients' medication history.

Patients were given information about their medicines and contact details if they had any problems.

- There was evidence of dispensing medicines to family members. We saw this information was recorded in a book which logged all medicines dispensed on site, and we saw this had happened on a number of occasions. This was not in accordance with the practice's own prescribing and medication policy which contained a section on family prescribing. This is also highlighted as not being deemed appropriate within professional medical guidelines.
- Staff also told us that they would not routinely share information about treatment provided by the service with the patient's GP unless they were particularly complex cases. However, this is not in line with General Medical Council (GMC) guidance which states the service must be able to explain why they have prescribed for a patient not willing to share information with their regular prescriber.
- There were no effective protocols for verifying the identity of patients when prescribing remotely, the policy did not have any information and we could not verify what safeguards the service had in place. Therefore, the service did not have accurate details for patients before prescribing.
- The service provided Bioidentical Hormone Replacement Therapy. Some of the medicines this service prescribed were unlicensed. 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. These medicines are not

recommended by the National Institute for Health and Care Excellence (NICE). NICE Guidance states that clinicians must explain to women that the efficacy and safety of unregulated compounded bioidentical hormones are unknown. We were informed that patients completed a consent form which explained the medicines were unlicensed and the possible effects these could have upon the patient.

Track record on safety and incidents

- Comprehensive risk assessments in relation to safety issues were not available.
- We were informed that the lead GP received safety alerts including those issued by the Medicines and Healthcare products Regulatory Agency (MHRA). However, we were told that none had been relevant to the service.

Lessons learned and improvements made

The service learned and made improvements when things went wrong.

- The practice provided us with a significant event policy. This was generic and did not include mention of near misses or lower level incidents, or describe the internal procedure effectively.
- There was a system for recording and acting on significant events. The service used a self-administered feedback form (SAF) for staff to raise concerns and report incidents. Leaders and managers supported them when they did so. Staff understood their duty to report incidents.
- We saw that five significant events had been recorded over the preceding 12 month period.
- There were adequate systems for reviewing and investigating when things went wrong. The service learned and shared lessons identified themes and took action to improve safety in the service. We saw that staff received feedback on learning points at meetings and in addition, a form was also circulated for staff to sign once they had read details of the incident and the learning applied from it.
- We reviewed a significant event regarding intravenous vitamin therapy which the service provided to patients as an energy boost, rather than as a first-line treatment modality. Four patients experienced a negative reaction during August 2021. The service reported the incident to the MHRA under the yellow card scheme (a system for collecting and monitoring information on safety concerns such as suspected side effects or adverse incidents involving medicines and medical devices), and also instigated an independent review. Within the service, other measures were implemented in response to the incident, this included a review of consent forms; bloods tests being undertaken prior to the procedure; and annual update training for all staff involved in the procedure. Staff we spoke with were aware of the incident and the outcomes that had resulted, and we saw this was recorded in staff meeting minutes.
- 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.

Inadequate

Are services effective?

We rated effective as Inadequate because:

- The provider did not always obtain consent to care and treatment in line with legislation and guidance.
- There was limited evidence that clinical audit was being used to drive improvements, or that there was an established programme of quality improvement.
- Staff undertook some duties for which they were not appropriately trained.
- The service did not ensure effective communication with the patient's own registered NHS GP.

Effective needs assessment, care and treatment

We saw evidence that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service).

- There were systems to keep clinicians up to date with current evidence based practice. We saw evidence that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance relevant to their service.
- Patients' immediate and ongoing needs were assessed. Detailed information was available on the service website prior to them accessing the service.
- Arrangements were in place to deal with patients who required any follow up. This could be a telephone consultation, or if they needed to be seen, they were given an appointment at the next scheduled clinic.
- We saw no evidence of discrimination when making care and treatment decisions.
- A new information technology (IT) system had been introduced in April 2021. This system is used widely in general practice and therefore offered greater opportunities for the service to work with the NHS. It also offered more functionality such as coding and searches. The practice was embedding the system at the time of our inspection but were aware of the potential this held to strengthen their clinical systems and records. It would also help compliance with the General Data Protection Regulations (GDPR), a legal requirement relating to personal data and confidentiality. It would allow the practice to explore developments such as online bookings.
- Clinical meetings had been introduced in September 2021. This consisted of the two GPs and the nurse. Minutes were available from the first meeting and we saw that discussions at the last meeting included consent and Patient Group Directions. The plan was to hold clinical meetings on a monthly basis going forward. We were informed these had not been taking place as there had only been the two doctors working on site over the last few months, and they exchanged relevant information on an ongoing basis. The clinical meetings would be a more formal process and included minutes to record discussions and any outcomes. There was no formalised meeting with other clinicians who provided services as part of PrivateGP.Com Ltd's CQC registration, but we were informed that discussions took place on an ad hoc basis whenever this was required.

Monitoring care and treatment

The service was not actively involved in quality improvement activity.

- The service told us they used information about care and treatment to make improvements, although we did not see any clear evidence to support this.
- The service did not have an active programme of clinical audit in place to impact on the quality of care and outcomes for patients. We were provided with copies of various audits that had been undertaken, however these were basic checks of numbers, rather than an audit against a particular standard with an action plan to improve and review outcomes for patients. We were provided with an audit of clinical bloods in 2021. Various clinical blood tests were

reviewed which identified the number of patients who had received these, some stating that recalls would have to be set up. There was no action plan or explanation, nor any indication that the audit would be repeated to ensure all patients were followed up, that information was shared with their own GP, or had subsequently had an appropriate recall set up.

Effective staffing

Staff did not always have the skills, knowledge and experience to carry out their roles.

- Evidence of the qualifications stated in applications was not always checked as part of the recruitment process. The provider had an induction programme for all newly appointed staff.
- Relevant professionals (medical and nursing) were registered with the General Medical Council (GMC)/Nursing and Midwifery Council and were up to date with revalidation.
- The provider understood the learning needs of staff and provided protected time and training to meet them. Records of skills and training were maintained, although non-clinical staff had not completed the required level two child safeguarding training, and some staff said they had not completed any training/awareness on sepsis. Basic life support training was overdue as this had last been completed in 2019, but this was due to take place the month following our inspection, and had been delayed due to the pandemic. Staff told us they were encouraged and given opportunities to develop.
- Staff whose role included immunisation and reviews of patients with long term conditions had received specific training and could demonstrate how they stayed up to date. However, we did not see proof of clinical competency for BCG scar verification (indicating the patient was vaccinated against tuberculosis) for the nurse as specified in their job description. The job description stated the staff member "must be able to provide proof of clinical competency in BCG scar verification". In addition, this job description included roles which the nurse was not undertaking, for example sexual health.
- In addition we saw that another clinician was undertaking specific occupational health assessments for which they had not been accredited.

Coordinating patient care and information sharing

Staff worked together, but did not always communicate effectively with other organisations, to deliver effective care and treatment.

- Before providing treatment, doctors at the service had not always ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history. This was mostly dependent on the patient providing details of their own health history.
- Patients were not routinely asked for consent to share details of their consultation, and any medicines prescribed (including antidepressant and unlicensed medicines) or test results, with their registered GP on each occasion they used the service. We did not see evidence of letters sent to their registered GP in line with GMC guidance.

Supporting patients to live healthier lives

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

- Where appropriate, staff gave people advice so they could self-care. This was incorporated into patient consultations.
- Where patients needs could not be met by the service, staff redirected them to the appropriate service for their needs.

Inadequate

Are services effective?

Consent to care and treatment

The service did not always obtain consent to care and treatment in line with legislation and guidance.

- Not all clinical staff understood the requirements of legislation and guidance when considering consent and decision making. For example, a clinician was not aware of Gillick and Fraser competencies and their application within consultations of younger people. (Gillick competence is concerned with determining a child's capacity to consent. Fraser guidelines are used specifically to decide if a child can consent to contraceptive or sexual health advice and treatment).
- We reviewed a complaint response. It was unclear in what capacity the complainant was acting as the complaint related to the care received by another person. The response talked about this person but without their involvement. It was unclear how consent had been reviewed appropriately in this case.
- We observed that PrivateGP.com Ltd's Statement of Purpose (a requirement of CQC registration to describe the service) stated "for those patient who do not speak English, consent has to be obtained via a third party, who is usually a family member who can translate". This indicated that the procedure for obtaining consent required review.
- We observed from the significant event about the administration of intravenous vitamins that the service had sometimes given these without written consent, or when written consent was available these had been continued over a protracted timescale without review. An outcome from the significant event was that written consent would be required for all patients using this service and consideration would be given to review consent forms annually for long term patients.
- We saw the issue of the documentation required for parental consent had been discussed at a staff meeting in September 2021.
- We were told that where appropriate, staff assessed and recorded a patient's mental capacity to make a decision.

Good

Are services caring?

We rated caring as Good.

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- The service sought feedback from patients on their experience and quality of clinical care patients received.
- Feedback from patients was positive about the way staff treated them. The service provided us with examples of patient feedback which they had received, all of which were extremely complimentary.
- The service contacted 100 patients who had received treatment in the three months before our inspection to invite them to comment on their experience, and we received seven responses. All seven patients highlighted that they had received a caring and understanding approach from the team, and were treated with dignity and respect.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.
- The service gave patients timely support and information.

Involvement in decisions about care and treatment

Staff helped patients to be involved in decisions about care and treatment.

- We were told that interpretation services were available for patients who did not have English as a first language.
- Patients told us, through the CQC's online 'share your feedback' form, that they felt listened to and supported by staff and had sufficient time during consultations to make an informed decision about the choice of treatment available to them.

Privacy and Dignity

The service mostly respected patients' privacy and dignity.

- Staff mostly recognised the importance of people's dignity and respect.
- Staff knew that if patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.
- We observed that only one privacy screen was available for the three consulting rooms.

The service supported their own charitable foundation to help poverty, including projects in Ghana, and supported a local project called 'Soundcafe' in Leicester. Soundcafe provided an opportunity for people who are homeless, socially isolated, or living in vulnerable housing in Leicester and Leicestershire, to explore their own creativity.

Good

Are services responsive to people's needs?

Responding to and meeting people's needs

The service mostly organised and delivered services to meet patients' needs. However, it did not fully take account of patient needs and preferences.

- The provider understood the needs of their patients and improved services in response to those needs. For example, the service had introduced prescribing medical cannabis in response to an unmet need for patients.
- The premises were within a residential property and offered a welcoming and calm environment for patients to attend.
- There were steps into the building although we were informed a ramp was available, however access would still be problematic by wheelchair and electric scooter. Consultations took place on the second and third floor, and these were only accessible by stairs. We were informed that patients with reduced mobility could have a home visit or alternatively they would be seen downstairs in either the reception area or in the lounge. There was no accessible toilet and the practice did not hold equipment such as a hearing loop for those with a hearing impairment. The practice policy statement read "In the eventuality of support for sensory needs or disabilities being required, the National Service Framework (NSF) would be consulted as these have various bodies available that can offer help and support", however, NSFs were discontinued in 2013.

Timely access to the service

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

- The service opened from 8.30am until 5pm Monday to Thursday, and from 8.30am to 4.30pm on Friday.
- Patients had timely access to initial assessment, test results, diagnosis and treatment.
- Appointments were set at a minimum length of 15 minutes, but the appointment length was flexible depending on the individual's need and personal requirements.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Patients with the most urgent needs had their care and treatment prioritised.
- Patients reported that they were able to access care promptly and their preferred type of appointment was offered (face-to-face or remote). Home visits could be arranged for those patients who were unable to attend the practice.
- Referrals and transfers to other services were undertaken in a timely way.

Listening and learning from concerns and complaints

The service took complaints and concerns seriously but did not always respond to them appropriately. Complaints were used to improve the quality of care.

- Only one complaint had been received in the 12 months prior to our inspection. We reviewed the response sent to the complainant. It was unclear in what capacity the complainant was acting as the complaint related to the care received by another person. However, we saw that the response was compassionate and detailed. There was no reference to any further action that may be available to the complainant should they not be satisfied with the response to their complaint.
- We observed that the practice's statement of purpose said that if complainants were dis-satisfied with the outcome of a complaint investigation response, they had the right to complain to the CQC. However, the CQC does not have a remit to deal with patient complaints.
- Information about how to make a complaint or raise concerns was available. There was a written complaints resolution procedure which did reflect guidance.

Good

Are services responsive to people's needs?

- The service learned lessons from individual concerns and complaints and these would be shared and discussed at staff meetings.
- Interviews with staff highlighted that they would record a patient's complaint within the patient record. This is not in alignment with guidance for GPs in England which states that complaints should be stored separately from the patient's record.

Inadequate

Are services well-led?

We rated well-led as Inadequate because:

- We did not find evidence of clear and effective leadership.
- Governance arrangements were not working effectively.
- The provider was unable to demonstrate that there were effective systems in place to manage and mitigate risks.
- The provider was unable to provide assurances that staff were working competently with effective oversight of their work.
- There was limited evidence that the practice engaged with patient's own general practitioners to ensure continuity of care.

Leadership capacity and capability

Leaders did not have the capacity and skills to deliver high-quality, sustainable care.

- The service was directed by a Board consisting of four members, which included the two GPs. The Board met on a bi-monthly basis.
- At the time of the inspection, leaders did not display an adequate understanding of some issues and priorities relating to the quality and governance of services. There was no clearly defined oversight and assurance process in place, allowing for any emerging risk to be identified and subsequently addressed.
- Following our inspection, leaders took swift action to develop plans to address the areas we identified as concerns. They demonstrated a strong commitment to improve, and sought external advice and support.
- Leaders at all levels were visible and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.

Vision and strategy

The service had a clear vision and strategy although this was not always reflected in the delivery of high quality care and the promotion 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 Board developed its vision, values and strategy, and we saw an emphasis on growth. For example, with the development of the medical cannabis prescribing service, and plans to develop a new base in London.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them.

Culture

The service had a culture of high-quality sustainable care.

- Staff felt respected, supported and valued. They were proud to work for the service.
- The service focused on the needs of patients.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- All employed staff had received an appraisal in the last year, and GPs participated in the GP appraisal programme. Staff were supported to meet the requirements of professional revalidation where necessary.

Inadequate

Are services well-led?

- There were positive relationships between staff and teams. Staff told us they worked together as a team to support each other. One member of the team arranged social activities outside work hours which helped team building and fostered positive working relationships.

Governance arrangements

There were no clear responsibilities, roles and systems of accountability to support good governance and management.

- Structures, processes and systems to support good governance and management were not clearly set out or working effectively.
- Leaders had established policies and procedures to ensure safety but these were not always accurate, up to date, or being adhered to. There was no clear oversight in place to provide assurance that procedures were operating as intended.
- Staff were not always clear on their roles and accountabilities. For example, we observed that a clinician was doing a specific assessment on patients that they had not been accredited to do.
- The information used to monitor performance and the delivery of quality care was not always accurate and useful. There was limited evidence of plans to address any identified weaknesses.
- The service told us they submitted data or notifications to external organisations as required. For example, a yellow-card notification had been submitted to the MHRA following adverse patient reactions to intravenous therapy.
- We did not observe that robust arrangements were operational in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems. Staff told us they did not always lock their computers when leaving their workstation. We observed this frequently on the reception desk on the day of our inspection visit.

Managing risks, issues and performance

There was limited clarity around processes for managing risks, issues and performance.

- There was not an effective process to identify, understand, monitor and address current and future risks including risks to patient safety.
- Performance of clinical staff could not be demonstrated through audit of their consultations, prescribing and referral decisions. We did not see clear evidence of how the provider sought assurance on the quality of services delivered by sub-contracted clinicians.
- Clinical audit was limited. We were unable to see how the practice could demonstrate the positive impact on quality of care and outcomes for patients.
- The provider had plans in place to respond to major incidents.

Appropriate and accurate information

The service did not have appropriate and accurate information.

- We did not see how quality and operational information was used to ensure and improve performance, although we observed that the service did seek and review patient feedback.
- Quality and sustainability had been discussed in relevant meetings where all staff had sufficient access to information. Clinical team meetings commenced the week before our inspection.

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, and staff acted on them to shape services and culture.
- We were informed that staff meetings would normally be held every six to eight weeks, although the frequency of these had decreased during the pandemic. We requested to see the most recent minutes of these meetings and were provided with minutes from March and September 2021. Staff told us they received regular communications and as a small team this was easy to facilitate.
- The service worked with the Independent Doctors Federation.
- The service provided a lot of information for patients on their website. We were told that work was in progress to review and update the information. The service was hoping to develop a system for online appointment bookings.

Continuous improvement and innovation

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

- The service reviewed incidents and complaints. Learning was shared and used to make improvements.

The provider had recently worked with another agency on a research project to prescribe medical cannabis. The project aimed to monitor the health outcomes of 20,000 patients using cannabis based medicinal products, to create the largest body of evidence in Europe for the safety and efficacy of medical cannabis.

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 Family planning services Maternity and midwifery services Services in slimming clinics Treatment of disease, disorder or injury	Regulation 11 HSCA (RA) Regulations 2014 Need for consent There was evidence that patient consent was not always being sought appropriately and documented. • Written consent was not always being obtained when this was indicated. • Consent was not being reviewed when treatment was being provided over a prolonged timescale. • There was a lack of understanding of consent processes for younger people. This was in breach of Regulation 11 (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 Family planning services Services in slimming clinics Treatment of disease, disorder or injury Maternity and midwifery services	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The registered persons had not done all that was reasonably practicable to mitigate risks to the health and safety of patients receiving care and treatment. In particular: In relation to the safe management of medicines: • The service must ensure all medical equipment and medicines are in date. • The service must ask patients to consent to sharing information with their regular prescriber or justify any decisions to prescribe if a patient does not consent. • The service must have robust procedures to ensure safe prescribing during remote prescriptions. • The service must have sufficient and reliable information before prescribing for a patient. • The service must ensure all patient records are kept up to date promptly. • The service should conduct regular audits to check safe prescribing of antibiotics and the efficacy of unlicensed medicines. • The service must have procedures in place to accurately check patients' medical history. • The service must review how it shares information about patients' treatment with their regular prescriber following consent. There was limited assessment of the risk of, and preventing, detecting and controlling infections. In particular: • The service must arrange for a competent person to undertake a comprehensive infection prevention and control audit and develop an action plan.

This section is primarily information for the provider

Enforcement actions

- The service must ensure that clinical procedures are undertaken within an environment that adheres to good standards of infection control.
- The service must ensure effective oversight of waste management including the waste produced within clinical areas, and the clinical waste produced for collection with accompanying consignment notes.
- The service must ensure that appropriate equipment used on patients is kept sterile, cleaned after use, and consumables are disposed of once they reach their expiry date.

The registered persons had not done all that was reasonably practicable to mitigate risks to the health and safety of patients receiving care and treatment. In particular:

- Risk assessments relating to health and safety were not comprehensive in identifying potential concerns, or in implementing actions to control risk.

This was in breach of Regulation 12 (1) (2)(a)(b)(c)(d)(e)(g)(h)(i) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

We served a warning notice with a compliance date of 16 November 2021 for each of these enforcement actions.

Regulated activity	Regulation
Diagnostic and screening procedures Maternity and midwifery services Services in slimming clinics Treatment of disease, disorder or injury Family planning services	Regulation 17 HSCA (RA) Regulations 2014 Good governance There were limited systems or processes that enabled the registered person to assess, monitor and improve the quality and safety of the services being provided. In particular: • Practice policies were not always comprehensive, accurate, up to date, and in some cases were not always adhered to. • A programme of established clinical audit or quality improvement was not apparent.

This section is primarily information for the provider

Enforcement actions

- Staff were not adhering to information governance protocols, for example, the computer at the reception desk was frequently left unmanned with the information on the screen visible.
- The oversight of the work undertaken by contracted clinicians (including remote consultations) was unclear and not formalised in order to provide assurances, for example: that contracted clinicians were up to date in terms of clinical and professional knowledge; received regular appraisals; recorded patient notes for the service to an acceptable standard; and contributed to the recording of any significant incidents or complaints which arose through their work for the service.
- The controlled drugs cupboard was locked but it was not secured to the wall as required by the Misuse of Drugs (Safe Custody) Regulations.

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

We served a warning notice with a compliance date of 16 November 2021 for each of these enforcement actions.

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Maternity and midwifery services Services in slimming clinics Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed • Safe recruitment procedures could not always be evidenced due to the absence of some recruitment checks. Disclosure and Barring checks had not been undertaken for appropriate staff, and where risk had been identified from previous DBS checks, this had not always been fully considered. • The provider was not always ensuring that persons providing care or treatment to patients had the competence to do so safely. This was in breach of Regulation 19 (1)(2)(3)of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. We served a warning notice with a compliance date of 16 November 2021 for each of these enforcement actions.