

E-med Private Medical Services Ltd

# E-med Private Medical Services Ltd

## Inspection report

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## Overall summary

Letter from the Chief Inspector of General Practice

At our previous inspection on 5, 6 March 2018, we found, in addition to providing a service for patients through the provider website, [www.e-med.co.uk](http://www.e-med.co.uk); the provider was also providing consultations, private healthcare referrals and prescriptions for five external companies; 'Health Express Healthcare'; 'Menscare UK Ltd'; 'PharmacyDirectGB'; 'Healthwise'; and 'Uk-med'. On 8 March 2018 the provider was issued an urgent Notice of Decision under Section 31 of the Health and Social Care Act 2008, to impose conditions on their registration as a service provider as we found the provider was not providing a safe, effective, caring, responsive and well led service for patients.

We imposed the following urgent conditions on the registration of E-Med Private Medical Services Ltd:

- The registered provider must not provide online doctor consultations or prescribe any medicine or medicinal product that contains a medicine, for service users for any companies or websites other than [www.e-med.co.uk](http://www.e-med.co.uk).
- The registered provider must not prescribe to any service user any medicine, or medicinal product that contains a medicine, other than Naltrexone.

We carried out an announced comprehensive inspection at E-Med Private Medical Services Ltd on 1 November 2018 to follow up on breaches of regulations.

This report outlines our findings in relation to the service with the above three urgent conditions imposed:

Are services safe? – we found the service was providing a safe service in accordance with the relevant regulations. Specifically:

- Arrangements were in place to safeguard people, including arrangements to check patient identity.
- People were told about the risks associated with medicines used outside of their licence.
- Suitable numbers of staff were employed and appropriately recruited.
- Risks were assessed and action taken to mitigate any risks identified.

Are services effective? - we found the service was providing an effective service in accordance with the relevant regulations. Specifically:

- Following patient consultations information was appropriately shared with a patient's own GP, with their consent, in line with GMC guidance.

# Summary of findings

- Quality improvement activity, including clinical audit, took place.
- Staff received the appropriate training to carry out their role.

Are services caring? – we found the service was providing a caring service in accordance with the relevant regulations. Specifically:

- The provider carried out checks to ensure consultations by the doctor met the expected service standards.
- Patient feedback reflected they were satisfied with the service they had received.
- Patients had access to information about clinicians working at the service.

Are services responsive? - we found the service was providing a responsive service in accordance with the relevant regulations. Specifically:

- Information about how to access the service was clear and the service was available 7 days a week.
- The provider did not discriminate against any client group.

- Information about how to complain was available and complaints were handled appropriately.

Are services well-led? - we found the service was providing a well-led service in accordance with the relevant regulations. Specifically:

- The service had clear leadership and governance structures.
- A range of information was used to monitor and improve the quality and performance of the service.
- Patient information was held securely.

The areas where the provider should make improvements are:

- Increase the health information available to patients about leading healthier lives.
- Review the provision of a male consulting doctor to provide patients with a choice of either a male or female clinician to undertake their consultation.

**Professor Steve Field** CBE FRCP FFPH FRCGP

Chief Inspector of General Practice

# E-med Private Medical Services Ltd

## Detailed findings

### Background to this inspection

E-Med Private Medical Services Ltd was established in March 2000 and registered with the Care Quality Commission in October 2012. E-Med operates an online clinic for patients via a website ([www.e-med.co.uk](http://www.e-med.co.uk)), providing consultations and prescriptions for Low Dose Naltrexone (LDN) medicine.

The service, for consultations, is open between 9am and 5pm on weekdays and available to UK

and European residents. This is not an emergency service. Patients are required to join E-Med as a member to access the service and there is an annual membership fee of £20.

For each consultation there is a charge of £15 which includes issuing the prescription and if patients are not satisfied with the service they are given a refund. For each consultation the patient completes a free-text questionnaire for the symptoms or condition they believe they have and the prescription is issued or declined by the doctor as appropriate. The IT system in place enables doctors to request further information from patients via email, telephone or Skype.

If the doctor decides not to prescribe a requested medicine, the patient is sent an email stating the order will not be fulfilled and a refund is processed. Once approved by the doctor, patients are requested to indicate a pharmacy of their choice for their LDN prescription to be sent to. Patients were also able to request a paper prescription to be posted to them to be dispensed at a pharmacy of their choice. However, as LDN is an off-label medicine (a medicine licensed for a different indication to

that for which it is prescribed in this case), it is not readily stocked by all pharmacies and therefore the service directed patients to an affiliated pharmacy which is also recommended by the LDN Trust.

The provider employs one doctor on the GMC register to work remotely in undertaking patient consultations based on the information submitted by patients through website questionnaires. The provider also employs a doctor on the GMC register as a 'Clinical Lead' for the service. In addition to the clinical staff, the service employs a Registered Manager. A registered manager is a person who is registered with the CQC 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). An IT consultant was employed on an ad-hoc basis as required.

#### How we inspected this service

This inspection was carried out 1 November 2018 by a lead CQC inspector, a GP Specialist Advisor and a second CQC inspector.

Before the inspection we gathered and reviewed information from the provider. During this inspection we spoke to the Registered Manager and members of the management and clinical team.

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

- Is it safe?
- Is it effective?

# Detailed findings

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

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

## **Why we inspected this service**

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

# Are services safe?

## Our findings

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

### Keeping people safe and safeguarded from abuse

Staff employed by the provider had received training in safeguarding adults and Child Protection Level three and knew the signs of abuse. All staff had access to the safeguarding policy and knew how to report a safeguarding concern. It was a requirement for the doctors being employed by the service to provide evidence of up to date safeguarding Child Protection Level three training certification. All staff had access to the safeguarding policies and where to report a safeguarding concern.

The provider did not treat children and safeguards had been put in place on the [www.e-med.co.uk](http://www.e-med.co.uk) website to prevent children from accessing the service. For example, new patients were required to send in a form of ID after they had joined the service as a member. The request for proof of patient identity was included in the website's terms and conditions. Patients were asked to provide a scanned copy of a passport, photo driving license, or identity card. If this was not possible, patients were asked to provide other documentation such as two scanned copies of a bank statement, utility bill or similar. In addition to two of these documents, patients were also asked to provide a photo which had been countersigned to verify their identity. The website informed patients of the requirement of ID in order to join as a member. If the patient declined the ID request, the form was not allowed to proceed and the patient would not be able to access the service for a consultation.

### Monitoring health & safety and responding to risks

The provider website clearly informed patients the service did not prescribe medicines for insomnia, anxiety, mental health issues or pain-like symptoms. It was their policy that medicines of this nature which are at risk of being potentially abused would not be prescribed and patients would be signposted to access their NHS GP for such prescriptions.

The provider headquarters was located within a purpose-built office, housing the management staff. Patients were not treated on the premises and doctors carried out the online consultations remotely usually from

their home. All staff based in the premises had received training in health and safety including fire safety. The provider expected that all doctors would conduct consultations in private and maintain the patient's confidentiality. Each doctor used an encrypted, password secure laptop to log into the operating system, which was a secure programme. Doctors were required to complete a home working risk assessment to ensure their working environment was safe.

The service was not intended for use by patients with either long term conditions or as an emergency service. In the event an emergency did occur, the provider had systems in place to ensure the location of the patient at the beginning of the consultation was known, so emergency services could be called.

Regular meetings were held with staff, where standing agenda items covered topics such as audits and safety alerts.

### Staffing and Recruitment

Staff told us there were enough doctors to meet the demands for the service. The provider had a selection and recruitment process in place for all staff. There were several checks that were required to be undertaken prior to commencing employment, such as references and Disclosure and Barring service (DBS) checks. 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.

Potential provider doctor employees had to be registered with the General Medical Council (GMC) (on the GP register – if applicable). They had to provide evidence of having professional indemnity cover, an up to date appraisal and certificates relating to their qualification and training in safeguarding and the Mental Capacity Act.

A checklist was in place for newly recruited doctors to ensure all processes had been covered. We reviewed three recruitment files which showed the necessary documentation was available. The doctors could not be registered to start any consultations until these checks and training had been completed. The provider kept records for all staff including the doctors and there was a system in place that flagged up when any training or documentation was due for renewal such as their professional registration.

# Are services safe?

## Prescribing safety

Following our previous inspection, on 8 March 2018 the provider was issued an urgent

Notice of Decision under Section 31 of the Health and Social Care Act 2008, to impose conditions on their registration as a service provider as our inspection found the provider was not providing a safe, effective, caring, responsive and well led service.

The conditions imposed restricted the service to only being able to prescribe one medicine, Naltrexone, for patients through the provider website. At this inspection we found the provider had complied with the conditions imposed upon their service.

At our previous inspection on 5,6 March 2018, we were not assured staff understood the potential risk and legal implications of prescribing off-label medicines (a medicine licensed for a different indication to that for which it is prescribed). Medicines are given licences after trials have shown they are safe and effective for treating a particular condition. Use of a medicine for a different medical condition that is listed on their licence is called unlicensed use and can pose a higher risk because less information is available about the benefits and potential risks. The use of a licensed medicine outside the terms defined by the license; carries a greater responsibility for the healthcare professional prescribing. There are legal implications if there is a subsequent problem experienced by the patient associated with the use of the medicine. The risks associated with prescribing unlicensed medicines or a licensed medicine off-label include adverse reactions; product quality; and the 'Patient Information Leaflet' for this medicine referring to the licensed use of this medicine which would be confusing for the patient and put them at increased risk.

At this inspection we found staff did understand the potential risk and legal implications of prescribing off-label medicines. We reviewed 14 patient consultations for the prescribing of

Low Dose Naltrexone medicines (LDN) and found this medicine was appropriately prescribed for patients and the consultation forms were satisfactory. The service only prescribed LDN medicine for patients with conditions that LDN could help with as listed on the 'Low Dose Naltrexone (LDN) Research Trust' website. Patients were required to provide proof of diagnosis of one of these conditions in

order to proceed with a consultation with the service. If a prescription of LDN was deemed appropriate following a consultation, the doctor could issue a private prescription to patients.

We found the service website included information for patients on unlicensed medicines. The website also provided links for patients to access information to NICE guidance and factsheets produced by the LDN Research Trust. There was also information included within the prescription on how to take the medicine including the recommended dosage and links to the LDN Research Trust information fact sheets and the Multiple Sclerosis Research Centre.

Since our last inspection, peer review of consultations was being undertaken by the Clinical Lead and prescribing was monitored. We saw evidence of some consultations which had been rejected by the service.

There were protocols in place for identifying and verifying the patient and General Medical Council guidance, or similar, was followed.

Where prescriptions were generated for patients, patients were able to choose a pharmacy where they would like their prescription dispensed.

## Information to deliver safe care and treatment

On registering with the [www.e-med.co.uk](http://www.e-med.co.uk) website, and at each consultation patient identity was verified. The doctors had access to the patient's previous records if they had used the service previously. For patients returning for a repeat of any medicines, they were required to complete a new health assessment questionnaire to ensure it was still suitable for the doctor to continue to prescribe the treatment.

## Management and learning from safety incidents and alerts

We were not fully assured there was an effective system in place for the management and learning from safety incidents. There was a policy in place for identifying, investigating and learning from incidents, however, at our inspections in January 2017, March 2018 and November 2018, staff told us there had not been any occurrence of safety incidents and therefore there were no records for us to review.

## Are services safe?

However, staff were aware of the requirements of the Duty of Candour and the incidents policy reflected the Duty of Candour and stated that if an incident had compromised or potentially compromised the safety or well-being of a patient, this would be explained to them and an apology would be given.

At our previous inspection in March 2018 we were not assured there was an effective process in

place to ensure doctors were kept up to date with safety alerts. There was no system in place to provide employees with appropriate guidance to carry out their roles in a safe and effective manner.

Since our last inspection the service had developed a new system for the management of safety alerts. Arrangements were in place for the Clinical Lead to receive the safety alerts and ensure these were distributed to the doctor.

# Are services effective?

(for example, treatment is effective)

## Our findings

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

### Assessment and treatment

We reviewed 14 examples of medical records that demonstrated the doctor assessed patients' needs and prescribed Low Dose Naltrexone medicine in line with guidance from the 'Low Dose Naltrexone (LDN) Research Trust.

If the doctor had not reached a satisfactory conclusion there was a system in place where they could contact the patient again. The IT system enabled doctors to undertake video or telephone consultations with patients where necessary to request further information.

Patients completed an online form which included their past medical history and patients were required to provide the service with confirmation of diagnosis of their medical condition. There was a set template to complete for the consultation that included the reasons for the consultation and the outcome to be manually recorded, along with any notes about past medical history and diagnosis. We reviewed 14 medical records which were complete records. We saw adequate notes were recorded and the doctor had access to all previous notes.

Staff providing the service were aware of both the strengths (speed, convenience, choice of time) and the limitations (inability to perform physical examination) of working remotely from patients. They worked carefully to maximise the benefits and minimise the risks for patients. If a patient needed further examination they were directed to an appropriate agency. If the provider could not deal with the patient's request, this was explained to the patient and a record kept of the decision.

### Quality improvement

At our previous inspection we found the provider did not monitor patient consultations or carry out consultation and prescribing audits in order to improve patient outcomes. Staff told us they monitored the numbers of patients using the service.

At this inspection we found the service took part in quality improvement activity and had an audit programme in place. Monthly and six-monthly audits were in place.

Monthly audits included a review of consultations which included if patient identity had been appropriately obtained; confirmation of diagnosis was provided; patient questions were responded to in a timely manner; if patient consent had been obtained; and if a copy of the consultation had been sent to the patient's GP where consent for this had been given. Six monthly audits included a review of any patient refunds for consultations; complaints received; and patient feedback.

### Staff training

All staff had to complete induction training which included safeguarding and information governance. Staff also had to complete other training on a regular basis which included lone working. The registered manager had a training matrix which identified when training was due.

Staff received support if there were any technical issues or clinical queries and could access policies. If any updates were made to the IT systems, staff told us the doctors would receive further online training.

All the doctors had to have received their own appraisals before being considered eligible at recruitment stage. Doctors who had an external appraisal included their online work as part of this appraisal. An in-house appraisal for the consulting doctor was in place with the Clinical Lead being the appraiser for this and all other staff received an in-house appraisal from the Director of the service.

### Coordinating patient care and information sharing

When a patient contacted the service, they were asked if the details of their consultation could be shared with their registered GP. If patients agreed we were told that a letter was sent to their registered GP in line with GMC guidance.

At our previous inspection we found some patient records where patients consented for their consultation to be shared with their GP yet there was no evidence recorded this had been undertaken for these patients. At this inspection we found a new monthly audit was in place to check if the patient consented for their consultation to be shared with their GP, that this had been completed by the service. The audit also ensured patients provided the service with proof of their diagnosis from their GP before the consulting doctor proceeded with the consultation.

### Supporting patients to live healthier lives

# Are services effective?

(for example, treatment is effective)

The service website provided information for patients relating to travel health including vaccinations and immunisations; and health advice relating to undertaking scuba diving activities.

# Are services caring?

## Our findings

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

### **Compassion, dignity and respect**

We were told the doctor undertook online consultations in a private room and were not to be disturbed at any time during their working time. The Clinical Lead carried out monthly checks to ensure the doctor was complying with the expected service standards and communicating appropriately with patients. Feedback arising from these spot checks was relayed to the doctor.

We did not speak to patients directly on the days of the inspection. However, we reviewed patient feedback which had been collected by the service as part of the six-monthly patient feedback audit as part of this inspection which showed patients were satisfied with the service provided.

### **Involvement in decisions about care and treatment**

At our previous inspection, patients did not have access to information about all of the clinicians working at the service. However, at this inspection we found patients had access on the service website to brief descriptions about the consulting doctor and the Clinical Lead. As there was only one consulting doctor working for the service, patients were unable to request to book a consultation with a male doctor at this stage.

Patients could have a copy of their consultation if they made a written request to the provider.

The service website provided a telephone number to assist patients in using the service and to answer any queries. Staff told us that translation services were not available for patients who did not have English as a first language. However, the consulting doctor spoke Romanian in addition to English and the service website had a translation function for patients in Arabic.

# Are services responsive to people's needs?

(for example, to feedback?)

## Our findings

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

### Responding to and meeting patients' needs

Patients accessed the service via the website from their computer or other portable device with internet access. Consultations were provided between 9am and 5pm on weekdays but access via the website to request a consultation was all day every day. The digital application allowed people to contact the service from abroad but all medical practitioners were required to be based within the United Kingdom. Patients could sign up to receiving this service on a mobile phone (smart phones that met the required criteria for using the app).

The provider made it clear to patients what the limitations of the service were. This was not an emergency service and unlikely to be a service a patient would access in case of an emergency. The service website advised patients that if they needed immediate medical assistance, to dial 999 or if appropriate, to contact their own GP or the NHS 111 service.

Any prescriptions issued were delivered within the UK to a pharmacy of the patient's choice or patients could request a paper prescription to be posted to them to be dispensed at a pharmacy of their choice.

### Tackling inequity and promoting equality

The service offered consultations to anyone who requested and paid the appropriate fee, and did not discriminate against any client group. The service had an Equality Policy in place to ensure both patients and staff were not discriminated against, either directly or indirectly.

### Managing complaints

Information about how to make a complaint was available on the service website under the 'Terms and Conditions' section. The service had a complaints policy and procedure

in place. The policy contained appropriate timescales for dealing with the complaint. Following receipt of a complaint, written acknowledgement was sent to the patient within two working days unless a full response could be made within five working days and a full response was sent to patients within 20 working days. There was an escalation guidance within the policy.

At our previous inspection there was no evidence of complaints received in the last 12 months to assess if these were handled appropriately. Since our last inspection, there had been one complaint received. The service was able to demonstrate the complaint we reviewed was handled correctly and the patient received a satisfactory response. There was evidence of learning as a result of the complaint and this had been communicated to staff.

### Consent to care and treatment

There was information on the service website with regards to how the service worked and what costs applied. The service telephone number was clearly displayed on the website and there was an 'Information Request' link for patients to utilise if they wanted to make any enquiries via email.

All of the provider doctors had received training on the Mental Capacity Act 2005. However, at our previous inspection, as a result of staff interviews and a review of patient consultations, we were not assured staff understood and sought patients' consent to care and treatment in line with legislation and guidance. Clinicians failed to respond appropriately to scenarios we gave them relating to patients' mental capacity to make decisions. Additionally, there were no audits of patient records in place to monitor the process for seeking consent. At this inspection we found the consulting doctor gave appropriate responses to scenarios we gave them relating to patients' mental capacity to make decisions and monthly audits were now in place to check patient consent was gained as part of the consultation.

# Are services well-led?

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

## Our findings

We found that this service was providing a well-led service in accordance with the relevant regulations.

### **Business Strategy and Governance arrangements**

Staff told us they had a clear vision to help people who need healthcare quicker and faster and to provide a service for patients who were not able to access a GP and receive a face to face consultation.

There was a clear organisational structure and staff were aware of their own roles and responsibilities. Policies and procedures were available online on a secure admin page for staff to access at any time and these were reviewed annually. Staff had also acknowledged and signed they were aware of the policies and procedures being available on this page. Staff were required to sign a checklist against every policy name they had read and acknowledged, and these checklists were kept within individual staff personnel files.

Monthly and six-monthly checks were in place to monitor the performance of the service. These included peer review of consultations and patient feedback. The information from these checks was discussed at staff team meetings.

There were arrangements for identifying, recording and managing risks, issues and implementing mitigating actions.

The care and treatment records we reviewed were complete, accurate, and securely kept.

### **Leadership, values and culture**

At our previous inspection the provider had recently recruited a doctor to act as a 'Clinical Lead' however this role was yet to be embedded and there were no formal arrangements for clinical

supervision or peer review to support the doctors to undertake their role. At this inspection we found the Clinical Lead was responsible for reviewing and distributing safety alerts to the consulting doctor; undertook regular monthly audits to peer review their consultations; and had responsibility for any medical issues arising.

Staff told us if there were unexpected or unintended safety incidents, the service would give affected patients reasonable support, truthful information and a verbal and written apology.

### **Safety and Security of Patient Information**

Systems were in place to ensure that all patient information was stored and kept confidential.

There were policies and IT systems in place to protect the storage of patient information and the security of patients' personal data was ensured through third party technical support and encryption services. The service could provide a clear audit trail of who had access to records and from where and when. There was a working from home and remote locations policy; a working from home and remote locations employee self-assessment; and an employer working from home and remote locations assessment in place. All staff were required to complete and sign the self-assessment.

The self-assessment form questions included, if consultations and access to the service was undertaken in a private room; if the devices used were password protected; and if the internet connections used were secure. Once the self-assessment form was completed, this was followed up by the employer working from home and remote locations assessment. These assessments were stored in the staff personnel files. The service was registered with the Information Commissioner's Office. Staff had received training in confidentiality and information governance.

At our previous inspection there was no process in place for patient records if the provider ceased trading. The provider had now developed a 'Termination of activities' policy which included a process for patient electronic and paper records.

### **Seeking and acting on feedback from patients and staff**

There was a specific feedback box on the patient consultations forms to record patient feedback for every consultation generated via the service website. It was company policy that if any members were dissatisfied with their consultation via the service website; a full refund was given. At our previous inspection an audit was undertaken annually to detail each refund

# Are services well-led?

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

undertaken within the year and the reasons for the refunds. At this inspection we found this audit had been changed to take place every six months and also included a review of complaints and patient feedback.

At our previous inspection we found documented, structured meetings had not taken place on a regular basis to support staff feedback and had discontinued. At this inspection we saw evidence of meeting minutes which had taken place on a regular basis.

The provider had a whistleblowing policy in place. (A whistle blower is someone who can raise concerns about practice or staff within the organisation.) The Director was the nominated person for dealing with any issues raised under whistleblowing.