

e-med Private Medical Services Ltd

e-med Private Medical Services Ltd

Inspection report

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Overall summary

We previously carried out an announced comprehensive inspection at E-Med Private Medical Services Ltd on 31 January 2017 and found this provider was not providing safe, effective and well led services in accordance with the relevant regulations but was providing a caring and responsive service. As a result of this inspection, the provider was required to take urgent action in relation to breaches identified of Regulation 12 of the Health and Social Care Act 2008: 'Safe care and treatment' and was issued a Notice of Decision to impose conditions on their registration as a service provider to develop effective systems and processes to govern activity.

The full comprehensive report of the 31 January 2017 inspection can be found by selecting the 'reports' link for E-Med Private Medical Services Ltd on our website at <http://www.cqc.org.uk/location/1-2179748601/reports>.

An announced focussed inspection was carried out on 2 August 2017 to review the issues previously identified at our inspection on 31 January 2017 and, to check and confirm that the service had carried out its plan to meet the legal requirements. At this stage we found that the

provider had taken appropriate action to meet the requirements of the regulations relating to providing a safe, effective and well led service for the provider website; www.emed.co.uk.

The full comprehensive report of the 2 August 2017 inspection can be found by selecting the 'reports' link for E-Med Private Medical Services Ltd on our website at <http://www.cqc.org.uk/location/1-2179748601/reports>.

At our inspection on 2 August 2017 it was further established that the provider was providing an online doctor service for a number of external companies. As a result of this information the provider was issued with a series of letters which requested a definitive list of all companies that the provider had provided medical advice for in the past, presently or planned to do so in the future; further information about the roles and responsibilities for carrying out the regulated activities for these external companies; a list of all of the websites associated with these companies for which the provider were providing medical advice, including undertaking patient consultations and prescribing; and a copy of signed contracts between the provider and these companies.

Summary of findings

Following receipt of this information we carried out an announced comprehensive inspection at E-Med Private Medical Services Ltd on 5 and 6 March 2018 to inspect the online doctor service provided by the provider for these external companies in addition to the service provided to patients accessing the provider's own website; www.e-med.co.uk.

Our findings in relation to the key questions were as follows:

Are services safe? – We found this provider was not providing a safe service in accordance with the relevant regulations.

Specifically:

- Staff were unclear what arrangements were in place for identity checks for the external companies they provided the online doctor service for or how children were safeguarded from accessing these services.
- Prescribing was not always in line with national guidance, and people were not told about the risks associated with all medicines used outside of their licence.
- There were no prescribing audits to monitor the quality of prescribing for patients.
- We were not assured there was an effective system in place for the management and learning from safety incidents and alerts.

Are services effective? - We found this provider was not providing an effective service in accordance with the relevant regulations.

Specifically:

- We were not assured, from both our interviews with the doctors and the review of patient records, that doctors had taken into account relevant nationally recognised guidance, particularly in relation to medicines management for the prescribing of asthma, diabetes and erectile dysfunction medicines.
- Our review of patients' records found multiple examples of patient consultations where there was no evidence of any further follow up questions asked by the doctor to the patient for exploration of patient symptoms for the safe prescribing of some medicines.

- The service did not monitor patient consultations or carry out consultation and prescribing audits in order to improve patient outcomes.
- There was no system in place to identify the ongoing learning needs of staff.
- Following patient consultations information was not appropriately shared with a patient's NHS GP in line with GMC guidance.

Are services caring? – We found this provider was not providing a caring service in accordance with the relevant regulations.

Specifically:

- The service did not carry out checks to ensure consultations by doctors met the expected service standards.
- Patients did not have access to information about all the doctors working at the service.

Are services responsive? - We found this provider was not providing a responsive service in accordance with the relevant regulations.

Specifically:

- Although the websites were not an emergency service and unlikely to be a service that a patient would access in case of an emergency; not all of the websites advised patients that if they needed immediate medical assistance, to dial 999 or if appropriate to contact their own GP or NHS 111 service.
- Patients were not able to access brief descriptions of the doctors available on any of the websites with the exception of www.e-med.co.uk which gave brief details about one of the doctors undertaking the consultations.
- Information about how to complain was not always available and there was no evidence of complaints received in the last 12 months to assess if these were handled appropriately. We were not assured the provider had oversight of the governance arrangements for how complaints were managed by the companies they provided the online doctor service for.

Summary of findings

- 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.

Are services well-led? - We found this provider was not providing a well-led service in accordance with the relevant regulations.

Specifically:

- There was a lack of oversight of the governance arrangements of the external companies for which the provider provided online doctor consultations.
- We found the provider had no assurance regarding who was undertaking the pre-screening clinical function of patient consultations or their professional competence to do so, for three of the external companies for which they provided an online doctor service.
- Our review of patient records found no evidence that the doctors clarified medical history or treatment with the patient's NHS GP, which put patients at potential risk of harm as it meant that the service was reliant upon patients for entering accurate and truthful information about their medical history.
- There was no quality improvement programme in place to monitor the quality of patient consultations and prescribing and make improvements.
- We were not assured the provider had an adequate system in place to provide employees with appropriate guidance to carry out their roles in a safe and effective manner.
- The Director had a lack of oversight of the governance arrangements of the external companies for which the provider provided online doctor consultations and there was a lack of management and clinical leadership in place for the doctors.
- There was a lack of oversight of how the external companies for which the provider provided online doctor consultations, managed and maintained the safety and security of patient information.

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

- Ensure that care and treatment of patients is only provided with the consent of the relevant person.
- Ensure care and treatment is provided in a safe way to patients.
- Ensure there is an effective system for identifying, receiving, recording, handling and responding to complaints by patients and other persons in relation to the carrying on of the regulated activity.
- Ensure persons employed in the provision of the regulated activity receive the appropriate support, training, professional development, supervision and appraisal necessary to enable them to carry out the duties.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.

You can see full details of the breach of regulations at the end of this report.

Enforcement action

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.

We imposed the following conditions:

- 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
- The registered provider must not prescribe to any service user any medicine, or medicinal product that contains a medicine, other than Naltrexone.

Professor Steve Field CBE FRCP FFPH FRCGP

Chief Inspector of General Practice

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found this provider was not providing a safe service in accordance with the relevant regulations.

Are services effective?

We found this provider service was not providing an effective service in accordance with the relevant regulations.

Are services caring?

We found this provider was not providing a caring service in accordance with the relevant regulations.

Are services responsive to people's needs?

We found this provider was not providing a responsive service in accordance with the relevant regulations.

Are services well-led?

We found this provider was not providing a well led service in accordance with the relevant regulations.

e-med Private Medical Services Ltd

Detailed findings

Background to this inspection

Background

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), providing consultations, private healthcare referrals and prescriptions. 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 or private healthcare referral 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, the patient can take their prescription to a pharmacy of their choice. For prescriptions for Low Dose Naltrexone (LDN) medicines patients were 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.

At the time of this inspection on 5 and 6 March 2018; 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'. The majority of patient consultations, referrals and prescriptions undertaken by the provider were generated through these websites.

With the exception of the 'Healthwise' company; patient consultations were operated via various websites. At the time of this inspection, these companies operated the following websites, which we were told by provider staff is not a definitive list:

- www.healthexpress.co.uk
- www.121doc.com
- www.euroclinx.net
- www.onlineclinic.co.uk
- www.menscare.com
- www.rxbank.com
- www.pharmacydirectgb.co.uk
- www.uk-med.co.uk
- www.uk-clinic.co.uk

At the time of this inspection, none of the external companies as listed above were registered with the CQC to provide regulated activities.

Detailed findings

The provider employs three doctors 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 an IT consultant on an ad-hoc basis as required. At the time of our inspection the provider was in the process of applying for a new registered manager with the CQC. 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).

How we inspected this service

This inspection was carried out on 5 and 6 March 2018 by a lead CQC inspector; two GP specialist advisers, a second CQC inspector, and a member of the CQC medicines team.

Before the inspection we gathered and reviewed information from the provider. During this inspection we spoke to the Director, Clinical Lead, GP Mentor and three doctors.

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?

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. We carried out an announced comprehensive inspection at E-Med Private Medical Services Ltd on 5 and 6 March 2018 to inspect the online doctor service provided by the provider for the external companies listed above in addition to the service provided to patients accessing the provider's own website; www.e-med.co.uk.

Are services safe?

Our findings

We found that this provider was not providing a safe service in accordance with the relevant regulations.

Staff were unclear what arrangements were in place for identity checks for the external companies they provided the online doctor service for or how children were safeguarded from accessing these services. Prescribing was not always in line with national guidance, and people were not told about the risks associated with all medicines used outside of their license. There were no prescribing audits to monitor the quality of prescribing for patients. We were not assured there was an effective system in place for the management and learning from safety incidents and alerts.

Keeping people safe and safeguarded from abuse

Staff employed by the provider had received training in safeguarding adult and Child Protection Level 3 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 GPs registering with the service to provide evidence of up to date safeguarding Level 3 training certification.

The provider did not treat children and safeguards had been put in place on the 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 had been added to 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 etc. 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.

However, when we asked staff about the arrangements in place for identity checks for the external companies they provided the online doctor service for they were unclear what processes were in place or how children were safeguarded from accessing these services.

Monitoring health & safety and responding to risks

The www.e-med.co.uk 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 sort 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.

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.

None of the websites were intended for use by patients as an emergency service. However, there was no evidence available of any processes in place to manage any emerging medical issues during a consultation.

Staffing and Recruitment

Staff told us there were enough doctors to meet the demands for the service. We found the majority of patient consultations were processed in under a minute.

The provider had a selection and recruitment process in place for all staff. There were a number of 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.

An induction checklist was in place for newly recruited doctors to ensure all processes had been covered. We

Are services safe?

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 induction training had been completed.

Prescribing safety

If a medicine was deemed necessary following a consultation, the doctors were able to issue a private prescription to patients. There were no controlled drugs prescribed by the doctors working for the provider.

However, 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). 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.

We reviewed patient consultations for the prescribing of Metformin medicine. Metformin is a licensed medicine for the treatment of Type 2 diabetes to control blood sugar levels. Our review of patient consultations found examples of Metformin prescriptions generated for patients for the treatment of symptoms of Polycystic Ovarian Syndrome (PCOS) and not diabetes and were therefore being prescribed Metformin as an "off-label" medicine (medicine intended for unlicensed indications). A patient must give informed consent to an unlicensed or off-label medicine. However, we saw no evidence of information on the websites used for patients to be prescribed Metformin medicine or any information within the patient questionnaires about this medicine being unlicensed or used off label.

As part of this review of patient consultations we also found examples of patient consultations in which the HbA1c test results were not requested from the patients and examples of HbA1c test results being submitted by patients which were over three months old.

We reviewed patient consultations for the prescribing of Low Dose Naltrexone medicines via the www.e-med.co.uk website and found this 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 Low Dose Naltrexone (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. We found this medicine was appropriately prescribed for patients and the consultation forms were satisfactory.

We reviewed patient consultations for the prescribing of Ventolin and Salbutamol inhalers used to treat asthma. Following a review of eight of these consultations we found all eight patients had been prescribed medicines unsafely and there was no documentation of the clinical rationale for decisions to prescribe medicines where consent was not given to contact a patient's registered GP. There was no evidence of any further follow up questions asked by the doctor to ensure the asthma inhalers were not being overprescribed for the patient.

We were not assured the provider followed current prescribing guidelines. There were no prescribing audits to monitor the quality of prescribing for the online questionnaires and the provider did not have a set list of medicines which was adhered to for prescribing.

Where prescriptions were generated for patients, patients were able to choose a pharmacy where they would like their prescription dispensed. Where medicines were delivered direct to patients, the websites offered patients a next day delivery service where possible.

Information to deliver safe care and treatment

On registering with the www.e-med.co.uk website, and at each consultation patient identity was verified. However, we were not assured patient identity was verified for patients accessing care via the external companies for which the provider was providing a doctor service. The GPs 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.

Are services safe?

Management and learning from safety incidents and alerts

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

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.

We were not assured there was an effective process in place to ensure doctors were kept up to date with safety alerts. One doctor told us they were sent alerts by 'Health Express Healthcare' and provided emails to demonstrate this. However we had no evidence of how the other two doctors working for the service were keeping themselves up to date as there was no internal process in place for this. We were therefore not assured the provider had an adequate system in place to provide employees with appropriate guidance to carry out their roles in a safe and effective manner.

The provider computer system did not have the functionality to be able to search for a patient according to a medicine name. As a result, following the receipt of a safety alert; the provider would not be able to quickly search for patients using the service for which the alert would be relevant.

Are services effective?

(for example, treatment is effective)

Our findings

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

We were not assured from both our interviews with the doctors and the review of patient records, doctors had taken into account relevant nationally recognised guidance, particularly in relation to medicines management for the prescribing of asthma, diabetes and erectile dysfunction medicines. Our review of patients' records found multiple examples of patient consultations where there was no evidence of any further follow up questions asked by the doctor to the patient for exploration of patient symptoms for the safe prescribing of some medicines. The service did not monitor patient consultations or carry out consultation and prescribing audits in order to improve patient outcomes. There was no system in place to identify the ongoing learning needs of staff. Following patient consultations information was not appropriately shared with a patient's NHS GP in line with GMC guidance.

Assessment and treatment

We were not assured from both our interviews with the doctors and the review of patient records, doctors had taken into account relevant nationally recognised guidance, particularly in relation to medicines management for the prescribing of asthma, diabetes and erectile dysfunction medicines. Two of the doctors we interviewed were not aware that renal function could be affected with use of Metformin medicine and there was no question relating to renal function on the patient consultation forms for the prescribing of this medicine. Within the patient consultation forms for the prescribing of erectile dysfunction medicines, there was no specific question to ask patients if they were taking any Nitrate medicine. National guidance issued relating to nitrate and erectile dysfunction medicines state this combination must be avoided as it can produce significant hypotension (low blood pressure) and is potentially fatal.

Patients completed online forms which included their past medical history. There were set template questions on each website for patients to complete for the consultation which included the reasons for the consultation. However, our review of patients' records found multiple examples of

patient consultations where there was no evidence of any further follow up questions asked by the doctor to the patient for exploration of patient symptoms for the safe prescribing of some medicines.

As part of our patient records review we found numerous examples of patient consultation forms for various medicine prescriptions which asked patients to select from a drop-down option on the patient questionnaire a range for their blood pressure and were not able to enter their specific blood pressure reading. One of the drop-down options was "Normal - Between 90/60 - 150/100." This feature as part of the patient questionnaires could put patients at risk of harm as a blood pressure level of 140/90 is considered to be "High" blood pressure according to guidelines from the National Institute for Health Care Excellence (NICE). Having a blood pressure which is higher than the recommended level increases a person's chance of having a heart attack or stroke.

Quality improvement

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.

Staff training

All staff had to complete induction training which included safeguarding, information governance, record keeping, mental capacity act, and health and safety. Staff also had to complete other training on a regular basis such as basic life support and fire safety.

The provider had recently employed two additional new doctors to undertake online patient consultations and a third doctor to undertake a Clinical Lead role. As these doctors had recently been employed they had not undergone a performance appraisal. However, it was not clear who would be undertaking the appraisals for the doctors in the future and the ongoing learning needs of staff were not identified as there was no system in place for any staff one-to-one meetings.

Coordinating patient care and information sharing

When a patient signed up to use the service from www.e-med.co.uk they were asked if the details of their consultation could be shared with their NHS GP. If patients agreed we were told that a copy of the consultation notes were shared with the GP.

Are services effective?

(for example, treatment is effective)

As part of our patient records review, we identified that the majority of patients did not consent for the information about their consultation and medicines prescribed for them, to be shared with their GP. However, 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; and we found some consultation forms which did not include a question to patients to ask them if they wanted their consultation shared with their GP.

Where patients indicated they did not consent for their consultation information to be shared with their GP, we found no documentation within any of the patient records we reviewed, of the clinical rationale why the prescription was appropriate despite being unable to share information with a GP or how patient safety would be assured in the absence of information sharing.

For patients requiring a private referral to a specialist; the online doctors emailed or faxed the specialist the patient had identified or the doctors would assist the patient in finding an appropriate specialist on behalf of the patient. The doctors processed the referral information within the service computer system and generated a referral letter for the patient. Whilst there was no evidence the service monitored the appropriateness of referrals to improve patient outcomes our review of patient records found no evidence of inappropriate referrals.

Supporting patients to live healthier lives

The www.e-med.co.uk website provided information for patients relating to travel health including vaccinations and immunisations; and health advice relating to undertaking scuba diving activities. The Health Express Healthcare websites and the www.pharmacydirectgb.co.uk website also offered patients travel health information.

Are services caring?

Our findings

We found that this provider was not providing a caring service in accordance with the relevant regulations.

The service did not carry out checks to ensure consultations by doctors met the expected service standards. Patients did not have access to information about all the doctors working at the service.

Compassion, dignity and respect

We were told that the doctors undertook online consultations in a private room at home and were not to be disturbed at any time during their working time.

However, there were no systems in place to ensure the doctors were complying with the expected service standards and communicating appropriately with patients.

We did not speak to patients directly on the days of the inspection. However, we checked patient feedback which was reported on the various websites we reviewed as part of this inspection which showed patients were satisfied with the service provided.

Involvement in decisions about care and treatment

All of the websites we reviewed 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, two of the doctors spoke Romanian and one of the doctors spoke Greek in addition to English. On the www.e-med.co.uk website there was a translation function for patients in Arabic.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this provider was not providing a responsive service in accordance with the relevant regulations.

Although the websites were not intended for use in an emergency and unlikely to be a service that a patient would access in case of an emergency; not all of the websites advised patients that if they needed immediate medical assistance, to dial 999 or if appropriate to contact their own GP or NHS 111 service. Patients were not able to access brief descriptions of the doctors available on any of the websites with the exception of www.e-med.co.uk which gave brief details about one of the doctors undertaking the consultations. Information about how to complain was not always available and there was no evidence of complaints received in the last 12 months to assess if these were handled appropriately. We were not assured the provider had oversight of the governance arrangements for how complaints were managed by the companies they provided the online doctor service for. 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.

Responding to and meeting patients' needs

E-Med Private Medical Services Ltd

The provider service was open between 9am and 5pm on weekdays however patients could access the website; www.e-med.co.uk; 24 hours a day. Patients accessed the service via the website from their computer or other portable device with internet access. Patients could complete an online questionnaire. The IT system enabled doctors to undertake video or telephone consultations with patients where necessary. However, from our review of patient consultations we found no evidence of patients being contacted by the doctors via these methods to request further information. This was not an emergency service and unlikely to be a service that a patient would access in case of an emergency. The www.e-med.co.uk website advised patients that if they needed immediate medical assistance, to dial 999 or visit their local A&E department.

For certain medicines patients could request a pharmacy of their choice for their prescription to be sent to or could request a paper prescription to be posted to them to be dispensed at a pharmacy of their choice.

UK Med

Staff told us the 'UK-Med' service operated two websites; www.uk-clinic.co.uk and www.uk-med.co.uk. Both websites offered patients online consultations to diagnose and suggest treatments for impotence (erectile dysfunction). The www.uk-med.co.uk website also offered patients treatments for hair and weight loss. The www.uk-clinic.co.uk service was open between 9am and 5pm on weekdays however patients could access the website 24 hours a day. The www.uk-med.co.uk service offered a membership which gave patients telephone access to a GMC registered doctor 24 hours, seven days a week to answer any medical questions and patients could access the website 24 hours a day. These websites were not an emergency service and unlikely to be a service that a patient would access in case of an emergency. However, there was no information on either of these websites to advise patients that if they needed immediate medical assistance, to dial 999 or if appropriate to contact their own GP or NHS 111 service. Both websites offered patients a next day delivery service. The www.uk-clinic.co.uk website offered patients erectile dysfunction medicine packaged discreetly in opaque unmarked bags with no brand or medicines mentioned on the bags.

Pharmacy Direct GB

Staff told us 'Pharmacy Direct GB' operated one website www.pharmacydirectgb.co.uk. This website offered patients online consultations to diagnose and prescribe a range of treatments for hay fever and allergies; statins and cholesterol; erectile dysfunction; arthritis and gout; asthma; contraception; cystitis; incontinence; malaria; migraine; premature ejaculation; period delay; sexually transmitted disease; smoking cessation; hair loss and weight loss. There was no information on the website to inform patients of the operating time of this service however patients could access the website 24 hours a day. A special next day delivery service was offered to patients for an additional fee. This website was not an emergency service and unlikely to be a service that a patient would access in case of an emergency. However, there was no information on this website to advise patients that if they

Are services responsive to people's needs?

(for example, to feedback?)

needed immediate medical assistance, to dial 999 or if appropriate to contact their own GP or NHS 111 service. The website informed patients that all deliveries were sent using plain, unbranded packaging.

Menscare UK Ltd

Staff told us 'Menscare UK Ltd' operated two websites; www.menscare.com and www.rxbank.com. The service offered to patients via these websites was between 9am and 5pm on weekdays however patients could access the websites 24 hours a day. Both websites offered patients online consultations to diagnose and prescribe treatments for impotence, obesity, hair loss however the www.menscare.com website also offered patient consultations for influenza. These websites were not an emergency service and unlikely to be a service that a patient would access in case of an emergency. However, there was no information on these websites to advise patients that if they needed immediate medical assistance, to dial 999 or if appropriate to contact their own GP or NHS 111 service. Both websites offered patients a next day delivery service. The www.menscare.com website informed patients medicines purchased would be dispatched with discreet packaging.

Health Express Healthcare

Staff told us 'Health Express Healthcare' operated four websites; www.healthexpress.co.uk, www.121doc.com, www.euroclinux.net, www.onlineclinic.co.uk. Each of these websites informed patients the service was open from 8am to 5:30pm weekdays, however patients could access these websites 24 hours a day. These websites were not an emergency service and unlikely to be a service that a patient would access in case of an emergency. However, the websites advised patients that if they needed urgent assistance not to use this service and to telephone 111 or 999. These websites offered patients online consultations to diagnose a range of conditions. All of the websites offered patients a next day delivery service. All of the websites informed patients medicines purchased would be dispatched with discreet packaging.

Healthwise

Staff informed us 'Healthwise' did not operate a website and patients were screened by 'Customer Services' staff who passed on questionnaire information recorded over

the telephone to E-Med Private Medical Services Ltd doctors to process the prescription. We were not provided with information regarding the operating times of this service for patients. Staff told us 'Healthwise' offered patients a service to treat erectile dysfunction.

Tackling inequity and promoting equality

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

Patients were not able to access brief descriptions of the doctors available on any of the websites with the exception of www.e-med.co.uk which gave brief details about one of the doctors undertaking the consultations. Therefore, patients did not have the option available to choose either a male or female doctor to undertake their online consultation.

Managing complaints

Information about how to make a complaint was available on the www.e-med.co.uk service's website under the 'Terms and Conditions' section. Information about how to make a complaint was available for patients on the www.pharmacydirectgb.co.uk. At the time of this inspection, none of the other websites we checked for which the provider provided an online doctor service for, detailed information for patients on how to make a complaint. The provider 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 escalation guidance within the policy.

At our previous inspection on 31 January 2017, we were provided with two complaints which had been received in the last 12 months. At this inspection staff told us no further complaints had been received as a result of the www.e-med.co.uk website. Staff told us the provider undertook over 1000 patient consultations per week for the external companies they provide an online doctor service for. We requested evidence of any complaints received from patients accessing the online doctor services from

Are services responsive to people's needs?

(for example, to feedback?)

these external company websites however there was no evidence of any patient complaints. We were not assured the provider had oversight of the governance arrangements for how complaints were managed by the companies they provided the online doctor service for.

Consent to care and treatment

There was information on all of the websites we checked as part of this inspection with regards to how the service worked and what costs applied. Each website had a 'Contact Us' link which provided patients with details on how to contact the services with any enquiries.

All of the provider doctors had received training about the Mental Capacity Act 2005 however, 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. Staff told us that the patient's ability to complete the online questionnaires demonstrated their consent to care and treatment. Additionally, there were no audits of patient records in place to monitor the process for seeking consent.

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 provider was not providing a well led service in accordance with the relevant regulations.

There was a lack of oversight of the governance arrangements of the external companies for which the provider provided online doctor consultations. We found the provider had no assurance regarding who was undertaking the pre-screening clinical function of patient consultations or their professional competence to do so, for three of the external companies for which they provided an online doctor service. Our review of patient records found no evidence that the doctors clarified medical history or treatment with the patient's NHS GP, which put patients at potential risk of harm as it meant that the service was reliant upon patients for entering accurate and truthful information about their medical history. There was no quality improvement programme in place to monitor the quality of patient consultations and prescribing and make improvements. We were not assured the provider had an adequate system in place to provide employees with appropriate guidance to carry out their roles in a safe and effective manner. The Director had a lack of oversight of the governance arrangements of the external companies for which the provider provided online doctor consultations and there was a lack of leadership in place for the doctors. There was a lack of oversight of how the external companies for which the provider provided online doctor consultations, managed and maintained the safety and security of patient information.

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.

Policies and procedures were available online on a secure admin page for staff to access at any time. Staff had also acknowledged and signed that they were aware of the policies and procedures being available on this page. Staff were now also required to sign a checklist against every policy name they had read and acknowledged, and these checklists were kept within individual staff personnel files.

Despite undertaking over 1000 patient consultations per week, there was no evidence of any complaints received by the provider from these external companies and staff were

not clear what the complaints processes were or how these were managed by these external companies. There was also no evidence of any incidents or significant events reported and recorded for any of these external companies.

Our inspection established that patient consultations for 'Health Express Healthcare' were pre-screened by four doctors who were not registered with the GMC and did not have a license to practice in the UK. Patients who accessed the www.menscare.com website were informed their consultation forms were pre-screened by EU registered doctors. Patients who accessed the 'Healthwise' service were screened by 'customer services' staff who passed on the patient questionnaire information recorded over the telephone to the provider doctor to process the prescription. We found the provider had no assurance who was undertaking this pre-screening clinical function or their professional competence to do so. Patients were therefore put at potentially significant risk of harm as a result of staff undertaking the pre-screening of consultations without the assurance these staff members had the clinical skills and qualifications to provide this function safely.

The provider did not have oversight of how identity checks to verify the identity of patients were being carried out by all of the external companies for which the provider doctors were providing the online doctor service for. There was therefore no assurance there were effective systems in place to ensure children could not access the services and a risk that patients under the age of 18 could access these. As our review of patient records found no evidence that the doctors clarified medical history or treatment with the patient's NHS GP, this also put patients at potential risk of harm as it meant that the service was reliant upon patients for entering accurate and truthful information about their medical history.

There was no evidence of any clinical meetings minuted since July 2017, despite two new doctors being recruited to the service in September and November 2017. There was no evidence of any clinical audits being undertaken since our last inspection in August 2017 to monitor the quality of patient consultations or prescribing. There was no quality improvement programme in place including second-cycle clinical audit used to monitor quality and to make improvements.

We were not assured there was an effective process in place to ensure doctors were kept up to date with NICE guidance and safety alerts. One doctor told us they were

Are services well-led?

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

sent alerts by 'Health Express Healthcare' and provided emails to demonstrate this. However we had no evidence of how the other two doctors working for the service were keeping themselves up to date as there was no internal process in place for this. We were therefore not assured the provider had an adequate system in place to provide employees with appropriate guidance to carry out their roles in a safe and effective manner.

We were not assured there was an effective system in place to ensure patient consultation information was shared with patients' GPs when they had consented for this to be done for them. We found no evidence of patient consultations being shared despite finding some consultations where patients had requested the online doctor to do this for them. We also found evidence of some consultation forms which did not give patients the option to have details of their consultation shared with their GP.

As part of our information gathering prior to this inspection, on 31 October 2017 we requested a copy of signed contracts between the provider and the external companies for which the provider provides online doctor consultations for. We were subsequently informed there were no formal signed contracts in place with any of these external companies.

Leadership, values and culture

The Director had overall responsibility for the corporate management of the company. Our inspection found the Director had a lack of oversight of the governance arrangements of the external companies for which the provider provided online doctor consultations and there was a lack of leadership in place for the doctors. The service was reliant upon the three doctors undertaking patient consultations generated from the provider website and the patient consultations generated via the various websites of the external companies.

At our previous inspection in January 2017 there was no clinical leadership in place. At the time of this 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 still no formal arrangements for clinical supervision or peer review to support the doctors to undertake their role and no evidence of any clinical meetings since July 2017.

Staff told us that if there were unexpected or unintended safety incidents, the service would give affected patients

reasonable support, truthful information and a verbal and written apology. However, there were no significant events recorded and therefore there was no evidence to support this.

Safety and Security of Patient Information

There were policies and IT systems in place to protect the storage of patient information for the www.e-med.co.uk website and the security of patients' personal data was ensured through

third party technical support and encryption services. 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 is undertaken in a private room; if the devices used are password protected; and if the internet connections used are 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 provider was registered with the Information Commissioner's Office. Staff had received training in confidentiality and information governance however there was no process in place for patient records if the provider ceased trading.

The provider could not provide us with details of the systems or processes in place to protect the storage of patients' personal data for the external companies for which they provide online doctor consultations for. There was a lack of oversight of how the external companies for which the provider provided online doctor consultations, managed and maintained the safety and security of patient information.

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 www.e-med.co.uk website. It was company policy that if any members were dissatisfied with their consultation via the www.e-med.co.uk website; a full refund was given. An annual report was produced to detail each refund undertaken within the year and the reasons for the refunds

Are services well-led?

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

of the patient consultations. Patients could also contact the service directly to ask questions or raise a concern and the contact form and telephone number was clearly displayed on the www.e-med.co.uk website.

Staff were not able to provide us with information on how feedback from patients was acted on by the external companies for which the provider provided online consultations. There was a lack of oversight of the feedback received from patients accessing these services and subsequently a lack of engagement with patients in the delivery of the service.

At our inspection in January 2017 we found feedback from staff had been gathered through ad-hoc discussion. Staff told us regular, documented and structured meetings would be implemented for the future to support staff feedback. However, since July 2017 there had been no staff meetings.

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.

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
Transport services, triage and medical advice provided remotely	Section 31 HSCA Urgent procedure for suspension, variation etc.
Treatment of disease, disorder or injury	<p>Regulation 12 Safe care and treatment</p> <p>How the regulation was not being met:</p> <p>We found numerous examples of poor quality of consultations for patients, with lack of requests for further information and exploration of patient symptoms; potential over prescribing for asthmatic patients; medicines being prescribed for off label use and this not being communicated to patients; prescribing with deviation from national guidance; no records to show patients requests for information to be shared with their GP being completed; questionnaires not asking patients specific questions for the safe prescribing of some medicines.</p> <p>Regulation 12, 1</p> <p>Regulation 17 Good Governance</p> <p>How the regulation was not being met:</p> <p>There was a lack of oversight of governance arrangements for companies working with E-Med Private Medical Services Ltd. No complaints had been received by the provider from the affiliated companies and the provider was not sure what the process was or how these were managed by the affiliated companies. There were no incident or significant events reported and recorded by provider staff for any of the affiliated companies.</p> <p>There was no assurance of who was completing the pre-screening clinical function for some of the patient consultations or their clinical qualifications or competencies to do so.</p> <p>No clinical meetings had been minuted since July 2017.</p>

Enforcement actions

There were no clinical audits being undertaken to monitor the quality of consultations or prescribing and improve patient consultations.

We were not assured there was an effective process in place to ensure E-Med doctors were kept up to date with NICE guidance and safety alerts.

We were not assured there was an effective system in place to ensure patient consultation information was shared with patients GPs.

Regulation 17, 1

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.

We imposed the following conditions:

- 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
- The registered provider must not prescribe to any service user any medicine, or medicinal product that contains a medicine, other than Naltrexone.