BMH Medical Administration

Inspection report

International House
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London
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Tel:

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

Ratings

Overall rating for this location	Requires Improvement
Are services safe?	Requires Improvement
Are services effective?	Good
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Requires Improvement

Overall summary

Letter from the Chief Inspector of General Practice

We rated this service as Requires improvement overall.

The key questions are rated as:

Are services safe? – Requires improvement

Are services effective? – Good

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Requires improvement

We carried out an announced comprehensive inspection at BMH Medical Administration on 5 October 2022 as part of our rated inspection programme.

BMH Medical Administration, is registered to provide the regulated activity treatment of disease, disorder or injury. They are an online provider who deliver clinical care remotely.

The service provided treatment for both men and women who had hormonal imbalances.

The service consisted of a registered manager, an operations manager, three doctors. A team of non-clinical staff from another organisation were also involved in the provision of the regulated activity.

A registered manager is a person 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 runs.

Clients are introduced to BMH Medical Administration through an online platform called Balance My Hormones, which is a separate service owned by the provider. That platform is not within CQC scope of registration as determined by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the registration regulations 2009.

All appointments offered by BMH Medical Administration are provided remotely. There was, at the time of our inspection, no physical premises where consultations could take place. However, the provider told us that this was something they were considering.

At this inspection we found:

- Patient records showed that the provider had systems in place to ensure safe prescribing.
- The care and treatment documented in the patient records that we reviewed showed that the provider adhered to current practice and guidelines.
- Patient and staff feedback was positive.
- There were systems to verify patient identity and share information with a patient's GP where appropriate.

Overall summary

- Patients could get appointments easily and were supported by a team of case managers.

However:

- Not all staff had completed appropriate training and recruitment checks had not been completed for all staff.
- There was limited quality improvement activity using clinical audit; though the service had identified areas for improvement and had acted on these.
- The service's safeguarding policy did not include contacts for safeguarding teams across the country.
- Clinical governance was lacking as there was no clinical lead, no evidence of clinical meetings, no system for a clinician to review clinical consultations to ensure care and treatment adhered to current guidelines and no centralised clinical oversight of safety alerts on behalf of the provider.

The provider **must**

- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.

The provider **should**

- Consider the needs of service users who may require language translation.
- Develop a programme of quality improvement activity which focuses on the improvement of clinical care.
- Appoint a member of clinical staff working in the organiation to oversee safety alerts.
- Implement a system that provides a full audit trail in respect of access to patient records

Dr Sean O'Kelly BSc MB ChB MSc DCH FRCA

Chief Inspector of Hospitals and Interim Chief Inspector of Primary Medical Services

Our inspection team

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

Background to BMH Medical Administration

The provider Balance My Hormones Ltd is registered to provide the regulated activity treatment of disease, disorder or injury. This is an exclusively online remote consultation service which has a registered office address of International House, 24 Holborn Viaduct, London, EC1A 2BN

BMH Medical Administration provides treatment for both men and women over the age of 18 who have a diagnosed hormone imbalance.

The service consisted of a registered manager, an operations manager, three doctors who worked as independent contractors and a team of non-clinical staff. The service told us that they offer 10 clinical consultations each week and that their linked business' website received around 55 new enquiries each month. We were told that the service has approximately 240 – 300 active patients.

The service employed case managers who were assigned to patients. These were the patient's first point of contact and we were told they supported patients throughout their journey. Case managers would pass on any clinical queries to the patient's assigned clinician.

Clients were introduced to BMH Medical Administration by an online platform, Balance My Hormones, which was a separate service owned by the provider which was not within CQC scope of regulation.

BMH Medical Administration does not have its own specific website. The provider's main website reflects the services of the separate unregistered service Balance My Hormones. Patients who make enquiries via the Balance My Hormones website have the option to be directed into the registered service, BMH Medical Administration, for assessment and possible treatment.

BMH Medical Administration offers online appointments to fee paying clients.

How we inspected this service

This inspection was carried out on 5 October 2022; the inspection team consisted of a CQC Lead Inspector, GP Specialist Advisor, a member of the CQC medicines team and another CQC inspector.

During the inspection we spoke to the Registered Manager, the Operations Manager and a clinician working for the service.

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.

Requires Improvement

Are services safe?

We rated safe as Requires improvement because:

- Professional registrations were not being periodically monitored and recruitment checks had not been undertaken for non-clinical staff.
- Valid in date safeguarding training had not been completed by all staff and the service's safeguarding policy did not include contact information for all local authorities in which the service provided care to patients.

However, we also found that:

- There was a system for reporting and taking action in response to significant events.
- Clinicians verified patient identification prior to remote consultations.
- Prescribing was safe and followed guidance and best practice.

Keeping people safe and safeguarded from abuse

- All clinical staff whose files we reviewed had received safeguarding training. However, the training for one member of clinical staff whose file we reviewed had expired. Up to date training was completed after our inspection. The provider told us that, following an inspection of previously registered service they did not believe that non-clinical staff working across this service and another service, which did not require registration, needed to have this training or recruitment checks completed. The role of these non-clinical staff members was outlined during inspection and it was evident, given their involvement in the provision of the regulated activity, that completion of recommended training and recruitment checks were required.

- All staff had access to safeguarding policies which detailed how to report a safeguarding concern internally. The safeguarding policy only had the details of one local authority safeguarding team despite being a national service that consulted with patients across the country. After our inspection the provider submitted two spreadsheets containing local authority contact information. Neither of these spreadsheets appeared to have contact information from any local authority safeguarding teams and the policy provided after our inspection still had contact information for just one local authority safeguarding team.

- The service told us that they did not treat patients under the age of 18 though staff were aware of the possibility that they could identify child safeguarding issues in the course of their interactions with adults.

Monitoring health & safety and responding to risks

- All clinical consultations were conducted remotely; typically, from the clinician's home. The provider expected that all doctors would conduct consultations in private and maintain patient confidentiality.

- Each doctors used a password secure laptop to log into the operating system, which was a secure programme.

- There were processes in place to manage any emerging medical issues during a consultation and for managing blood results. In the event an emergency did occur, doctors were directed by the provider to call emergency services.

Staffing and Recruitment

- There were enough staff, including doctors, to meet the demands for the service. We were told that doctors were able to offer more sessions as the demand for services increased.

Requires Improvement

Are services safe?

- The provider had a selection and recruitment process in place for clinical staff but some checks had not been completed. For example, there were no documented references, though a call note on the recruitment system indicated referees had been contacted at the time of appointment, and there was no system to periodically check the professional registration of clinical staff to ensure that their registrations remained valid. All doctors who worked at the service were on the GMC register with a license to practice.

- For non-clinical staff, the provider told us that, following an inspection of a now deregistered location, they did not believe these staff members fell under their CQC registration and therefore recruitment checks were not required. However when the provider outlined the role of these staff it was evident that they were involved in the carrying out of the regulated activity. We reviewed the files of two non-clinical staff members including the Director of Operations and found that recruitment checks had not been completed including proof of identity, 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.)

- Clinical staff had professional indemnity policies in place.

- There was an induction programme in place for new staff.

Prescribing safety

- Patients looking to use the service fill out an initial clinical questionnaire. After, or at the same time as they complete the questionnaire, patients are required to provide a blood sample. For the initial blood sample, testing could be arranged for patients through a third-party mobile phlebotomy company. The blood tests cover 66 clinical markers. If any examinations were needed to ensure safe prescribing; patients would need to request these from their own GP. On the basis of two satisfactory blood tests and relevant examination results a clinician would, in consultation with the patient, make a decision as to whether it was clinically appropriate for the patient to start treatment. During this initial consultation the clinician would discuss allergies and any relevant past medical history. Patients would be directed back to the NHS or an alternate provider if treatment was deemed unsuitable.

- Patients were provided with a treatment plan which was signed, and prescription was issued following a consultation with a doctor, if appropriate.

- The service directed patients to use one ampule of product per dose and discard the remainder to avoid the risk of contamination.

- After the initial blood test, patients were required to have a further blood test after 6 weeks of starting treatment and then further tests after six months. Doctors checked the results of blood monitoring to ensure that it was safe to continue to prescribe medication. If any problems or risk factors were identified the clinician may adjust the dosage and this would reset the blood monitoring cycle. The provider ran monthly reports to check for patients who were due blood tests and contacted patients to notify them.

- Patients' GP details were requested at the start of the patient journey. If clinical risk factors were identified, the provider liaised with the patient's GP. If consent to do this was refused the provider would not agree to treat the patient.

- A condition of treatment was that patients had to agree to receive prescriptions through the provider's nominated pharmacy. We were told that prescriptions were issued within 24 hours of the consultation.

Requires Improvement

Are services safe?

- We reviewed the records of nine patients and were satisfied that the prescribing was safe and appropriate.

Information to deliver safe care and treatment

- There were protocols in place for identifying and verifying the patient and General Medical Council guidance was followed. Patients registering with the service were required to provide photographic ID which was uploaded to the provider system and this was checked by the clinician at each consultation.
- Consulting doctors could access the patient's previous consultation records held by the service.

Management and learning from safety incidents and alerts

- We were shown the system for responding to patient alerts. Clinical safety alerts were sent to clinical staff for actioning by the registered manager. We were told that there was no clinical lead employed by the service who triaged safety alerts. However we were told that safety alerts were reviewed by a pharmacist employed by another organisation owned by the provider.

- There were systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members. The provider had one significant event and demonstrated that there had been learning as a result of this.

Good

Are services effective?

We rated effective as Good because:

- Care and treatment were provided in accordance with guidance and standards of the International Society of Sexual Medicine and the British Society of Sexual Medicine.
- There was an effective system to record informed patient consent
- Clinicians had access to the appropriate information to enable them to effective care and treatment

However:

- There was limited quality improvement activity
- Not all staff had completed the required training

Assessment and treatment

- We reviewed examples of medical records that demonstrated each doctor assessed patients' needs and delivered care in line with relevant and current evidence-based guidance and standards, including the International Society of Sexual Medicine and the British Society of Sexual Medicine.

- We were told that each remote consultation was scheduled for between 30 to 45 minutes but there was no fixed time limit in place and the consultation could continue for longer if necessary.

- Patients completed a clinical questionnaire and patient's past medical history and allergies were discussed during the initial consultation.

- The clinical record system included a free text box for the entry of consultation notes, relevant diagnostic information and treatment plans.

- We found that adequate notes were recorded for all nine patients whose records we reviewed including a thorough clinical assessment.

Quality improvement

- There was limited evidence of quality improvement activity using clinical audit. The service had completed one single cycle audit reviewing the proportion of patients who had a blood test after six weeks and six months of treatment being started. The service had met and, in the case of six-month testing, exceeded their audit standard. They had identified potential barriers to patients not having tests at the set intervals and had proposed actions to try and further improve adherence to these testing intervals. A re-audit was due in 12 months' time to test if the implemented improvement actions had been effective.
- The service had process mapped the number of steps between a patient making an enquiry to receiving treatment. As a result of the review the process was shortened from 34 steps taking six to eight weeks to 17 steps taking approximately four weeks.

Staff training

- Recommended training had not been completed by all staff at the service. We were told this was because the service was under the impression, following our inspection of a now deregistered location, this was not required. Records of

training for one of the service's doctors showed that all recommended training had expired; though the service provided an excel spreadsheet that indicated that valid information governance training was in place at the time of our inspection. Records showed that both child and adult safeguarding and mental capacity act training had expired in September 2021. Up to date training for this staff member was completed following our inspection.

- There were records of external appraisals for doctors and internal appraisals for non-clinical staff.
- There was no mechanism in place to conduct periodic clinical records reviews checking the quality of consultations to ensure the care and treatment provided adhered to guidance and best practice.

Coordinating patient care and information sharing

- When a patient registered with the service they were asked to provide details of their registered GP and we found that information was shared with patient's GP where appropriate. If clinical risk factors were identified the service would ask the patient if they could share this information with their GP. If the patient refused, the service would refuse to provide treatment.
- The service ordered blood tests for patients using several mobile phlebotomy providers. Results were filed directly to the patient's record when they were sent by the phlebotomy organisations to the provider. We were told that the phlebotomy laboratories would flag any results which indicated possible imminent risks or concerns to the provider.
- Clinicians were notified of results via email and there was a buddy system in place so that other clinicians could access these in one another's absence.
- For diagnostics that were required in person, for example prostate examinations, the provider directed the patient to alternate healthcare providers and would ask the patient to supply results before prescribing; including the patient's own GP.

Supporting patients to live healthier lives

- The service told us that they supported patients to live healthier lives through the provision of hormone replacement therapies. We were told that doctors may provide additional advice, where appropriate, on actions patients could take to support the treatments offered including information on diet, lifestyle and fitness.
- The service told us that they were considering expanding their offering to include support from a dietician, life coach and fitness instructor.

Consent to care and treatment

- Not all staff, including one member of clinical staff, had in date training about the Mental Capacity Act 2005 on file. Staff we spoke with were aware of the relevant issues and legislation around consent and capacity and we saw that the provider had a robust system for ensuring that informed consent was obtained.

Good

Are services caring?

We rated caring as Good because:

- Feedback about the care and treatment provided was largely positive.

Compassion, dignity and respect

- We were told that the doctors undertook video consultations in a private room and the only people able to access the remote consultation video links were the patients and the clinicians.
- We did not speak to patients directly on the day of the inspection. However, we reviewed the service's own patient survey information.
- For scores related to the care and treatment provided by clinicians, 119 patients surveyed collectively rated the service over 4.5 out of 5 across a variety of questions related to interpersonal interactions with the clinical staff.
- The rating related to overall experience of the 119 patients surveyed was 4.77 out of 5.
- Of 80 patients who gave an opinion on how happy they were with the service 82% said they were happy or very happy.

Involvement in decisions about care and treatment

- Patients could book a consultation with one of the three doctorss of their choice. This clinician would be assigned to the patient throughout their journey to ensure continuity of care. Only in the event the patient relationship broke down on either side would the patient be reassigned to another clinician.
- The service provided a number of tools to support patients receiving treatment including videos, an online blog and various sources of information on how to independently inject medicines safely.
- Clinicians explained the purpose, side effects and other relevant health information related to use of hormone products during the patient consultation and this was clearly documented in the notes we reviewed.

Good

Are services responsive to people's needs?

We rated responsive as Good because:

- Patients could access care and treatment at a range of times
- There was a system to manage complaints

Responding to and meeting patients' needs

- We were told that clinical consultations could be provided on a flexible basis to meet patient demand though availability would be based on the capacity of their clinical staff to provide appointments. The service used enquiry data from their website to forecast demand.

- Patients were given access to an online booking portal and could view appointment availability.

- We were told that consultations were between 30 and 45 minutes each.

- Patients were told by clinicians that if they experienced any perceived adverse reaction to treatment when the service was closed then they should access their local emergency service.

- The provider did not have an interpreter service for patients who did not have English as a first language. We were told that only one patient had required this service since the service began operating and that they brought their own interpreter.

Tackling inequity and promoting equality

- The provider offered consultations to anyone aged over 18 years regardless of any protected characteristics.

- Patients could choose either a male or female clinician. We were told that the doctor assigned to a patient at their initial consultation would be their clinician throughout their treatment unless either the clinician or patient requested this to be changed.

Managing complaints

- Information about how to make a complaint was available on the Balance My Hormones website which acted as the website for the regulated service. The provider had a complaints policy and procedure which contained information about escalation for patients who were unsatisfied with the service's response.
- The provider told us that they had not received any formal complaints in the last 12 months. We were told that any learning or changes to the service as a result of complaints would be communicated to staff.

Requires Improvement

Are services well-led?

We rated well-led as Requires improvement because:

- Governance arrangements in relation to training, recruitment and safeguarding needed to be improved.
- There were no formalised clinical meetings and no clinical lead within the service.

However

- There was a clear vision and the provider was aware of future challenges facing the service.
- The service involved patients and staff in the development of the organisation.
- Action had been taken to improve the service and there were clear future improvement plans, though clinical audit did not demonstrate quality improvement

Vision, Strategy and Governance arrangements

- The provider told us they had a clear vision to help men and women on a journey to achieving an optimum hormone balance.

- There was a clear organisational structure and staff were aware of their own roles and responsibilities. There was a range of service specific policies which were available to all staff. These were reviewed and updated when necessary.

- There were arrangements for identifying, recording and managing risks, issues and implementing mitigating actions in most areas. However, governance and systems of oversight in relation to recruitment and training needed to be improved. The practice's safeguarding policy needed further revision to ensure that staff had access to contact information for external safeguarding agencies across the country.

- Care and treatment records were complete, accurate, and securely kept. During the inspection the service told us that they did not have arrangements in place to store clinical records in line with legislation should they cease trading. We were told that if a patient left the service records would be destroyed after a period of six months and that if the provider ceased trading they would destroy patient records. However we were told after our inspection that the contract with their IT provider ensures that, if the organisation were to cease trading, records would be retained and accessible. The service would provide records to a patient's GP if they left the service upon the patient's request.

- The service did not hold any formalised clinical meetings. However, we were told that clinicians could communicate using an online messaging service and that the registered manager was a central point of contact for any operational queries from the doctors.

Leadership and culture

- The service was managed by both the registered manager and supported by the operations manager. There was no clinical lead for the organisation. Staff were aware of challenges to their business including the impact of the cost of living crisis on some of their patients. In response the service told us that they would devise payment plans for those who were in financial difficulties in order to enable these patients to continue their treatment.
- There was an organisational flow chart which showed the structure of the provider's small team and how this interacted with other businesses owned by the provider that were outside of CQC regulation.
- The registered manager was aware of and had systems to ensure compliance with the requirements of the duty of candour.

Requires Improvement

Are services well-led?

- The three doctors who worked at the service had independent annual appraisals and were considered valued members of the team by the provider.

Safety and Security of Patient Information

- Systems were in place to ensure that all patient information was stored and kept confidential. The service's records system was cloud based. Individuals could only access the system if they were granted permission with a username and password.
- There were no paper patient records.
- The patient record system highlighted the last time a record was accessed and by whom, but the system did not provide a comprehensive audit trail to show each time someone accessed and amended records.
- The service was registered with the Information Commissioner's Office.
- IT support was available 24/7 if there were any technical problems with the patient record system.

Seeking and acting on feedback from patients and staff

- The provider had surveyed patients. Most of the feedback was positive about the care and treatment provided.
- Staff we spoke with during the inspection were positive about working at the service.
- The operations manager held informal meetings on Mondays with non-clinical staff that were not minuted. We saw minutes from one of the away days that the organisation told us were held every six months for all non-clinical staff. Clinical staff attendance was optional, and we saw that one of the doctors was in attendance at the last away day. Slides from the last of these events showed discussion of future planning, vision and changes in governance.

Continuous Improvement

- Though the provider had only completed a single cycle clinical audit, they were able to outline improvements they had made to their service and future plans to develop and refine their offering including streamlining the processes to reduce the time and make it easier for patient to access treatment.
- The service also told us that they felt their case manager support staff were an innovative feature that was not seen elsewhere within their industry.
- The provider had made arrangements to replace their current clinical system which, we were told, would enable them to have a better overview of quality at the service.
- We were told that there were plans to participate in a study related to testosterone replacement therapy.
- Plans were also in place to establish a physical presence which would facilitate in person clinical consultations.

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
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **How the regulation was not being met:** • Absence of staff training and recruitment records indicated that the provider did not have adequate oversight in these areas. • The service's safeguarding policy did not include contacts for safeguarding teams across the country. • Clinical governance was lacking as there was no clinical lead, no evidence of clinical meetings, no systems to check clinical consultations to ensure care and treatment adhered to current guidelines. This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.