Overall summary

We carried out an announced comprehensive inspection on 27 March 2018 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

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

Are services effective?

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

Are services caring?

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

Are services responsive?

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

Are services well-led?

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

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.

The service provides treatment for men experiencing testosterone deficiency syndrome, erectile dysfunction and prostate health concerns. The service made use of patient feedback as a measure to improve services. They had produced their own survey form and results were analysed on an annual basis. Results obtained from a survey carried out in November 2017 found that 100% of eligible patients said they were able to make an informed decision about the treatment they might receive.

We also received seven Care Quality Commission comment cards. These were very positive regarding the care delivered by the service and mentioned the friendly and caring attitude of staff. Responses stated that the service was professional and easy to access in comfortable hygienic surroundings. In particular, people who had used the service said that they felt listened to, had received thorough support and were treated with dignity.

Our key findings were:

- The service was offered on a private, fee paying basis only and was accessible to people who chose to use it.
Summary of findings

• Assessment and referral processes were safely managed and there were effective levels of patient support and aftercare.
• The service had systems in place to identify, investigate and learn from incidents relating to the safety of patients and staff members.
• There were systems, processes and practices in place to safeguard patients from abuse, and staff were able to access relevant training to keep patients safe.
• Information for service users was comprehensive and accessible.
• Patient outcomes were evaluated, analysed and reviewed as part of quality improvement processes and clinical audit.
• We saw evidence that when a complaint was received it was investigated thoroughly and mechanisms were in place to make subsequent improvements to the service based on complaints.

• There was a clear leadership structure, with governance frameworks which supported the delivery of quality care.
• The service encouraged and valued feedback from service users. Comments and feedback for the clinic showed high satisfaction rates.
• Communication between staff was effective with and there was a positive and open culture.

There were areas where the provider could make improvements and they should:

• Review and improve how clinical treatment pathways could be formally agreed and documented across the clinical team.
• Review and improve the implementation plan associated with their most recent clinical audit and consider an ongoing programme of audit activity.
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 that this service was providing safe care in accordance with the relevant regulations.

**Are services effective?**
We found that this service was providing effective care in accordance with the relevant regulations.

We found several areas where improvements should be made relating to the effective provision of treatment:

- The provider should review and improve how clinical treatment pathways could be formally agreed and documented across the clinical team.
- Review and improve the implementation plan associated with their most recent clinical audit and consider an ongoing programme of audit activity.

**Are services caring?**
We found that this service was providing caring services in accordance with the relevant regulations.

**Are services responsive to people's needs?**
We found that this service was providing responsive care in accordance with the relevant regulations.

**Are services well-led?**
We found that this service was providing well-led care in accordance with the relevant regulations.
Background to this inspection

The Centre for Men’s Health is an independent service provider which is registered in London, and operates from locations in London and Manchester. This report reflects findings from the Manchester location which is based at 10 St John Street, Manchester, M3 4DY. The service provides treatment for men experiencing testosterone deficiency syndrome, erectile dysfunction and prostate health concerns.

The provider operates from premises which are easily accessible for those using public transport and on street parking is available. The premises are equipped with aids for disabled access if required (such as an internal passenger lift) and occupies rooms on the first floor. The Centre for Men's Health leases a treatment and consulting room with an adjoining office. The waiting room and toilets are shared with other providers.

The service is owned by three shareholders. Of these, one is a sole director. The director works as the practice and business manager and is the Registered Manager for the provider. Clinical care at the location is provided by the Senior Medical Consultant for the provider, with occasional cover provided by clinical colleagues from the London location. The clinician is trained and experienced in this area of medicine. The provider also employs a small administrative team that provides booking support for patients through the London location. Patients visiting 10 St John Street are greeted by a receptionist employed by the landlord. The Manchester based service usually provides a weekly clinic, seeing up to 18 patients each month.

The inspection was led by a CQC inspector who was accompanied by a GP specialist advisor.

Before visiting, we reviewed a range of information we hold about the service and asked other organisations to share what they knew. Stakeholders we contacted did not raise any information of concern with us.

During our visit we spoke with staff and reviewed CQC comment cards where patients and members of the public shared their views.

To get to the heart of patients' experiences of care and treatment, we always 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.
Our findings

Safety systems and processes

The service had clearly defined and embedded systems, processes and practices in place to minimise risks to patient safety.

- Arrangements for safeguarding reflected relevant legislation and local requirements. Policies and protocols had been developed which covered safeguarding, information governance and consent.
-Clinicians and staff had received training on safeguarding children and vulnerable people relevant to their role. The clinician was trained to child protection or child safeguarding level three.
-Chaperones had not been previously requested by users of the service. However, there was clear information on display offering this service. Following the inspection, the provider confirmed that any non-clinical staff undertaking this role in future will only do so once they had received a DBS check and awareness training (a chaperone is a person who serves as a witness for both a patient and a medical professional as a safeguard for both parties during an intimate medical examination or procedure).
-Records completed by the provider showed that the lead clinician was up to date with revalidation. Revalidation is the process by which all licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise in their chosen field in order to provide a good level of care.

The service had a range of health and safety documentation in place and had undertaken a number of appropriate risk assessments. The provider also had other control measures in place and we found that:

- All electrical equipment was checked to ensure it was safe to use.
- Clinical equipment was checked and calibrated regularly to ensure it was working properly.
-A limited range of medicines were stored onsite and we saw that these were stored and managed appropriately.
-The provider liaised with the premises management to ensure compliance with fire alarm testing and fire safety including evacuation drills.

The service maintained appropriate standards of cleanliness and hygiene.

The service had an infection control policy and procedures were in place to reduce the risk and spread of infection. We inspected the consulting room where examinations took place and found that it was hygienic and well maintained.

Other rooms such as the waiting area generally appeared to be clean and were in good overall condition.

The Registered Manager was the infection prevention and control (IPC) lead who kept up to date with current IPC guidelines in relation to best practice. There was an IPC protocol in place and staff had received up to date training. An IPC audit had recently been carried out and any identified issues had been acted upon.

The service had appropriate arrangements for the disposal of clinical waste.

Equipment in use to deliver the service was subject to regular maintenance and cleaning and disinfection as appropriate.

Risks to patients

The service had arrangements in place to respond to emergencies and major incidents.

- Clinicians had received basic life support training. The service had a defibrillator and an emergency oxygen supply. We saw that this equipment was checked regularly. A first aid kit and accident book was also available on-site.
- Emergency medicines were safely stored, and were accessible to staff in a secure area of the service. We saw that the emergency medicine stock included adrenalin. Adrenalin is a medicine used for the emergency treatment of allergic reactions. The clinician we spoke with on the day of inspection knew of their location. We saw evidence that medicines were checked on a regular basis. All the medicines we checked during the inspection were in date and fit for use.

We saw that mandatory training records were kept and were informed that clinicians also undertook self-directed learning to support their own professional development. Non-clinical members of staff received training and induction appropriate to their roles.
Are services safe?

Staffing for the service was planned around the scheduled patient appointments.

We reviewed personnel files for the clinical staff who delivered the service. Files contained appropriate details and included CVs, details of training and evidence of indemnity insurance. We also saw that all clinical and non-clinical staff (with the exception of the landlord’s receptionist) could evidence a Disclosure and Barring Service (DBS) check (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 persons who may be vulnerable).

**Information to deliver safe care and treatment**

The clinic had appropriate measures to assure the identity and consent of patients using the service. New patients undertook a range of blood tests to direct clinicians to identify the most appropriate course of treatment. Patients were invited to consent to the sharing of medical records with their GP.

**Safe and appropriate use of medicines**

The arrangements for managing medicines, including emergency medicines in the service minimised risks to patient safety (including obtaining, prescribing, recording, handling, storing, security and disposal).

Overall prescribing for the service appeared appropriate.

We saw that medication had been regularly checked, was within date, and was stored safely and securely.

A small range of medicines were administered by the provider. These included a schedule four controlled drug which was subject to minimal control. We saw these were appropriately managed by the provider who had sought external pharmacy advice and training for staff to ensure compliance with legal requirements.

**Track record on safety**

The service had clearly defined and embedded systems, processes and practices in place to identify record, analyse and learn from incidents and complaints. We were told that all staff had a role to play in the identification of incidents and that the Registered Manager of the service had the overall lead for investigating complaints.

There was a system in place for reporting and recording significant events and complaints. We saw significant events and complaints policies which demonstrated that where patients had been impacted they would receive a timely apology, including details about any actions taken to change or improve processes when appropriate. We were told that all significant events and complaints received by the service were discussed by the clinicians involved in delivering the service whenever these were received, and we saw meeting minutes which confirmed this. The provider had not had a recent significant event. However, we reviewed a historical event and saw that the policy had been appropriately followed.

**Lessons learned and improvements made**

The provider was aware of and complied with the requirements of the Duty of Candour. This means that people who used services were told when they were affected by something which had gone wrong; were given an apology, and informed of any actions taken to prevent any recurrence. The provider encouraged a culture of openness and honesty. There were systems in place to deal with notifiable incidents.

Where there were unexpected or unintended safety incidents there were processes and policies in place which showed the clinic would give affected people reasonable support, truthful information and a verbal or written apology.

The provider reflected on any learning opportunities during their business and clinical governance meetings which took place three to four times a year. We saw that learning from a complaint directed at the London location had led to a change in process that improved communication between the clinic and patients.
Are services effective?  
(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment
The provider assessed need and delivered care in line with relevant and current evidence based guidance. However, we saw that there were two areas where improvements could be made:

- Review and improve how clinical treatment pathways could be formally agreed and documented across the clinical team.
- Review and improve the implementation plan associated with their most recent clinical audit and consider an ongoing programme of audit activity.

Patients had an initial consultation where a detailed medical history was taken. A range of blood tests were offered to patients which were undertaken by a third party provider. We saw that the initial assessment along with the blood testing provided a comprehensive history and any proposed treatment plan was devised in accordance with the latest good practice. The provider told us that individual doctors determined their clinical approach. We saw that comparative approaches were discussed during clinical governance meetings. During this inspection, the provider confirmed that following feedback from a recent inspection at the London location, The Centre for Men’s Health had agreed to review how clinical treatment pathways could be formally agreed and documented across the clinical team.

Monitoring care and treatment
There was evidence of quality improvement including clinical audit. We discussed a comprehensive audit undertaken between 2015-2016 that reviewed patient adherence to testosterone therapy over time. We saw that this audit had been compared with other studies and the findings analysed. We saw that an action plan had been developed, exploring possible methods to improve adherence to testosterone therapy for future patients. The provider had not yet evaluated outcomes of the action plan.

Effective staffing
Staff had the skills, knowledge and experience to deliver effective care and treatment. The lead clinician at 10 St John Street was an experienced GP with a special interest in and enhanced training in testosterone treatment and sexual health. The provider held regular clinical governance meetings across the clinical team which also included a consultant urologist. We saw that the service had a process in place to assure the organisation that professionally registered staff maintained and updated their registration. This also included assurance regarding revalidation.

Coordinating patient care and information sharing
Patients were invited to give permission to share information with their GP, but this was not a condition of treatment. However, we saw that when a patient’s test results suggested a potentially serious concern; patients were clearly advised to take this up with their GP and this was documented in the clinic’s notes.

Consent to care and treatment
We found that staff sought patients’ consent to care and treatment in line with legislation and guidance.

- The provider actively promoted the availability of a chaperone. However, this had not yet been requested by a user of the service. The provider confirmed that a DBS check and training would be arranged to provide assurance should a request be made in the future.
- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005.
Are services caring?

Our findings

Kindness, respect and compassion
The service demonstrated a good understanding of the personal needs of their patients. Treatment offered by the service addressed issues around sexuality and we saw that the dignity and privacy of patients was fundamental to the provider’s approach. This was reflected in the patient feedback received on our CQC comment cards.

Involvement in decisions about care and treatment
The provider ensured that clinical consultations were thorough and patients told us that they felt fully involved in treatment options.

Privacy and Dignity
Facilities for service users were private and we saw that patients were treated in ways which respected their dignity. For example:

• Privacy was provided in the separate procedure room used by the service which could be used to maintain patients’ dignity during examinations, investigations and treatments.

• Doors were closed during consultations and conversations taking place in these rooms could not be overheard.
Are services responsive to people's needs? (for example, to feedback?)

Our findings

Responding to and meeting people’s needs

The service was offered on a private, self-referral fee-paying basis. Men who chose to use it were screened by the service to ensure they could potentially benefit from treatment.

The service demonstrated to us on the day of inspection that they understood the needs of their service users and had developed services to meet these needs:

- The service had developed a range of information and support resources which were available to patients.
- The website for the service was comprehensive, informative and easy to understand.

Timely access to the service

The service operated one afternoon most weeks, and patients were able to access appointments in a way that was convenient to them. This was confirmed in the CQC patient feedback cards we received.

Listening and learning from concerns and complaints

The service had a complaints policy in place and information relating to making a complaint was displayed prominently at the location. We discussed complaint handling with the service and saw that one complaint had been received in the previous year. Complaints were reviewed by the provider across both locations responded to in a timely way and any learning was appropriately implemented. For example, we saw that the provider had adjusted a policy following a complaint that would reduce the likelihood of a future recurrence.
Are services well-led?
(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

Leadership capacity and capability;

There was a clear leadership structure in place. The Registered Manager was responsible for the strategic planning and governance. The provider had quarterly business and clinical governance meetings with all of the clinicians.

These meetings were appropriately minuted and we were shown evidence of this. Items discussed at each meeting included; key operational developments, clinical governance and significant events.

Vision and strategy

The practice had a clear vision to deliver high quality care and promote good outcomes for patients. When we discussed this patient centred approach with staff on the day of inspection it was clear that they understood and accepted this and the values that underpinned it.

Culture

The provider’s mission statement emphasised that the service sought to offer the latest innovations in treatment that promoted dignity and well-being with users of the service. We saw this approach reflected in the staff and clinician that we spoke to.

The provider was aware of, and complied with, the requirements of the Duty of Candour. Whilst no unexpected or unintended safety incidents had occurred within the service, we were told they would give affected patients reasonable support, truthful information and a verbal and written apology. Their policy regarding dignity and openness detailed their approach to candour.

Governance arrangements

The service had a governance framework in place, which supported the delivery of quality care. This outlined the structures and procedures in place and ensured that:

- There was a clear staffing structure. Staff, both clinical and non-clinical, were aware of their own roles and responsibilities, and the roles and responsibilities of others.
- Service specific policies and protocols had been developed and implemented and were accessible to staff in paper or electronic formats. These included policies and protocols with regard to:
  - Safeguarding
  - Dispensing of medicines
  - Whistleblowing
  - Consent and client identification
  - Chaperones
  - Infection prevention and control
  - Complaints

All the policies viewed were current and reflected the operations being delivered.

- All staff were engaged in the performance of the service.
- Clinical audit had been undertaken. However, the provider had yet to evaluate the implementation plan or their most recent audit or undertake additional clinical audit activity.

Managing risks, issues and performance

The service had measures in place to monitor and manage risks and to deliver services which met national standards. For example:

- Staff from the service had produced and published a number of medical papers in relation to testosterone deficiency and were actively engaged in research being developed nationally and internationally.

Appropriate and accurate information

The provider gathered detailed information concerning the health background of all patients prior to and during consultations. We saw that there were appropriate safeguards to manage data securely and accurately.

Engagement with patients, the public, staff and external partners

The clinic sought and made use of patient feedback gathered at each consultation as a measure to improve services. They had produced their own survey form and results were analysed on an annual basis. Results gathered from forms obtained by the clinic in November 2017 showed high overall satisfaction with the services provided.

We also received seven Care Quality Commission comment cards. These were very positive regarding the care delivered by the service and mentioned the friendly and
caring attitude of staff. Responses stated that the service was professional and easy to access in comfortable hygienic surroundings. In particular, people who had used the service said that they felt listened to, had received thorough support and were treated with dignity.

**Continuous improvement and innovation**

Staff were expected to and supported to continually develop and update their skills.

The clinic had developed a work plan to address key service areas where they sought to improve their performance. These areas included work in relation to:

- Strengthening the consistency of medical note taking
- Ongoing review of policies and procedures
- Seeking guidance from external consultants across various work streams

Staff from the clinic had published a number of medical papers in relation to testosterone therapy and attended national and international conferences to ensure alignment with the latest clinical research.