The Bodyline Clinic Limited

The Bodyline Clinic Limited Openshaw

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 4 September 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 not providing safe care in accordance with the relevant regulations. There were reliable safety systems and processes in place and risks to patients were well managed. However, clinicians did not always follow prescribing policies and record the rationale for prescribing decisions.

Are services effective?

We found that this service was not providing effective care in accordance with the relevant regulations. There was no audit system in place to monitor the effectiveness of the treatments provided and patients did not always have an effective initial assessment to establish their needs. Clinicians and staff had the necessary skills, training and support to undertake their role.

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations. Patients were treated with kindness and respect, and were routinely involved in decisions about their care and treatment. Patients told us their privacy and dignity needs were met at the clinic.

Are services responsive?

We found that this service was providing responsive care in accordance with the relevant regulations. The facilities were appropriate to meet people's needs. The provider routinely sought patient feedback, and carried out an analysis of patient needs when planning and delivering services. There was a procedure in place for handling concerns and complaints.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations. There was adequate leadership capacity and capability. A comprehensive set of policies and procedures governed all activities at the clinic, although some policy review

Summary of findings

dates had not been updated. Where audits found shortfalls in care or treatment, these had not been repeated to give assurance that improvement measures had been effective.

Background

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.

Bodyline Openshaw is a private clinic which provides medical treatment for weight loss, and has been registered with CQC since January 2018. The clinic is open on Tuesdays from 4:30pm until 7:30pm, and Saturdays from 9:30am until 12:30pm. The premises comprise of a reception and waiting area, and consulting rooms situated on the ground floor. There is a clinic manager and five nurses who carry out patient consultations. One of the nurses is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Nine people completed CQC comment cards prior to our inspection, and these were all positive. Patients told us staff were friendly and helpful and treated them with respect, and the facilities were clean and comfortable.

Our key findings were:

- The facilities were appropriate to meet people's needs
- Staff were caring, supportive, and treated patients with dignity and respect
- Clinicians did not always follow prescribing policies and record the rationale for prescribing decisions
- There were arrangements in place to audit medical records, however the actions taken in response to identified issues were not always effective
- There were a comprehensive set of policies and procedures governing all activities, although some policy review dates had not been updated

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

- Ensure systems and processes are established to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users

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

- Review the clinical records and filing system to ensure clinicians have access to all relevant information when consulting with patients
- Review policies and procedures to ensure review dates are appropriate

The Bodyline Clinic Limited Openshaw

Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection of Bodyline Openshaw on 4 September 2018. The inspection team was led by a CQC pharmacist specialist, and included a member of the CQC medicines team. During the inspection, we interviewed staff, made observations, and reviewed documents.

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.

Are services safe?

Our findings

Safety systems and processes

There was a safeguarding policy in place which included details of how to contact safeguarding teams. The medical director was the safeguarding lead; all staff had undertaken safeguarding training at a level appropriate for their role. Although the service only treated adults, staff had completed safeguarding children training and demonstrated an awareness of safeguarding responsibilities for children who may accompany adults to appointments.

The service offered chaperones, and this was supported by a written policy. Chaperoning was provided by a second nurse and all patients were asked on their registration form if they wished to have a chaperone during their consultation.

The premises were in a good state of repair. Consulting rooms were private and confidential, and staff areas and consulting rooms were secured to prevent unauthorised access. We saw evidence that electrical equipment was checked to ensure it was safe to use. Medical equipment had been calibrated in accordance with manufacturer recommendations. A fire risk assessment had been undertaken by an external agency and a fire evacuation procedure was in place which was supported by a written policy. Firefighting equipment had been serviced in accordance with manufacturer recommendations.

The premises were clean and tidy, and facilities were appropriate for the service being provided. Hand washing facilities and alcohol gel were available in consulting rooms. Nurses carried out daily cleaning of consulting rooms and were also responsible for cleaning equipment after each consultation. The clinic manager completed cleaning for the rest of the premises. There was a cleaning schedule in place, and records were kept when cleaning was completed. The service had an infection control policy which included a Legionella risk assessment (Legionella is a term for a bacterium which can contaminate water systems in buildings).

There was evidence that nurses were appropriately registered and up-to-date with professional revalidation. We checked employment records for all the staff at the clinic and found records were not always complete. For example, Disclosure and Barring Service (DBS) checks were not available for one person (these checks identify whether a person has a criminal record or is on an official list of persons barred from working in roles where they may have contact with children or adults who may be vulnerable), and there were no employment records for another member of staff. Following our inspection, the provider sent us evidence that recruitment checks had been carried out.

Risks to patients

This is a service where the risk of needing to deal with a medical emergency is low. A risk assessment had been carried out regarding what may be needed in the event of a medical emergency. In addition, staff had completed basic life support training. There was evidence that clinicians had appropriate indemnity insurance to cover all potential liabilities that may arise from their work at the clinic.

Information to deliver safe care and treatment

Paper patient records were stored safely and securely, and confidentiality was maintained. Records were completed by the nurse during the patient's consultation. The new client health questionnaire and consent form had previously been held centrally at head office. We saw that since August 2018, this information was held with the patient's medical record so that it was available to the prescriber during a consultation.

Safe and appropriate use of medicines

The provider had a range of policies to support the safe handling of medicines, and these were regularly reviewed. There was also a separate policy for the management of controlled drugs. We checked how medicines were stored, dispensed and supplied to patients. Medicines were stored securely in line with safe custody requirements, and access was restricted to authorised staff members. Medicines were supplied to patients during their consultation with the nurse prescriber, and were dispensed into appropriate containers. However, the labels on the containers did not meet legal requirements because they did not state the dose the patient should take. We discussed this with the provider who showed us updated dispensing labels that contained all the required information, which were in the process of being rolled-out. Records were made of medicines received and supplied to patients in a record

Are services safe?

book in the clinic room. In addition, the clinic manager maintained a daily log of stock balances which was checked at the beginning and end of each clinic against the record held in the consultation room.

The medicines this service prescribes for weight loss are unlicensed. Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy. These medicines are no longer recommended by the National Institute for Health and Care Excellence (NICE) or the Royal College of Physicians for the treatment of obesity. The British National Formulary states that 'Drug treatment should never be used as the sole element of treatment (for obesity) and should be used as part of an overall weight management plan'. At Bodyline Openshaw, the choice of treatment was made in partnership with the patient. Nurses discussed the relative risks and benefits of each treatment, including the unlicensed status of the medicine where appropriate. This information was also included in the client information guide which was given to each patient at their first consultation.

There was a prescribing policy and a Body Mass Index (BMI) policy in place which set out when medicines could be prescribed. The clinic also had an appropriate policy for repeat prescriptions and the delivery of medicines to remote patients. We checked 21 patient records and found the clinic policy regarding BMI thresholds had not been followed for five patients, although they all had a BMI greater than 25 which is classed as overweight. It was not possible to identify the reasons for prescribing outside of the clinic policy from the medical notes. The prescribing policy also stated all patients should have a break from treatment after 12 weeks. From the records we reviewed, one patient had received treatment for 19 weeks without a break. There was evidence of regular blood pressure checks. However, of the 21 patient records we reviewed, we saw one example where a patient had been prescribed appetite suppressants when their blood pressure was marginally higher than the limit set in the provider's prescribing policy; no rationale for this prescribing decision had been recorded in the medical notes. In addition, the policy stated a letter should be sent to the patient's GP informing them of the raised blood pressure. There was no evidence of a letter and the notes did not state one had been sent.

Track record on safety, lessons learned and improvements made

The provider was aware of and complied with the requirements of the Duty of Candour (observing the Duty of Candour means that patients who use the service are told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result). The provider encouraged a culture of openness and honesty with their staff. Staff understood their

responsibilities to record incidents and report them where appropriate, however, there was no written policy for incident reporting. There had been two incidents in the last 12 months, which we reviewed. There were detailed records which included the actions taken as a result of the investigation, and we saw that learning from the incident had been shared with staff at every clinic across the organisation. There were arrangements in place to receive and act upon patient safety alerts, recalls, and rapid response reports issued through the Medicines and Healthcare products Regulatory Agency (MHRA) and similar bodies.

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment, care and treatment

Patients who were new to the clinic completed a registration form including a new client health questionnaire which captured existing medical conditions and medicines, past medical history and any comorbidities.The nurse prescriber reviewed this information and recorded the patient's height, current weight, waist measurement and blood pressure.The patient's Body Mass Index (BMI) was calculated, and if appropriate treatment was prescribed. We saw one patient had transferred to the Openshaw clinic from another bodyline location. Staff did not have access to the previous paper medical record, and had not completed a new patient medical history before treating the patient, in accordance with the prescribing policy.

Following their initial face to face consultation, patients could access remote consultations via video call. They were taught how to correctly monitor their own pulse and blood pressure, and readings were shared with the clinician during the consultation to ensure supplying a repeat prescription was safe and appropriate. The clinic policy stated patients must be seen in a face to face consultation at least every 12 weeks.

Monitoring care and treatment

There was an annual audit schedule in place which comprised of a retrospective review of patient medical records, however, there was no audit system in place to monitor the effectiveness of the treatments provided. The provider told us they planned to introduce a further audit of all patients after 12 weeks' treatment to monitor weight loss, but this had not yet been completed. A revised client consultation record had recently been implemented, which allowed clearer documentation of starting BMI, target weight and 12-week review date.

Effective staffing

Clinicians and staff had the necessary skills, training and support to undertake their role. For example, the registered manager had completed a postgraduate certificate in obesity care and management. There was a record of mandatory training, and we saw evidence staff had completed training in basic life support and safeguarding. All staff employed for over a year had received annual meaningful appraisals, which included clinical supervision with the registered manager.

Coordinating patient care and information sharing

Patients were encouraged to consent to sharing information about their treatment with their registered GP. Where patients did not consent, staff encouraged sharing of information where this was clinically appropriate, for example if the patient had raised blood pressure. However, copies of correspondence were not stored with the patient medical record. We discussed this with the provider who told us they would review their records and filing system to ensure clinicians had access to all relevant information when consulting with patients.

Supporting patients to live healthier lives

Patients were supplied with written information about their medicines in the form of a client information guide. We saw that medicines formed part of a wider weight management plan which also included diet and exercise. The patient guide contained written information about eating healthily, suggested meal plans, and tips on exercising to aid weight loss and improve overall health.

Consent to care and treatment

Written consent was obtained from each patient before treatment was commenced. Staff we spoke with explained how they would ensure a patient had the capacity to consent to treatment in accordance with the Mental Capacity Act 2005. Where unlicensed medicines were prescribed, the implications of this were explained to the patient. Before treatment commenced, the provider gave patients details of the cost of the main elements of treatment which included the cost of medicines, and further treatment or follow-up.

Are services caring?

Our findings

Kindness, respect and compassion

Patients completed CQC comment cards before our inspection to tell us what they thought about the service. We received nine completed cards which were all positive. We also spoke with two patients on the day of our inspection. Patients said they felt staff were friendly, supportive, and treated them with dignity and respect. We observed staff interacting with patients and found they were pleasant and professional. Staff displayed understanding and a non-judgemental attitude towards and when talking about patients who had a diagnosis of obesity.

Involvement in decisions about care and treatment

Patients could discuss treatment options and agree weight loss goals at the start of treatment. However, we saw that weight targets were not recorded in five out of 21 records we reviewed. We saw evidence of ongoing treatment being reviewed in partnership with the patient considering effectiveness and any side effects experienced. Patients told us staff took the time to listen and ensure their treatment was right for them.

Privacy and Dignity

The provider had ensured that consultations were conducted in private rooms and could not be overheard. Patients told us their privacy and dignity needs were met at the clinic.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The facilities were appropriate to meet people's needs. Consultation rooms were on the ground floor for patients with mobility difficulties, and there was wheelchair access to the building. There was no induction loop available for patients who experienced hearing difficulties and information and medicine labels were not available in large print, Braille, or in any other languages. The provider told us they had never been asked for these, but would do their best to make information more accessible if a patient needed it. Staff were aware of telephone translating services which could be offered to patients at additional cost. The provider routinely sought patient feedback through a feedback form which was handed out during the clinic, and carried out an analysis of patient needs when planning and delivering services.

Timely access to the service

Consultations were offered either by appointment or on a walk-in basis. The provider told us new patients were encouraged to book an appointment because the initial consultation took longer. The clinic was open on Tuesdays from 4:30pm until 7:30pm, and Saturdays from 9:30am until 12:30pm. Patients told us they could access care and treatment at a time to suit them.

Listening and learning from concerns and complaints

There was a procedure in place for handling concerns and complaints which was supported by a written policy. Information was available about the steps people could take if they were not satisfied. There had been no complaints received in the last 12 months.

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; culture

The registered manager was aware of the need for openness and honesty with patients if things went wrong, and would comply with the requirements of the Duty of Candour. Observing the Duty of Candour means that patients who use the service are told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result. We saw the manager encouraged an open and honest culture. Staff were given the opportunity to contribute when changes or improvements to the service were needed.

Vision and strategy

The staff we spoke with were all aware of the vision for the service and strived to provide high quality care which was consistent across the organisation. The provider gave a six-monthly update to all staff which set out the wider strategy of the organisation.

Governance arrangements; managing risks, issues and performance; appropriate and accurate information

There were a comprehensive set of policies and procedures governing all activities at the clinic. However, we saw some of the policies had not had their review dates updated when they had been rewritten. All staff we spoke with understood their roles and responsibilities.

There were arrangements in place to identify risks and poor performance, for example annual audits of medical records. The last audit from March 2018 identified clinical documentation was inappropriate for 65% of repeat clients and 40% of new clients and prescriptions were not written clearly for 70% of repeat clients and 80% of new clients. On the day of our inspection, we found similar concerns regarding poor clinical documentation and clinicians not recording the rationale for prescribing outside of the provider's policy. The provider had not sought any further assurance that improvement measures put in place since the last audit had been effective. Therefore, the systems in place to manage identified risks and poor performance were not effective.

Engagement with patients, the public, staff and external partners

The provider encouraged and routinely sought feedback from patients. There were regular staff meetings with comprehensive minutes and an action log to ensure actions were followed up in a timely manner.

Continuous improvement and innovation

Learning from incidents was shared with all staff to reduce the chance of recurrence. Staff were encouraged to develop the service rather than just provide it, and they could share ideas with the registered manager and the medical director to make improvements. For example, reviewing and updating the content of the patient consultation model.

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
Services in slimming clinics	Regulation 17 HSCA (RA) Regulations 2014 Good governance How the regulation was not being met: The provider had not established systems and processes to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users. In particular: · Medical records were not complete and accurate, and did not include the rationale for decisions taken in relation to the care and treatment provided · The systems in place did not enable the provider to effectively assess, monitor and improve the quality and safety of the services provided