

The Bodyline Clinic Limited

The Bodyline Clinic Limited Stockport

Inspection report

Heaton House
Heaton Lane
Stockport
Cheshire
SK4 1AQ
Tel: 0845 4918750
Website: www.bodylineclinic.com

Date of inspection visit: 31 July 2018
Date of publication: 12/09/2018

Overall summary

We carried out an announced comprehensive inspection on 31 July 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

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 Stockport is a private clinic which provides medical treatment for weight loss, and has been registered with CQC since January 2018. Prior to this, the clinic was in operation but due to the service model employed, they did not need to register with CQC. The clinic is open on Tuesdays from 12:00pm until 3:00pm, Thursdays from 4:00pm until 7:00pm, and Saturdays from 1:30pm until 4:30pm. The premises comprise of a reception area and two consulting rooms situated on the ground floor. There is a clinic manager and four 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

Summary of findings

'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.

16 people completed CQC comment cards prior to our inspection, and these were all positive. Patients told us staff were friendly and helpful, the facilities met their needs, and care was delivered professionally.

Our key findings were:

- The facilities were appropriate to meet people's needs
- Medicines were used safely and appropriately
- There was an annual audit of patient records to support safe prescribing

- Staff were caring, supportive, and treated patients with dignity and respect
- The manager encouraged an open and honest culture, and staff we spoke with were aware of the vision for the service
- There was a comprehensive set of policies and procedures governing all activities

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

- Review dispensing labels to ensure they meet legal requirements
- Review prescribing practices to ensure they are in line with the prescribing policy

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 that this service was providing safe care in accordance with the relevant regulations. There were reliable safety systems and processes in place, risks to patients were well managed and medicines were used safely and appropriately.

Are services effective?

We found that this service was providing effective care in accordance with the relevant regulations. Clinicians and staff had the necessary skills, training and support to undertake their role. Valid consent was obtained before treatment was started, and patients were supported to live healthier lives. Care and treatment was monitored to ensure it was safe, and plans were in place to improve this monitoring to ensure the treatments offered were effective.

Are services caring?

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

Are services responsive to people's needs?

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 providing well-led care in accordance with the relevant regulations. There was adequate leadership capacity and capability. Learning from incidents was shared with all staff to reduce the chance of recurrence and there were regular staff meetings. A comprehensive set of policies and procedures governed all activities at the clinic and there were robust arrangements for identifying, recording and managing risks.

The Bodyline Clinic Limited Stockport

Detailed findings

Background to this inspection

We carried out an announced comprehensive inspection of Bodyline Stockport on 31 July 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. Staff were able to describe the process to follow if they had any concerns. Although the service only treated adults, the nurse we spoke with demonstrated an understanding 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 serviced in accordance with manufacturer's recommendations, and there was a schedule in place to ensure checks happened at the right time. 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.

The clinic was clean and tidy, and facilities were appropriate for the service being provided. Nurses carried out daily cleaning of the premises and were also responsible for cleaning equipment after each consultation. There was a cleaning schedule, 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 particular bacterium which can contaminate water systems in buildings).

We checked employment records for all the staff at the clinic and found records were not always complete. For example, proof of identity and Disclosure and Barring Service (DBS) checks were not available (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). There was evidence that nurses were

appropriately registered and up-to-date with professional revalidation. Following the inspection, the provider sent us evidence that employment records had been fully completed and DBS checks had been requested for two remaining staff members.

Risks to patients

This is a service where the risk of needing to deal with a medical emergency is low, however no risk assessment had been carried out with regards to what may be needed in the event of a medical emergency. In addition, there was no evidence available that staff had completed life support training on the day of our inspection. An adrenaline auto-injector was available if a patient had a severe allergic reaction, and nursing staff had completed training in dealing with this. Following our inspection, the provider sent us an updated medical emergency policy which included a risk assessment. In addition, they sent us evidence that all 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

Individual patient records were stored safely and securely, and confidentiality was maintained. Records were completed during the patient's consultation. We reviewed consultation records and found they were contemporaneous and kept in line with professional guidance. The new client health questionnaire was held centrally at head office. We discussed this with the provider as the information should be available to the prescriber during a consultation. The provider told us they would hold this information with the client's medical record in future.

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. 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. Where medicines required cold storage, staff carried out regular checks to ensure they remained within recommended temperatures. 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

Are services safe?

dose the patient should take. We raised this with the provider who told us they would amend their dispensing labels immediately. Records were made of medicines received and supplied to patients in a record book in the clinic room. In addition, reception staff maintained a daily log of stock balances which was checked at the beginning and end of each clinic.

Some of 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 Stockport, the choice of medicine was made in partnership with the patient. Nurses discussed the relative benefits of each treatment, and if the patient chose an unlicensed treatment, the implications of this were clearly explained, including the unlicensed status of the medicine. Patients were provided with written information about the medicines they were prescribed at the clinic. In the case of injections, this included information on how to safely administer the medicine. The

prescribing nurse explained and demonstrated to patients how to give the first injection. The patient was then observed and supervised as they administered the first dose themselves.

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, and staff understood their responsibilities to raise concerns, to record incidents, and to report them where appropriate. This was supported by a written policy for incident reporting. There had been one incident 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

New patients 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 then 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.

There was a prescribing policy and a Body Mass Index (BMI) policy in place which set out when medicines could safely be prescribed. We checked 18 patient records and found the clinic policy regarding BMI thresholds had not been followed on one occasion. However, we also saw the nurse had declined to supply medicines on two occasions where treatment was either not safe or appropriate. There was evidence of regular blood pressure checks and appropriate breaks in treatment for all the patient records we reviewed. A revised client consultation record was being trialled which allowed clearer documentation of starting BMI, target weight and 12-week review date.

The clinic also had a policy for repeat prescriptions and the delivery of medicines to remote patients. Following their initial face to face consultation, patients could access remote consultations via video call and were taught how to correctly monitor their own pulse and blood pressure. 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. Where medicines requiring cold storage were sent by recorded delivery, this was supported by a written policy. The prescriber ensured the patient was aware of the reduced expiry date specified by the manufacturer, to ensure the medicine remained effective.

Monitoring care and treatment

There was an annual audit schedule in place which comprised of a retrospective review of patient medical records to ensure safety. This was overseen by the medical director. We reviewed the last audit which had been completed in October 2017 and saw that where shortfalls had been identified, clear improvement measures had been recorded. This had led to a change in practice to

improve clinical record keeping. The provider told us they planned to introduce a further audit of all patients after 12 weeks' treatment to demonstrate the effectiveness of the treatments they were offering, in addition to safety. Data collection for this audit had started, and we saw a review template had been created to capture the required information.

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 fire safety, Mental Capacity Act and safeguarding. Following the inspection, the provider also sent us evidence that all staff had completed basic life support training. All staff had annual meaningful appraisals, which included clinical supervision overseen by the medical director.

Coordinating patient care and information sharing

Patients were encouraged to consent to sharing of 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. We saw evidence of correspondence sent out and received back from patient's GPs.

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. The patient guide also contained written information about eating healthily and increasing exercise 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 clearly explained

Are services effective?

(for example, treatment is effective)

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 to tell us what they thought about the service. We received 16 completed cards which were all positive. Patients said they felt staff were caring, 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. Nurses discussed the relative benefits of each treatment, and if the patient chose an unlicensed treatment, the implications of this were clearly explained, including the unlicensed status of the medicine. We saw evidence of ongoing treatment being reviewed in partnership with the patient taking into account effectiveness and side effect profiles. 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 could not be overheard, and that conversations with receptionists were not overheard in the waiting room. 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. Both consultation rooms were on the ground floor for patients with mobility difficulties, however there was no wheelchair access. The provider told us they would signpost patients to one of their other clinics if they had difficulties accessing the Stockport clinic. 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 one of their patients needed it. Staff were aware of telephone translating services, however this had never been required. The provider routinely sought patient feedback through a feedback form, and carried out an analysis of patient needs when planning and delivering services. For example, an extra clinic session had been introduced in an evening in response to patient feedback.

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 12:00pm until 3:00pm, Thursdays from 4:00pm until 7:00pm, and Saturdays from 1:30pm until 4:30pm. Most patients told us they could access care and treatment at a time to suit them, however one patient stated the choice of more clinic days would be more convenient for 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 and the medical director were 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. Senior 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, and these were

regularly reviewed. All staff we spoke with understood their roles and responsibilities. There were robust arrangements for identifying, recording and managing risks. We saw examples of mitigating actions put in place to minimise known risks, for example fire risk and patient safety in the waiting area. There was a systematic programme of clinical audit which was in the process of being expanded to cover the effectiveness of the treatments on offer.

Engagement with patients, the public, staff and external partners

The provider encouraged and routinely sought feedback from patients. There were regular staff meetings, however all the nursing staff were not included in monthly clinical meetings. The registered manager was responsible for passing on relevant information from clinical meetings to nursing staff. Comprehensive minutes and an action log were maintained 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.