

The Bodyline Clinic Limited

The Bodyline Clinic Limited Birkenhead

Inspection report

124 Chester Street
Birkenhead
Merseyside
CH41 5DL
Tel: 08454 918 750
Website: www.bodylineclinic.com

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Overall summary

We carried out an announced comprehensive inspection on 21 November 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.

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.

Bodyline Birkenhead is a private clinic which provides medical treatment for weight loss and has been registered with CQC since January 2018. This service is registered with CQC under the Health and Social Care Act 2008 in respect of the provision of advice or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of weight reduction.

The nurse lead 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.

Summary of findings

We reviewed 28 CQC comment cards completed by patients prior to our inspection. The feedback was positive for the majority. Patients told us staff were professional, friendly and caring. The clinic and facilities were described as clean and safe.

Our key findings were:

- The facilities were clean, tidy and appropriate for people's needs.
- Staff were friendly and caring and treated patients with dignity and respect.
- The new clinical record was implemented to enable monitoring of patients and appropriate 12 week review.
- The service had a clear vision and strategy that staff were involved in shaping and achieving.
- There was a comprehensive set of policies and procedures covering the clinic activities that were reviewed and updated at staff meetings.
- Supply of more than one medicine with the same action had resulted in a patient safety incident where a patient incorrectly took the two medicines at the same time.

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

- Ensure care and treatment is provided in a safe way so that patients are protected from the risks of supplying more than one medicine with the same action.

You can see full details of the regulations not being met at the end of this report.

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

- Review their systems for storing information to ensure relevant information is accessible to the prescriber at the point of consultation.
- Review policies that require local information to ensure this is in place, for example Safeguarding and medical emergency.
- Review audit action plans to provide assurance.
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.

Professor Steve Field CBE FRCP FFPH FRCGP Chief Inspector of General Practice

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Detailed findings

Background to this inspection

Bodyline Birkenhead 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 Mondays from 4pm until 8pm, Tuesdays from 4pm to 7pm and Wednesdays 11am until 3pm. Consultations are provided by appointment for first time patients and on a walk-in basis for repeat visits. The premises comprise of a reception waiting area and two consulting rooms all situated on the ground floor. There is a clinic manager and five nurses who carry out patient consultations.

We carried out an announced comprehensive inspection on the 21 November 2018. Our inspection team was led by a CQC pharmacist specialist and included a member of the CQC medicines team. During our 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

The service did have clear systems to keep people safe and safeguarded from abuse.

- There was a safeguarding policy in place, the policy required updating to detail local safeguarding contacts. Staff we spoke to were aware how to find this information and the policy was updated following the inspection. 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 the staff we spoke to were aware of their 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.
- The premises were in a good state of repair. Consulting rooms were private and confidential. We saw evidence that electrical equipment was checked to ensure it was safe to use. Medical equipment was serviced in accordance with manufacturers recommendations and there was a process to ensure checks were carried out when needed. A fire risk assessment was undertaken by an external agency and fire alarms were checked regularly and supported by a written policy. Firefighting equipment was serviced in accordance with manufacturer recommendations.
- There was an effective system to manage infection prevention and control. The premises were clean and tidy and cleaning records were available. Handwashing was available in one clinic and alcohol gel was accessible in all rooms. The clinic had a Legionella risk assessment in place. (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 their professional revalidation. The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. Disclosure and Barring Service (DBS) checks were undertaken where required. (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).

Risks to patients

There were systems to assess, monitor and manage risks to patient safety.

- Though the risk of a medical emergency was low staff had completed basic life support and anaphylaxis training. A generic risk assessment was carried out by the provider and an updated risk assessment for this location was sent to us after the inspection.
- There was appropriate indemnity arrangements to cover all potential liabilities which may arise as a result of their work at the service.

Information to deliver safe care and treatment

Staff did not have the information they needed to deliver safe care and treatment to patients.

- Individual care records were written and managed in a way that kept patients safe. The majority of records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way. A new clinical record was being implemented and not all previous records were onsite. We discussed this with the provider as the prescriber should be able to access relevant patient information during the consultation. The provider advised us that they would maintain the full medical record on site.
- The service had systems for sharing information with the patients registered GP to enable them to deliver safe care and treatment.

Safe and appropriate use of medicines

The service did not have reliable systems for appropriate and safe handling of medicines.

- The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of this occurring in the future is low once it has been put right. We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).
- The systems and arrangements for managing medicines, including controlled drugs, emergency medicines and equipment minimised risks. The provider

Are services safe?

had a range of policies to support the safe handling of medicines, however we identified a practice of supplying more than one medicine with the same action that had resulted in a patient safety incident. We discussed this with the provider who told us after the inspection they had reviewed the prescribing policy to prevent future supplies of more than one medicine with the same action, however we need to see the action embedded.

- The service carried out medicines audit to ensure prescribing was in line with best practice. Audit results were communicated to allow changes in practice to improve care, the audit frequency being increased to provide assurance.
- Medicines were stored securely according to safe custody procedures and access was restricted to appropriate staff. During their consultation nurses prescribed and supplied medicines to patients and gave advice on medicines in line with legal requirements and current national guidance. Processes were in place for checking medicines and staff kept accurate records of medicines.
- 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'.

Track record on safety

- The service monitored and reviewed activity. This helped staff to understand risks and gave a clear, accurate and current picture that led to safety improvements. Regular senior management team meetings were held and information was shared from all clinics to inform policies.

Lessons learned and improvements made

The service learned and made improvements when things went wrong.

- There was a system for recording and acting on significant events. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- There were adequate systems for reviewing and investigating when things went wrong. The service learned and shared lessons, identified themes, and took action to improve safety in the service. There was an incident reporting policy. There had been two incidents reported and investigated in the last 12 months. We discussed the incident with the provider who then reviewed their prescribing policy at the next clinical team meeting.
- The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty.
- The service had an effective mechanism in place to disseminate external safety events as well as patient and medicine safety alerts to all members of the team including sessional and agency staff.

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. Nurses reviewed the information and completed the clinical record during the initial consultation. Patients were then assessed by the nurse and height, weight, body mass index (BMI), blood pressure and waist measurement were documented. If appropriate treatment was prescribed.
- Patients immediate and ongoing needs were fully assessed. Where appropriate, this included their clinical needs and their mental and physical wellbeing. We saw no evidence of discrimination when making care and treatment decisions.
- Arrangements were in place to deal with repeat patients, however staff did not always have access to the previous medical record. We looked at 16 patient records and the prescribing policy had been followed for all, two people were declined treatment as it was not appropriate. .

Monitoring care and treatment

The service was involved in quality improvement activity.

- The service used information about care and treatment to make improvements. The service made improvements through the use of completed audits. As a result of audit and staff feedback the clinical consultation record had been reviewed. The service had recently increased the audit frequency to monthly to ensure a review of prescribing and clinic documentation based on inspection feedback. .

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles.

- All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff. All nurses were registered with the Nursing and Midwifery Council and were up to date with revalidation. Up to date records of skills, qualifications and training were maintained.

- Staff were encouraged and given opportunities to develop. We saw that staff had undergone mandatory training in basic life support, anaphylaxis, infection control and fire safety.

Coordinating patient care and information sharing

Staff worked together, to deliver effective care and treatment.

- Before providing treatment, nurses at the service ensured they had adequate knowledge of the patient's health and their medicines history. We saw examples of patients being signposted to their own GP for review before treatment was provided.
- All patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service. Where patients agreed to share their information, we saw evidence of letters sent to their registered GP in line with GMC guidance.

Supporting patients to live healthier lives

Staff were consistent and proactive in empowering patients, and supporting them to manage their own health.

- A written client information booklet was provided to patients and nurses provided additional specific verbal advice to support patients. The patient guide contained information about exercise, diet and meal plans.

Consent to care and treatment

The service obtained consent to care and treatment in line with legislation and guidance.

- Staff understood the requirements of legislation and guidance when considering consent and decision making. Staff supported patients to make decisions. 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 by the nurse and information was provided in the client information booklet.

Are services caring?

Our findings

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- Feedback from the 28 comment cards were positive about the way staff treated patients. Patients told us staff were professional, friendly and caring.
- Staff understood patients' personal needs. They displayed an understanding and non-judgmental attitude to all patients.

Involvement in decisions about care and treatment

Staff helped patients to be involved in decisions about care and treatment.

- Patients told us through comment cards, that they felt listened to and supported by staff. Patients had sufficient time during consultations to make an informed decision about the choice of treatment available to them.

Privacy and Dignity

The service respected patients' privacy and dignity.

- The consulting rooms were private and people could not be overheard during their consultation. Staff recognised the importance of people's dignity and respect, this was confirmed by patients comment cards.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.

- The facilities and premises were appropriate for the services delivered. Patients with mobility difficulties could access the consulting rooms which were on the ground floor and accessible by wheelchair.
- There was no induction loop available for patients who experienced hearing difficulties. Medicine labels were not available in large print, Braille, or in any other languages. We discussed this with the provider and they advised they had never been asked for these but would review availability if a patient needed it.
- For patients who did not have English as a first language staff were aware of an interpretation service, although the cost had to be covered by the patient. Patient feedback was collated by the provider to enable an analysis of patients' needs when reviewing the service provision.

Timely access to the service

Patients were able to access care and treatment from the service within an appropriate timescale for their needs.

- Patients had timely access to initial assessment by appointment, and a walk-in service was available for repeat patients. The clinic was open on Mondays from 4pm until 8pm, Tuesdays from 4pm to 7pm and Wednesdays 11am until 3pm.
- Patients could access help and support by telephone outside of clinic opening hours.

Listening and learning from concerns and complaints

The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.

- Information about how to make a complaint or raise concerns was available. Staff treated patients who made complaints compassionately. The service informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint. We reviewed one complaint and saw that it was managed in accordance with the services complaints policy. The complaint was reviewed appropriately and the patient was advised accordingly.

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;

The Registered Manager, Managing Director and Clinical Director had the capacity and skills to deliver high-quality, sustainable care.

- They were knowledgeable about issues and priorities relating to the quality and future of services and were visible and approachable. They understood the challenges and were addressing them.
- They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.

Vision and strategy

There was a clear vision and set of values. The service had a realistic strategy and supporting business plans to achieve priorities.

- Staff were aware of and understood the vision, values and strategy and their role in achieving them
- The service monitored progress against delivery of the strategy and staff were updated regularly.

Culture

The service had a culture of high-quality sustainable care.

- Staff felt respected, supported and valued. They were proud to work for the service. Openness, honesty and transparency were demonstrated when responding to incidents and complaints.
- The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- Staff told us they were able to raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were processes for providing all staff with the development they need. This included appraisal and career development conversations. All staff had received regular annual appraisals in the last year and nurses were supported with revalidation. There was a strong emphasis on the safety and well-being of all staff.

Governance arrangements

There were clear responsibilities, roles and systems of accountability to support good governance and management.

- Staff were clear on their roles and accountabilities. The senior clinical team activities to ensure safety and assured themselves that they were operating as intended.
- Clinical audit had recently increased however the action plans will need to be monitored at future audits to provide assurance.

Managing risks, issues and performance

- There was an effective process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The service had processes to manage current and future performance. Performance of clinical staff could be demonstrated through audit of their consultations and prescribing. However, this needed to be maintained and actions reviewed.
- The Clinical Director had oversight of safety alerts, incidents, and complaints.

Appropriate and accurate information

The service acted on appropriate and accurate information.

- Quality and operational information was used to ensure and improve performance. Performance information was combined with the views of patients obtained from clinic feedback.
- Quality and sustainability were discussed with senior management in relevant meetings and information was cascaded to the whole staff team at annual update.
- The provider was aware of submitting data or notifications to external organisations as required.

Engagement with patients, the public, staff and external partners

The service involved patients and staff to support high-quality sustainable services.

- Patients' and staff's views and concerns were encouraged, heard and acted on to shape services and culture.

Are services well-led?

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

- There were regular management meetings and staff were able to give feedback to the registered manager to discuss at the meetings.
- The service was transparent, collaborative and open with stakeholders about performance.

Continuous improvement and innovation

There were systems and processes for learning, continuous improvement and innovation.

The service made use of internal reviews of incidents and complaints. Learning was shared and used to make improvements. For example, the new client clinical record card was reviewed and developed in conjunction with the nursing team.

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	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>The provider had failed to ensure care and treatment was provided in a safe way for service users. In particular:</p> <p>The inappropriate supply of more than one medicine with the same action that had resulted in a patient safety incident.</p>