

***We are the regulator:** Our job is to check whether hospitals, care homes and care services are meeting essential standards.*

## The Naltrexone Clinic

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Tel: 02031264899

Date of Inspection: 12 September 2014

Date of Publication: October 2014

We inspected the following standards as part of a routine inspection. This is what we found:

|                                                                  |   |                   |
|------------------------------------------------------------------|---|-------------------|
| <b>Consent to care and treatment</b>                             | ✓ | Met this standard |
| <b>Care and welfare of people who use services</b>               | ✓ | Met this standard |
| <b>Management of medicines</b>                                   | ✓ | Met this standard |
| <b>Requirements relating to workers</b>                          | ✓ | Met this standard |
| <b>Assessing and monitoring the quality of service provision</b> | ✓ | Met this standard |

## Details about this location

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Registered Provider     | The Naltrexone Clinic Limited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Registered Manager      | Dr Vicente Gradillas                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Overview of the service | <p>The Naltrexone Clinic provides treatment to adults who are experiencing alcohol and opiate drug addiction problems. Healthcare services include private consultations and health assessments by a medical practitioner, registered nurse or counsellor, physical examinations, prescribing of medicines, administration of some long acting medicines, and the surgical implantation treatment of Naltrexone implants under the skin, inserted during a minor surgical procedure using local anaesthetic.</p> |
| Type of services        | <p>Doctors consultation service</p> <p>Doctors treatment service</p>                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Regulated activities    | <p>Diagnostic and screening procedures</p> <p>Surgical procedures</p> <p>Treatment of disease, disorder or injury</p>                                                                                                                                                                                                                                                                                                                                                                                            |

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## Summary of this inspection

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### Why we carried out this inspection

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This was a routine inspection to check that essential standards of quality and safety referred to on the front page were being met. We sometimes describe this as a scheduled inspection.

This was an unannounced inspection.

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### How we carried out this inspection

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We carried out a visit on 12 September 2014, observed how people were being cared for, talked with people who use the service and talked with staff. We reviewed information given to us by the provider and were accompanied by a pharmacist.

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### What people told us and what we found

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The clinic had a consent policy which stated that everyone undergoing the Naltrexone implant procedure must give written consent before any treatment was given. We observed an assessment and saw that the counsellor explained fully the need for the different types of consent.

People's records contained their medical and social histories, consent forms, risk assessments and treatment details. We saw they were able to contact a counsellor at the clinic for support seven days a week, between the hours of 6.30am and 10pm.

The practice manager told us that all patients were asked to complete a feedback form once they had undergone the procedure. There was also a complaints policy and procedure in place which was stated on the clinic's information leaflet.

We found that appropriate checks were undertaken before staff began work including criminal records checks with the Disclosure and Barring service (DBS) and registration checks with professional bodies.

You can see our judgements on the front page of this report.

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### More information about the provider

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Please see our website [www.cqc.org.uk](http://www.cqc.org.uk) for more information, including our most recent judgements against the essential standards. You can contact us using the telephone number on the back of the report if you have additional questions.

There is a glossary at the back of this report which has definitions for words and phrases we use in the report.

## Our judgements for each standard inspected

### Consent to care and treatment

✓ Met this standard

Before people are given any examination, care, treatment or support, they should be asked if they agree to it

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### Our judgement

The provider was meeting this standard.

Before people received any care or treatment they were asked for their consent and the provider acted in accordance with their wishes.

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### Reasons for our judgement

Before people received any care or treatment they were asked for their consent and the provider acted in accordance with their wishes.

The clinic had a consent policy which stated that everyone undergoing the procedure must give consent for the procedure and to allow the clinic to contact their GPs and next of kin. The manager told us they contacted GP's to inform them about the implant and the risks associated with them and that they would only contact next of kin in the event of the clinic not being able to get in contact with the patient. All consent had to be in writing.

We observed an assessment and saw that the counsellor explained fully the need for the different types of consent. People were told that if consent was not given then the procedure could not go ahead. We saw that people discussed and agreed the information that would be exchanged with their next of kin. All personal records we checked contained signed consent forms.

People we spoke with told us that given some of the potential side effects they may experience, they understood why their GP and family members needed to be contacted by the clinic.

The manager told us all staff had attended Mental Capacity Act (MCA) training and we saw records to confirm this. However, they said since the clinic opened they had not treated anyone where they had any concerns about capacity.

**People should get safe and appropriate care that meets their needs and supports their rights**

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**Our judgement**

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The provider was meeting this standard.

Care and treatment was planned and delivered in a way that was intended to ensure people's safety and welfare.

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**Reasons for our judgement**

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People's needs were assessed and care and treatment was planned and delivered in line with their individual care plan. We saw that people underwent various tests in order for the clinic to assess whether they were suitable for the procedure. Once it was agreed they could proceed, people would then be seen by a counsellor for a consultation to discuss details of the treatment. This was to ensure they fully understood the procedure had not been approved by the National Institute for Health and Care Excellence (NICE) and therefore there were some potential risks. People's records contained their medical and social histories, consent forms, risk assessments and treatment details.

Care and treatment was planned and delivered in a way that was intended to ensure people's safety and welfare. We observed a consultation and saw people were given advice about how to care for the wound and discussed the main risks which included acquiring infections, abscesses and the risk of overdoses. People were informed they needed to carry a card which provided information for emergency services should the need arise. They also discussed how they would be supported by the clinic. People were able to contact a counsellor at the clinic for support seven days a week between the hours of 6.30am and 10pm.

People's records contained details of the clinic's follow up calls. They contacted people one week after the procedure and then every four weeks until the implant had dissolved. Letters were also sent to GPs detailing the treatment, risks and what support the GP should give whilst people were undergoing the treatment.

There were arrangements in place to deal with foreseeable emergencies. All staff attended medical emergency training and there was a defibrillator and emergency oxygen in the office and these were in date.

People should be given the medicines they need when they need them, and in a safe way

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## Our judgement

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The provider was meeting this standard.

People were protected against the risks associated with medicines because the provider had appropriate arrangements in place to manage medicines.

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## Reasons for our judgement

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We looked at the medicines and records relating to medicines kept at the service and talked to staff.

Medicines used in the service were stored securely and appropriately and were only accessible to authorised people. We saw that they were all in date and appropriate emergency medicines and equipment was available for use.

Appropriate arrangements were in place in relation to obtaining and using medicines. All medicines were managed by doctors and records made at the time of use, including the batch numbers of the implants. We saw that these implants were ordered with copies of the prescriptions as they were unlicensed medicines. All medicines were prescribed on private prescriptions and were obtained by people from local pharmacies. On rare occasions people were given medicines from the service to take home with them to continue their treatment. The provider may find it useful to note that these medicines were not labelled with the person's name or instructions.

People were provided with information about their medicines which supported their decision-making and continuing treatment. People working in the service were well informed about the treatment they were offering and the risks and benefits associated with it. We saw that this was communicated clearly to people using the service. We saw that the provider followed up any concerns relating to medicines and communicated with relevant people and authorities when needed.

## Requirements relating to workers

✓ Met this standard

People should be cared for by staff who are properly qualified and able to do their job

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### Our judgement

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The provider was meeting this standard.

People were cared for, or supported by, suitably qualified, skilled and experienced staff.

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### Reasons for our judgement

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There were effective recruitment and selection processes in place. This included checking an applicant's work history, face to face interviews and identifying any training needs. References were sought prior to employment.

We found that appropriate checks were undertaken before staff began work. Staff records contained proof of identification, Disclosure and Barring Service (DBS) criminal records checks and General Medical Council (GMC) and Nursing and Midwifery Council (NMC) registration checks.

New staff had an induction programme which included mandatory training in safeguarding people from abuse, Mental Capacity Act (MCA) and Cardiopulmonary resuscitation (CPR).

## Assessing and monitoring the quality of service provision

✓ Met this standard

The service should have quality checking systems to manage risks and assure the health, welfare and safety of people who receive care

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### Our judgement

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The provider was meeting this standard.

The provider had an effective system to regularly assess and monitor the quality of service that people receive.

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### Reasons for our judgement

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People who used the service were asked for their views about their care and treatment and they were acted on. The practice manager told us that all patients were asked to complete a feedback form once they had undergone the procedure. We saw people were asked to comment on the information provided before treatment, the consultation and assessment and the surgical procedure. People had made positive comments about the care and treatment the clinic had provided. People we spoke with said they were happy with the information provided by the clinic before the treatment and felt the support on offer was "invaluable".

There was evidence that learning from incidents and near misses took place. The manager told us they carried out a 'significant event analysis' after all incidents. These took place during clinical practice meetings. We saw where there had been three recent incidents appropriate changes were implemented. Staff we spoke to confirmed this.

The practice had a complaints policy and procedure and the clinic's information leaflet advised people how to make a complaint. The manager told us they had only received informal complaints since the clinic opened and these were mostly about price or the deposits requested by the clinic. We looked at one such complaint and saw that it had been addressed in line with the policy.

The manager told us they carried out random quality checks of documentation where they would check people's treatment records, risk assessments, satisfaction survey reports, equipment maintenance records and infection control audits. Staff we spoke with confirmed this. However, the provider may find it useful to note written records of these checks were not available at our inspection.

## About CQC inspections

We are the regulator of health and social care in England.

All providers of regulated health and social care services have a legal responsibility to make sure they are meeting essential standards of quality and safety. These are the standards everyone should be able to expect when they receive care.

The essential standards are described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. We regulate against these standards, which we sometimes describe as "government standards".

We carry out unannounced inspections of all care homes, acute hospitals and domiciliary care services in England at least once a year to judge whether or not the essential standards are being met. We carry out inspections of other services less often. All of our inspections are unannounced unless there is a good reason to let the provider know we are coming.

There are 16 essential standards that relate most directly to the quality and safety of care and these are grouped into five key areas. When we inspect we could check all or part of any of the 16 standards at any time depending on the individual circumstances of the service. Because of this we often check different standards at different times.

When we inspect, we always visit and we do things like observe how people are cared for, and we talk to people who use the service, to their carers and to staff. We also review information we have gathered about the provider, check the service's records and check whether the right systems and processes are in place.

We focus on whether or not the provider is meeting the standards and we are guided by whether people are experiencing the outcomes they should be able to expect when the standards are being met. By outcomes we mean the impact care has on the health, safety and welfare of people who use the service, and the experience they have whilst receiving it.

Our inspectors judge if any action is required by the provider of the service to improve the standard of care being provided. Where providers are non-compliant with the regulations, we take enforcement action against them. If we require a service to take action, or if we take enforcement action, we re-inspect it before its next routine inspection was due. This could mean we re-inspect a service several times in one year. We also might decide to re-inspect a service if new concerns emerge about it before the next routine inspection.

In between inspections we continually monitor information we have about providers. The information comes from the public, the provider, other organisations, and from care workers.

You can tell us about your experience of this provider on our website.

## How we define our judgements

The following pages show our findings and regulatory judgement for each essential standard or part of the standard that we inspected. Our judgements are based on the ongoing review and analysis of the information gathered by CQC about this provider and the evidence collected during this inspection.

We reach one of the following judgements for each essential standard inspected.

**✓ Met this standard** This means that the standard was being met in that the provider was compliant with the regulation. If we find that standards were met, we take no regulatory action but we may make comments that may be useful to the provider and to the public about minor improvements that could be made.

**✗ Action needed** This means that the standard was not being met in that the provider was non-compliant with the regulation. We may have set a compliance action requiring the provider to produce a report setting out how and by when changes will be made to make sure they comply with the standard. We monitor the implementation of action plans in these reports and, if necessary, take further action. We may have identified a breach of a regulation which is more serious, and we will make sure action is taken. We will report on this when it is complete.

**✗ Enforcement action taken** If the breach of the regulation was more serious, or there have been several or continual breaches, we have a range of actions we take using the criminal and/or civil procedures in the Health and Social Care Act 2008 and relevant regulations. These enforcement powers include issuing a warning notice; restricting or suspending the services a provider can offer, or the number of people it can care for; issuing fines and formal cautions; in extreme cases, cancelling a provider or managers registration or prosecuting a manager or provider. These enforcement powers are set out in law and mean that we can take swift, targeted action where services are failing people.

## How we define our judgements (continued)

Where we find non-compliance with a regulation (or part of a regulation), we state which part of the regulation has been breached. Only where there is non compliance with one or more of Regulations 9-24 of the Regulated Activity Regulations, will our report include a judgement about the level of impact on people who use the service (and others, if appropriate to the regulation). This could be a minor, moderate or major impact.

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**Minor impact** - people who use the service experienced poor care that had an impact on their health, safety or welfare or there was a risk of this happening. The impact was not significant and the matter could be managed or resolved quickly.

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**Moderate impact** - people who use the service experienced poor care that had a significant effect on their health, safety or welfare or there was a risk of this happening. The matter may need to be resolved quickly.

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**Major impact** - people who use the service experienced poor care that had a serious current or long term impact on their health, safety and welfare, or there was a risk of this happening. The matter needs to be resolved quickly

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We decide the most appropriate action to take to ensure that the necessary changes are made. We always follow up to check whether action has been taken to meet the standards.

## Glossary of terms we use in this report

### Essential standard

The essential standards of quality and safety are described in our *Guidance about compliance: Essential standards of quality and safety*. They consist of a significant number of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. These regulations describe the essential standards of quality and safety that people who use health and adult social care services have a right to expect. A full list of the standards can be found within the *Guidance about compliance*. The 16 essential standards are:

Respecting and involving people who use services - Outcome 1 (Regulation 17)

Consent to care and treatment - Outcome 2 (Regulation 18)

Care and welfare of people who use services - Outcome 4 (Regulation 9)

Meeting Nutritional Needs - Outcome 5 (Regulation 14)

Cooperating with other providers - Outcome 6 (Regulation 24)

Safeguarding people who use services from abuse - Outcome 7 (Regulation 11)

Cleanliness and infection control - Outcome 8 (Regulation 12)

Management of medicines - Outcome 9 (Regulation 13)

Safety and suitability of premises - Outcome 10 (Regulation 15)

Safety, availability and suitability of equipment - Outcome 11 (Regulation 16)

Requirements relating to workers - Outcome 12 (Regulation 21)

Staffing - Outcome 13 (Regulation 22)

Supporting Staff - Outcome 14 (Regulation 23)

Assessing and monitoring the quality of service provision - Outcome 16 (Regulation 10)

Complaints - Outcome 17 (Regulation 19)

Records - Outcome 21 (Regulation 20)

### Regulated activity

These are prescribed activities related to care and treatment that require registration with CQC. These are set out in legislation, and reflect the services provided.

## Glossary of terms we use in this report (continued)

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### **(Registered) Provider**

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There are several legal terms relating to the providers of services. These include registered person, service provider and registered manager. The term 'provider' means anyone with a legal responsibility for ensuring that the requirements of the law are carried out. On our website we often refer to providers as a 'service'.

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### **Regulations**

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We regulate against the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

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### **Responsive inspection**

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This is carried out at any time in relation to identified concerns.

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### **Routine inspection**

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This is planned and could occur at any time. We sometimes describe this as a scheduled inspection.

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### **Themed inspection**

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This is targeted to look at specific standards, sectors or types of care.

## Contact us

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