

Review of compliance

University Hospitals Bristol NHS Foundation Trust Central Health Clinic

Region:	South West
Location address:	Tower Hill Bristol BS2 0JD
Type of service:	Acute services with overnight beds Ambulance service
Date the review was completed:	May 2012
Overview of the service:	Central Health Clinic is an NHS hospital that provides a range of services, including termination of pregnancy.

Summary of our findings for the essential standards of quality and safety

What we found overall

We found that Central Health Clinic was not meeting one or more essential standards. Improvements are needed.

The summary below describes why we carried out the review, what we found and any action required.

Why we carried out this review

This review was part of a targeted inspection programme to services that provide the regulated activity of termination of pregnancies. The focus of our visit was to assess the use of the HSA1 forms which are the forms used to certify the grounds under which a termination of pregnancy may lawfully take place.

How we carried out this review

We carried out a visit on 20 March 2012. We checked the provider's records and looked at medical forms relating to the termination of pregnancy service provided.

What people told us

We did not speak to people who used this service as part of this review. We looked at a sample of medical forms. This was to check that current practice ensured that treatment for the termination of pregnancy was not commenced unless two certificated opinions from doctors had been obtained.

What we found about the standards we reviewed and how well Central Health Clinic was meeting them

Outcome 21: People's personal records, including medical records, should be accurate and kept safe and confidential

The registered provider failed to ensure that people were protected against the risks of unsafe or inappropriate care and treatment. There was a lack of proper information about people in so far as certificates of opinion (HSA1 forms), required as part of the management of the regulated activity of termination of pregnancy, were not properly maintained.

Action we have asked the service to take

We have asked the provider to send us a report within 28 days of them receiving this report, setting out the action they will take to improve. We will check to make sure that the improvements have been made.

Where we have concerns the CQC has a range of enforcement powers it can use to protect the safety and welfare of people who use this service. Any regulatory decision that the CQC takes is open to challenge by a registered person through a variety of internal and external appeal processes. We will publish a further report on any action we have taken.

What we found
for each essential standard of quality
and safety we reviewed

The following pages detail our findings and our regulatory judgement for each essential standard and outcome that we reviewed, linked to specific regulated activities where appropriate.

We will have reached one of the following judgements for each essential standard:

Compliant means that people who use services are experiencing the outcomes relating to the essential standard.

A **minor concern** means that people who use services are safe but are not always experiencing the outcomes relating to this essential standard.

A **moderate concern** means that people who use services are safe but are not always experiencing the outcomes relating to this essential standard and there is an impact on their health and wellbeing because of this.

A **major concern** means that people who use services are not experiencing the outcomes relating to this essential standard and are not protected from unsafe or inappropriate care, treatment and support.

Where we identify compliance, no further action is taken. Where we have concerns, the most appropriate action is taken to ensure that the necessary improvements are made. Where there are a number of concerns, we may look at them together to decide the level of action to take.

More information about each of the outcomes can be found in the *Guidance about compliance: Essential standards of quality and safety*.

Outcome 21:

What the outcome says

People who use services can be confident that:

- * Their personal records including medical records are accurate, fit for purpose, held securely and remain confidential.
- * Other records required to be kept to protect their safety and well being are maintained and held securely where required.

What we found

Our judgement

There were moderate concerns with Outcome 21: Records

Our findings

What people who use the service experienced and told us
We did not speak with people who used the service as part of this review.

Other evidence
Section 1 (1) of the Abortion Act 1967 (as amended) and the Abortion Regulations 1991 (as amended) require that two doctors provide a certificated opinion, formed in good faith, that at least one and the same ground for a termination of pregnancy as set out in the Act, is met.

These opinions have to be given in a certificated form as set out in the regulations and must be given before the commencement of the treatment for the termination of pregnancy, except in the specified circumstances set out in the Act.

One of the ways in which the regulations provide for doctors to certify this opinion is in the use of an HSA1 form. When the HSA1 form is used, both of the certifying doctors must complete the form as required and sign and date the certificate. The opinion of each doctor is required to relate to the circumstances of the individual person's case.

We visited Central Health Clinic in Bristol on 20 March 2012. We met with staff at the Pregnancy Advisory Service. The clinic was a nurse-led practice where the majority of patients were assessed initially by a nurse. The patient may or may not then see a doctor during the process. We explained to staff the purpose of our visit and advised we wanted to look at a sample of patient records.

Staff told us certain parts of the patient notes were not kept at the Central Health Clinic but were transferred to other NHS hospitals for further use during treatment, or storage. We told staff we would therefore review the notes at these other locations in due course.

During our visit we asked staff to outline the procedure for the two doctors to provide their certificated opinion, formed in good faith, that at least one and the same ground for a termination of pregnancy was met. We were told that staff used pre-signed blank HSA1 forms. These forms had been signed without or ahead of a formal assessment of the individual's needs and circumstances being completed by the doctor. We asked to see examples of the pre-signed HSA1 forms and these were provided by staff.

We asked staff when the forms were then dated. We were told this was done when the nurse had assessed the patient and the booking for the termination of pregnancy had been made.

We asked how the pre-signed HSA1 forms were used. We were told for many patients the opinion of the first doctor was provided through the use of pre-signed HSA1 forms. If the patient was booked for a surgical procedure, the surgeon who performed the procedure signed the HSA1 form as the second-opinion doctor.

The surgeon would see the patient before the procedure took place. Patients who were booked for surgery would go to another NHS hospital or a provider of NHS-funded care. Some medical abortion procedures would be referred to another NHS provider if the woman wished to have a hospital-based procedure.

If a medical procedure was carried out, the doctor who wrote the prescription for the medication would sign the pre-signed HSA1 form as the second-opinion doctor. Staff told us the second doctor saw around 20% of all medical-termination patients. Other patients saw a nurse and the second-opinion doctor only reviewed the notes. We were told patients under the age of 16 must have seen a doctor, but only one doctor. Patients aged 16-18 generally saw a doctor, but again, only one doctor.

The pre-signed forms were also used for patients aged 18 and under.

Judgement

The registered provider failed to ensure that people were protected against the risks of unsafe or inappropriate care and treatment. There was a lack of proper information about people in so far as certificates of opinion (HSA1 forms), required as part of the management of the regulated activity of termination of pregnancy, were not properly maintained.

Action we have asked the provider to take

Compliance actions

The table below shows the essential standards of quality and safety that **are not being met**. Action must be taken to achieve compliance.

Regulated activity	Regulation	Outcome
Termination of pregnancy	20	Outcome 21 Records
	<p>How the regulation is not being met: The registered provider failed to ensure that people were protected against the risks of unsafe or inappropriate care and treatment. There was a lack of proper information about people in so far as certificates of opinion (HSA1 forms), required as part of the management of the regulated activity of termination of pregnancy, were not properly maintained.</p>	

The provider must send CQC a report that says what action they are going to take to achieve compliance with these essential standards.

This report is requested under regulation 10(3) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

The provider's report should be sent to us within 28 days of this report being received.

Where a provider has already sent us a report about any of the above compliance actions, they do not need to include them in any new report sent to us after this review of compliance.

CQC should be informed in writing when these compliance actions are complete.

What is a review of compliance?

By law, providers of certain adult social care and health 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 CQC has written guidance about what people who use services should experience when providers are meeting essential standards, called *Guidance about compliance: Essential standards of quality and safety*.

CQC licenses services if they meet essential standards and will constantly monitor whether they continue to do so. We formally review services when we receive information that is of concern and as a result decide we need to check whether a service is still meeting one or more of the essential standards. We also formally review them at least every two years to check whether a service is meeting all of the essential standards in each of their locations. Our reviews include checking all available information and intelligence we hold about a provider. We may seek further information by contacting people who use services, public representative groups and organisations such as other regulators. We may also ask for further information from the provider and carry out a visit with direct observations of care.

When making our judgements about whether services are meeting essential standards, we decide whether we need to take further regulatory action. This might include discussions with the provider about how they could improve. We only use this approach where issues can be resolved quickly, easily and where there is no immediate risk of serious harm to people.

Where we have concerns that providers are not meeting essential standards, or where we judge that they are not going to keep meeting them, we may also set improvement actions or compliance actions, or take enforcement action:

Improvement actions: These are actions a provider should take so that they **maintain** continuous compliance with essential standards. Where a provider is complying with essential standards, but we are concerned that they will not be able to maintain this, we ask them to send us a report describing the improvements they will make to enable them to do so.

Compliance actions: These are actions a provider must take so that they **achieve** compliance with the essential standards. Where a provider is not meeting the essential standards but people are not at immediate risk of serious harm, we ask them to send us a report that says what they will do to make sure they comply. We monitor the implementation of action plans in these reports and, if necessary, take further action to make sure that essential standards are met.

Enforcement action: These are actions we take using the criminal and/or civil procedures in the Health and Adult Social Care Act 2008 and relevant regulations. These enforcement powers are set out in the law and mean that we can take swift, targeted action where services are failing people.

Information for the reader

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