



Department  
of Health

# Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy

*A consultation*

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# Procedures for the approval of independent sector places for the termination of pregnancy

A consultation

Prepared by the Sexual Health Team, Public Health Directorate, Department of Health

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## Introduction

The Department of Health has updated the Procedures by which the Secretary of State approves independent sector places to perform termination of pregnancy. The Procedures set out the conditions and requirements for independent sector places to be approved by the Secretary of State. This consultation seeks views on the updated Procedures. In particular whether they include the necessary conditions to ensure women receive a safe, high quality, service from independent sector abortion providers which meet the requirements of the Abortion Act.

In July 2012, the Department of Health published Interim Procedures for the Approval of Independent Sector Places which contained updated interim Required Standard Operating Procedures (RSOPs). All currently approved independent sector providers for the termination of pregnancy agreed to comply with these and were re-approved to perform abortions until 28 February 2014. DH committed to consult on a further updated set of RSOPs prior to considering re-approvals for a period of a further four years. This consultation document fulfils that commitment. In February 2014, all current providers will be re-approved for an interim period of three months. During this time responses to this consultation will be considered and a final document against which all providers will be invited to re-apply for approval will be published. The new four year approval period will commence on 31 May 2014.

Details of the consultation process are set out in **Annex A**. Questions for consultation are included throughout the document and are summarised in **Annex B**. We welcome general comments as well as specific responses to the questions, though responders are asked to note the scope of the consultation (paragraph 7).

## 1. Legal requirements and why the Procedures are needed

1.1 Under Section 1(3) of the Abortion Act 1967 the Secretary of State for Health has a power to approve independent sector places (e.g. private and charitable sector places) as places where abortion can take place. The Secretary of State also maintains a register of Pregnancy Advice Bureaux (PABx).

1.2 Approval of independent sector places are based on a core set of principles, the aims of which are to:

- Ensure compliance with all legal requirements
- Provide the best quality of care for women
- Provide sound management, organisational and clinical governance arrangements.

1.3 The Procedures have been in existence, in different formats and with different titles, for many years. They were developed, and continue to exist, to make explicit the conditions and requirements for independent sector places to be approved by Secretary of State to perform termination of pregnancy. The RSOPs contained in the Procedures cover a range of issues including the regulatory framework, organisation of services and maintaining standards and quality.

1.4 In addition, all termination of pregnancy providers must be registered with the Care Quality Commission (CQC) and meet essential standards of quality and safety as set out in Part 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. It should be noted that these regulations will be changing in 2014. The CQC registers the service provider of the regulated activity and may place conditions on the registration – for example, where the regulated activity is carried out. Regulation 20 of the Care Quality Commission (Registration) Regulations 2009 also sets out a number of requirements relating to the termination of pregnancy. This regulation applies to a registered person who carries on or manages the regulated activity of termination of pregnancies and who is not an English NHS body.

1.5 Places where regulated activities are carried out are subject to regular unannounced inspections by the CQC. Secretary of State approval to perform abortions can be withdrawn at any time if the approved place fails to comply with or maintain the required standards under the Procedures.

1.6 The Government believes that the separate approval of independent sector places should continue, in line with the powers under the Abortion Act, but that the approval should reflect best practice and ensure that every woman receives high quality advice and support. This approach supports the objectives set out in the White paper *Healthy Lives, Healthy People*, our strategy for Public Health in England (November 2010) and *A Framework for Sexual Health Improvement in England* (March 2013), which sets out a number of ambitions for good sexual health and provides a comprehensive package of evidence, interventions and actions to improve outcomes.

## 2. Why update the Procedures?

2.1 Prior to the publication of the Interim RSOPs in July 2012, the last update of requirements for independent sector abortion providers took place in 1999. In 2012, a decision was taken to issue an interim version of the RSOPs to update requirements and take into account a number of regulatory changes, for example the introduction of the Health and Social Care Act 2008, which imposed additional regulations on providers. We have now made some additional

amendments to the RSOPs, since the interim version was issued, to bring it in line with current policies and guidance. **We seek comments on this updated version through this consultation exercise.**

### **3. Implications for independent sector service providers and governance**

3.1 All independent sector places will continue to operate within the existing quality framework and the arrangements for Secretary of State approval will not change. On successful completion of the CQC registration process, the service provider is required to seek the Secretary of State for Health's approval to provide abortion services and commit to comply with the requirements in the RSOPs. In 2012, 97% of abortions were funded by the NHS; of these over half (62%) took place in the independent sector under NHS contract.

### **4. Responsibilities of doctors and defining "good faith"**

4.1 At the request of the Secretary of State, the CQC undertook a series of unannounced inspections of all abortion providers in 2012 following concerns that some doctors might be pre-signing HSA1 abortion certification forms. This practice was identified in a total of 14 NHS hospitals. All 14 hospitals put in place procedures to ensure compliance. In subsequent inspections of all providers (both independent sector and NHS) the CQC have found no further evidence that pre-signing is occurring. Following the call from the Crown Prosecution Service (CPS) for guidance to doctors on how they should go about assessing the risk to physical or mental health to the pregnant woman and the proper process for recording the assessment carried out, the Chief Medical Officer wrote to all doctors on 22<sup>nd</sup> November (<https://www.cas.dh.gov.uk/Home.aspx>), This letter highlighted that "the law is clear that termination on the grounds of gender alone is illegal." Also, the expectation that "both doctors will have taken positive steps to obtain information specific to the woman seeking a termination as part of reaching their decision and to have turned their mind to the particular facts of that case when forming their opinion. Doctors should be able to evidence how this decision was reached if asked to justify it subsequently. The pre-signing of HSA1 forms or "counter-signing" decisions of other doctors is unacceptable in this process and incompatible with the requirement to form an opinion in "good faith". The RSOPs reflect this guidance. The final version will include any additional guidance developed with the General Medical Council, the British Medical Association and the Royal College of Obstetricians and Gynaecologists.

#### **Consultation Questions:**

Consultation Question 1. Do the updated RSOPs include the necessary conditions to ensure women receive a safe, high quality, service from independent sector abortion providers which meets the requirements of the Abortion Act?

Consultation Question 2. Are there any other RSOPs or requirements that you think should be included? If so, what are they, and why are they needed?

Consultation Question 3. Do you have any other comments you would like to make in relation to this consultation?

## Background

### 5. Wider service provision

5.1 Independent sector places are not just abortion providers but also providers of contraception and wider sexual health services. Abortion should not be seen in isolation, but in the context of wider public health issues, such as mental health and wellbeing, education and information giving, as the Public Health White Paper and the Sexual Health Framework makes clear. Care pathways should be in place to a range of services for those women with identified needs beyond unwanted pregnancy.

### 6. Key Abortion data

6.1 In 2012, for women resident in England and Wales (based on annual data):

- There were 185,122 abortions compared with 189,931 in 2011 – a fall of 2.5%
- The age standardised abortion rate was 16.5 per 1,000 resident women aged 15-44. 5.4% lower than in 2011
- The abortion rate was highest at 33 per 1,000 for women aged 19, the same as in 2009 and slightly lower than the highest rates in the year 2000
- The under 16 abortion rate was 3.0 per 1,000 women and the under 18 rate was 12.8 per 1,000 women, both lower than in 2011
- 97% of abortions were funded by the NHS, of these, over half, (62%) took place in the independent sector under NHS contract
- 91% of abortions were carried out at under 13 weeks gestation; 77% were at under 10 weeks
- Medical abortions accounted for 48% of the total
- 2,692 abortions (1%) were under Ground E (substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped)

## Consultation Scope

7.1 This consultation covers the proposed revisions to the current interim Required Standard Operating Procedures (RSOPs) issued in August 2012. The consultation paper seeks comments on the RSOPs and, in particular, specific questions (**see Annex B**). It does not seek views on:

- Whether the Secretary of State for Health should continue to approve independent sector places as legal powers to approve these places are already available within existing law;
- Any other aspect of abortion legislation. It is accepted Parliamentary practice that proposals for changes in the law on abortion come from back-bench members and that decisions are made on the basis of free votes.
- The ethics of abortion. Women should have access to legal and safe abortions in accordance with the provisions in the Abortion Act.



## Timetable

8.1 This consultation opens on 22 November 2013 and will close on 3 February 2014.

We invite responses from:

- NHS Trusts
- Foundation Trusts
- Clinical Commissioning Groups (CCGs)
- Independent sector abortion providers
- Royal Colleges
- Professional bodies
- other stakeholder and patient organisations that have an interest in the provision of abortion services.

Our preferred method of receiving your response is via our electronic consultation questionnaire, which can be found via the following link: <http://consultations.dh.gov.uk/abortion-clinics/approval-of-independent-sector-places-for-the-term>

Alternatively, you may complete the response form, found alongside this consultation document. If possible we would prefer this form to be returned to us electronically as an email attachment. The email address for responses or queries is: [Lisa.Westall@dh.gsi.gov.uk](mailto:Lisa.Westall@dh.gsi.gov.uk)

Postal responses can be sent to;

Sexual Health Team  
Department of Health  
Room 124 Richmond House  
79 Whitehall  
London SW1A 2NS

A hard copy of this consultation document, and the corresponding response form, is available on request, using the email address or telephone number given above.

If you have any questions about the content of this consultation then please send them to [Lisa.Westall@dh.gsi.gov.uk](mailto:Lisa.Westall@dh.gsi.gov.uk)

# Annex A

## Consultation Process

This consultation follows the 'Government Code of Practice'. In particular, we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for 8 weeks with consideration given to longer timescales where feasible and sensible;
- be clear about the consultation process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

The full text of the code of practice is on the Better Regulation website at:

<http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44458.html>

## Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator  
Department of Health  
2e08, Quarry House  
Leeds  
LS2 7UE

**e-mail:** [consultations.co-ordinator@dh.gsi.gov.uk](mailto:consultations.co-ordinator@dh.gsi.gov.uk)

**Please do not send consultation responses to this address.**

## Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's [Information Charter](#).

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

### Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action and will be placed on the Consultations response area of the GOV.UK website.

## Annex B

### Consultation Questions

Consultation Question 1. Do the updated RSOPs include the necessary conditions to ensure women receive a safe, high quality, service from independent sector abortion providers which meets the requirements of the Abortion Act?

Consultation Question 2. Are there any other RSOPs or requirements that you think should be included? If so, what are they, and why are they needed?

Consultation Question 3. Do you have any other comments you would like to make in relation to this consultation?