



Department
of Health

Changes to procedures for the approval of Independent Sector places for termination of pregnancy

Response to proposals in the consultation

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Changes to procedures for the Approval of Independent Sector places for termination of pregnancy

Response to proposals in the consultation

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Introduction

This document summarises the responses received to the consultation on the Updated Procedures for Approval of Independent Sector Places for Termination of Pregnancy (the Procedures) and sets out what action will be taken as a result.

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.

Approval of independent sector places is 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.

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 Required Standard Operating Procedures (RSOPs) contained in the Procedures cover a range of issues including the regulatory framework, organisation of services and maintaining standards and quality.

The consultation

The Department of Health undertook a public consultation between 22 November 2013 and 3 February 2014. The aim of the consultation was to ensure that the Procedures include the necessary conditions to ensure women receive a safe, high quality service from independent sector abortion providers which fully meet the requirements of the Abortion Act (**question 1**). The consultation also sought feedback on the RSOPs in general, with the opportunity to suggest how the RSOPs could be improved (**question 2**). Additionally the consultation sought other comments in relation to the consultation (**question 3**).

The consultation document and supporting documentation were published on the GOV.UK website and the Department's consultation platform Citizen Space. In addition, awareness was raised through a number of other mechanisms:

- notification in NHS e-bulletins
- use of stakeholder groups and organisations to raise awareness.

A total of 1,455 responses to the consultation were received from a variety of stakeholders and individuals including, service providers, NHS bodies, the voluntary sector, professional and statutory bodies, faith groups, academia and the education sector. A list of responding organisations can be found in **Annex A**. Names of individual respondents cannot be listed for data protection reasons. We would like to thank all respondents for taking the time to respond to the consultation.

Summary of responses

There were a number of overarching themes which emerged from the consultation responses, each of which is discussed in more detail below. Responses to the consultation were varied in their focus, length and content. Many of the comments received were out of scope for the consultation as they would require changes to the Abortion Act. Where possible, we have identified the top themes to help focus the Department's response. There were some detailed responses for which we have had to summarise the main points as it has not been possible to reflect all comments in this document. We have also reflected the importance of individual organisations when assessing comments and provided more detail on those that were within scope.

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

Responses: A significant number of respondents expressed concerns about some aspects of the RSOPs, particularly RSOP1. A small proportion chose not to answer the question. The remaining respondents were content that the RSOPs were fit for purpose.

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?

Responses: There were two main themes in the responses to this question.

- the first theme relates to **RSOP1 Compliance with the Abortion Act**; this is separated into what fell within the scope of the consultation, and what fell out of scope e.g. would require changes to the Abortion Act and/or regulations.
- the second theme relates to **RSOP 13 Counselling**, and again is divided into what fell in scope and what was out of scope.

The main comments received on each RSOP and whether these have been accepted, are set out below. We have only included those RSOPs on which comments were submitted.

RSOP 1: Compliance with the Abortion Act

Responses on RSOP1 included:

In scope

- that the interpretation of the law presented was that of the Department of Health and that the Department's interpretation goes beyond the requirements of the Abortion Act
- that the Department's interpretation would place additional requirements on doctors that could potentially delay women accessing procedures
- that, in the statement that doctors should evidence how they have reached their decision in good faith, some respondents highlighted that it should also be explained that the burden of proof lies with the prosecutor
- the need for a clear audit trail for both doctors signing the HSA1 form, and that the physical and mental health assessment should be clearly identified in the patient's medical records
- that there is no clinical evidence that women should be seen by doctors rather than trained nurses and counsellors and that there is no legal requirement to see a doctor ,
- that the Department should issue guidelines to providers asking them to establish that providers are able to demonstrate, through maintaining records, that their doctors have been trained in the requirements of the Abortion Act and how to interpret the notes of others in forming a well-grounded opinion
- that doctors relying entirely on the opinions of other health professionals would be potentially fraught with difficulties and ought to be the exception rather than the rule,
- that doctors should note in the patient record why they had not met the woman
- the requirement for both doctors to see and/or examine the pregnant woman is implicit in the Abortion Act; it was questioned how doctors can form and defend an opinion in good faith if they have never seen the woman,
- that doctors not seeing women reflects poor medical care and borders on medical negligence,
- that pre-signing and counter-signing should be described as "illegal practice" not unacceptable practice,
- concerns that the RSOPs contain no requirement for the good faith opinion to be monitored or assessed, and the wording was considered too vague and non-prescriptive,
- that the RSOPs should include a statement on gender selection abortions.

Out of scope

- strong support for it to be a requirement for a woman to see a doctor before an abortion could be authorised. Some respondents felt it should be a requirement for a woman to see two doctors before an abortion could be authorised,
- that, due to the perceived mental health risks of abortions, one of the doctors seen by the woman should be a qualified mental health practitioner.

Department of Health Response:

These comments have been taken into account, where appropriate, by the Department in developing new *Guidance in Relation to the Requirements of the Abortion Act 1967*. Since the 1967 Abortion Act was passed, the law has required that two doctors certify in good faith that there are lawful grounds for any abortion. The differing interpretations of what this requirement means in practice from those responding to the consultation are illustrated above. The guidance highlighted above has been produced for doctors and all those involved in providing and commissioning abortion care and contains the Department's interpretation of the law regarding an opinion given in good faith and other issues. Updated RSOP1 now states that all approved places must comply with this guidance.

RSOP2 – Provision of terminations at different gestation including early medical abortion (EMA) – delegation of duties and protocols:

Responses included:

In Scope:

- a need to strengthen statements on the need for follow-up and use of analgesia for women who choose to go home after the second drug for EMA has been administered – **agreed and RSOP amended.**
- that wording about women leaving the clinic after being administered the first dose of tablets and returning for the second dose needs to be clearer – **agreed and RSOP amended.**

Out of Scope:

- that nurses should also be able to perform surgical abortions
- that women should be able to take the second tablet for medical abortion at home
- that nurses cannot legally perform abortions

Department of Health response- Nurses' role in abortion treatment

A test case in 1981¹ established that nurses can administer abortion drugs, as long as a doctor personally decides upon and initiates the process and takes responsibility throughout for the termination; this consultation does not change that. A nurse should only ever act under the direction of a doctor. A nurse's role might include assessing the reasons for the abortion, noting them and referring to the two doctors to make a decision on whether an abortion would be legal in that case.

RSOP 3 – Follow Ups

Responses included:

In Scope:

- “emotional/psychological symptoms” should be added to the most common symptoms women should be informed of following an abortion – **agreed and RSOP amended.**
- that follow up appointments do not always need to be face to face or with the abortion provider – **agreed and RSOP amended.**
- that pathways to post abortion counselling need to be available for any woman who may require additional emotional support or whose mental health is perceived to be at risk – **agreed and RSOP amended.**
- the requirements relating to the 24 hour helpline should be strengthened – **agreed and RSOP amended.**

Out of Scope:

- that post abortion services should be commissioned separately from those who provide abortion care

RSOP 5 – Compliance with CQC Regulatory Framework

Responses included:

- that updated wording is needed to reflect planned changes to CQC regulations and guidance – **agreed and RSOP amended and relevant changes made throughout the document.**

¹ RCN v DHSS [1981] 1 All ER 545.

RSOP 6 (previously RSOP4) – Confidentiality

Responses included:

In Scope:

- that advice on sharing anonymised information with commissioners should be added – **agreed and RSOP amended,**
- the need to strengthen references to professional guidance, safeguarding and vulnerable adults – **agreed and RSOP amended.**

Out of Scope

- that there should be a requirement to record abortions in patient records.

RSOP 7 – Service Provision for Children, Young People and Vulnerable Adults

Responses included:

In Scope:

- that reference should be to Fraser Guidelines rather than Gillick Competence – **agreed and RSOP amended,**
- that references to *Working Together to Safeguard Children* should be strengthened, including highlighting staff training and qualifications – **agreed and RSOP amended,**
- that there should be reference to child sexual exploitation – **agreed and RSOP amended,**
- that there should be reference to the age of consent – **agreed and RSOP amended,**
- the need to add references to relevant guidance from GMC – **agreed and RSOP amended,**
- the need to strengthen the section on vulnerable adults – **agreed and RSOP amended,**
- references to domestic violence and intimate partner abuse should be added – **agreed and RSOP amended.**

RSOP 8 - Consent

Responses included:

- that wording should refer only to under 16s and adults as the current wording is confusing – **agreed and RSOP amended,**
- that age appropriate information should be available and health professionals seeing under 16s should have experience working with this age group – **agreed and RSOP amended,**
- that information about complications and risks should be part of the consent process – **not accepted as already covered under RSOP12 Information for Women.**

RSOP 9 - Gestational Limits

Responses included:

- that wording should be clear about specific gestations rather than referring to “late” abortions – **agreed and RSOP amended.**

RSOP 11- Access to timely abortion services

Responses included:

- avoiding the term “rapid transfer” as it is linked to clinical emergencies – **agreed and RSOP amended,**
- that mental health care pathways also need to be in place – **agreed and RSOP amended,**
- that counselling should also be available within five working days – **not accepted. We would expect that in the vast majority of cases women to see a counsellor much quicker than five days. We are not aware of any evidence base that supports the inclusion of this in the RSOP.**

RSOP 12 – Information for Women

Responses included:

- the addition of the words “impartial” and “accurate” to the information requirements for women – **agreed and RSOP amended,**
- that information should be standardised centrally. **Partially accepted. Reference now added to the recommendation in the Royal College of Obstetricians and Gynaecologists (RCOG) clinical guideline that local information leaflets should be based on information from their website or Family Planning Association patient information,**
- that information on the development of the fetus should be included in the information for women. **Not accepted.**

RSOP 13 - Contraception and STI Screening

Responses included:

- the addition of more explicit statements about pathways to sexual health services, particularly for repeat abortions and teenage pregnancies – **agreed and RSOP amended,**
- that women should be advised of the greater effectiveness of long acting reversible contraception (LARC) methods – **agreed and RSOP amended,**
- that it should be explicit that those fitting LARCs should be appropriately trained and qualified – **agreed and RSOP amended.**

RSOP 14 – Counselling

Responses included:

In Scope

- the need for counsellors to be trained to diploma level in pregnancy counselling and counselling must be non- directive – **agreed and RSOP amended,**
- that the offer of counselling should be mandatory. **Not needed. The RSOP already makes clear that “all women requesting an abortion should be offered the opportunity to discuss their options and choices with, and receive therapeutic support from, a trained pregnancy counsellor and this offer should be repeated at every stage of the care pathway”,**
- the addition of references to care pathways to ante-natal and adoption services for those women who chose not to proceed with the abortion – **agreed and RSOP amended,**
- the need to strengthen wording around referrals to formal, therapeutic counselling for those who require it – **agreed and RSOP amended.**

Out of scope

A significant number of responses said that pre and post counselling abortion should be made mandatory. Linked to this, some said that the counselling should be provided separately from the provider carrying out the abortion.

Department of Health Response - Counselling

As set out above, some of the responses to the consultation highlighted the need to separate counselling from the abortion provider. In the Government's ²Framework for Sexual Health Improvement (March 2013) we highlighted the following:

- all women requesting an abortion should be offered the opportunity to discuss their options and choices with a trained counsellor.
- or those women who accept an offer of counselling, this must always be provided in line with the following principles:
 - it should not impact on timely access to services by creating barriers or delays,
 - mandatory requirements for counselling must never be imposed,
 - counselling must be non-judgemental, and the counsellor must be willing to discuss the full range of options open to the woman,
 - if the counsellor is not contracted/employed by an abortion service, rapid onward referral should be made if abortion is the chosen option,
 - counselling must be impartial and put patients' needs first, irrespective of the contractor/employer of the counsellor.

This sets out our policy in relation to counselling clearly and we do not intend to issue any further guidance.

RSOP 16 – Performance Standards and Audit

We received a number of comments suggesting strengthening the audit indicators. These included rates of complications, prevention of infective complications and failure rates—**agreed and RSOP amended.**

² A Framework for Sexual Health Improvement in England

RSOP 18 – Staffing and Emergency Medical Cover

Responses included:

- that this RSOP is too detailed and should focus on having policies and procedures in place to cover staffing requirements and managing emergencies. – **agreed and RSOP amended,**
- there should be reference to the Royal College of Anaesthetists guidelines on the provision of Anaesthetic Services – **agreed and RSOP amended,**
- that counsellors should also have to undergo continuous professional development and training - **agreed but included in RSOP 14 Counselling,**
- the need for similar references to medical staff as in the 1999 version of the RSOPs – **not accepted. These matters are now regulated by the CQC,**
- the need for more detail about record keeping generally not just in relation to staffing – **not accepted. Again, record keeping requirements fall under the CQC's responsibilities.**

RSOP 19 - Confirmation of Professional Status

Responses included:

- that counsellors should be added to the list of staff against which checks should be made – **agreed and RSOP amended.**

RSOP 22 - Death of a Patient

Responses included:

- that the wording of this RSOP is unclear and should be simplified – **agreed and RSOP amended.**

RSOP 26 – Abortions beyond 9 weeks gestation

Responses included:

- that there should be a separate approval process for abortions performed over 20 weeks. In contrast others commented that there should be no additional requirements for these procedures. **Out of scope. The Secretary of State does not have the power to require a separate approval process for abortions over 20 weeks gestation. We consider the current practice where providers voluntarily notify the Department of Health when they are performing procedures beyond 20 weeks works well and the requirement remains unchanged.**

RSOP 27: Fetal Awareness and Fetal Abnormality

- a number of respondents commented that evidence on fetal pain is disputed and that this should be reflected in the RSOP. **Not accepted. The RSOP contains evidence from RCOG, the appropriate professional body.**

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

Responses: There was a lot of replication from question 2 responses. Also, some respondents answered question 2 or 3 only not both. There was a wide range of general comments but few common themes or consensus. This could reflect the fact that respondents were largely concentrating their substantive efforts on Question 2. However, the following issues were raised and are shown as in scope or out of scope.

In scope

- As highlighted in the comments above, some respondents were concerned about language around the interpretation of the law. They felt that where there were other possible interpretations and that less definitive language should be used.
- Whilst appropriate for the RSOPs to aim for a consistent standard of care, comments were made that there should be some acknowledgment that different practices might be appropriate for specialist, experienced clinicians to those for whom abortion is an occasional practice. **Not accepted. The RSOPs need to apply equally to all providers.**
- Continuing professional education and training was considered to be an essential ethical and professional requirement for counsellors and psychotherapists. **Agreed and relevant RSOPs amended.**

Out of scope

- That NHS numbers should be collected in order to aid research into physical and mental health issues associated with the procedure.
- Questioning the reliance on the 1981 House of Lord's Judgement *in RCN v DHSS* in the case of non-doctors carrying out abortions.
- Requests for a full consultation on the issue of good faith.
- That the language relating to impairment/disability and handicap within the RSOPs ought to be reconsidered and brought into line with the usage advocated by the WHO as the language surrounding this has changed significantly since the 1967 Act was passed.

Other issues arising which did not relate to specific questions

A number of respondents felt that the consultation had been poorly publicised and they had been given insufficient response time given its subject matter. Some respondents made suggestions for other changes, e.g. abortion time limits, which fell outside the scope of the consultation and of the questions posed.

Department of Health Reply

The Department is extremely grateful to those who responded to the consultation. The responses contained a number of wide ranging issues. Many of the comments received were out of scope, particularly in terms of suggesting changes to the law. However, all comments were carefully considered and those that were in scope are reflected in the revised RSOPs where appropriate.

Next Steps

The Government has considered carefully the comments from respondents. It was apparent that some responses reflected wider concerns about abortion in general which are outside the remit of this consultation. However a large number of helpful comments arising from this consultation have been taken on board in updating the RSOPs. All independent sector providers must agree to meet these requirements to be approved for a further four year period.

Annex A: List of respondents to the consultation

1st Donegore Presbyterian Church
3PB Barristers
Abortion Rights
Acorns Public Health Research Unit
Acts Community Church
Adam Outreach Project
Addiction Support Group
Albion St Church
All Party Parliamentary Pro-Life Group
All Saints Church Preston
Amber Crisis Pregnancy Centre
Anscombe Bioethics Centre
Ayrshire Pregnancy Crisis Centre
British Association of Counselling and Psychotherapy
Barrow upon Soar Baptist Church
BCHA
British Medical Association
BMS World Mission
Bolton CCG
British Pregnancy Advisory Service
Cape Hill Medical Centre
CARE
Care Confidential
Care Quality Commission
Catenian Association
Catenians Jersey Branch
Catholic Marriage Resource Centre
Catholic Medical Association
Central Baptist Church
Centre for Bio Ethical Reform UK
Centre for Health, Law, Science
Christ Church Balham
Christ Faith Tabernacle
Christian Concern
Christian Institute
Christian Legal Centre
Christian Medical Fellowship
Christian Parent Talk
Christian Peoples Alliance
Christian Spectrum
Christians on the Left
Church of England
City Church Liverpool
City Gate Church
City Hospital Liverpool
Connections Trust
Cornerstone Pregnancy Crisis Centre
Cranfield Baptist Church
Crisis
Crisis Pregnancy Centre
Crisis Pregnancy Support
Cross Factor Ministries
DWCA
EAST Sussex Life
EBRD
Elim Pentecostal Churches
Ely Pregnancy Centre
Emmanuel Congregation Church
Emmaus Group Ltd
Equestrian Order of Holy Sepulchre of Jerusalem Knights of St Columba
Essex Lodge GP Surgery
Eurovision Mission to Europe
Family Education Trust
Fardawn Christian Associates
Forsaken, Post Abortion Stress Recovery
FPA/Brook
Free Church
Faculty of Sexual and Reproductive Healthcare
Gateway Church
Glasgow Pregnancy Crisis Centre
Grace Church
Grace Church Wolverhampton
Grace Church Yate
Grampian NHS Trust
Gynae Centre
Hampshire Hospitals Foundation Trust
Health and Social Care Training
Herts Valley CCG
Holy Redeemer Church, Streatham
Hospitality and Hope
Hunsdon House Nursery School
Independent Healthcare Advisory Services
Kathmandu International Study Centre
Kingdom Advance Network Church
Kingsway Fellowship
KLC
KSG
L&D University Hospital
Lee Community Church
LIFE
LIFE – Northern Ireland

Longmeadow Evangelical Church
 Maidstone and Tunbridge Wells NHS Trust
 Marie Stopes International
 Marriage Care
 Medical Education Trust
 Methodist Church of Great Britain
 Mid Ulster Christian Helpline
 Missionary Congregation of the Xaverian Fathers
 Mitchell Ministries Trust
 Mortality Forum
 Murton Methodist Church
 New Life Christian Church
 Newark Evangelical Church
 Newlife Christian Church
 NHS Trust Bath
 OAC Ministries
 Options (Part of Care Confidential)
 Options Chichester
 Options, Chichester Crisis Pregnancy Centre
 Orthodox Church
 Oxford Students for Life
 Oxfordshire Community Churches
 Palm Tree Associates
 Pantygwydr Baptist Church
 Papri Research
 Pathways Post and Pre abortion support
 Pathways Support Group Oasis Church
 Pathways Wirral Crisis Pregnancy
 Pioneer Churches UK
 Post Abortion Support for Everyone
 Potter's House Christian Church
 Potton Vineyard Church
 PRIME (Partnerships in International Medical Education)
 Pro-Life Alliance
 Protestant Truth Society & Christ Church Teddington
 Public Health, Darlington Borough Council
 Reproductive Health Matters
 Revelation Church
 Right Cases
 Right to Life
 Rockwell Green Christian Fellowship
 Rora Christian Fellowship Trust
 Royal College of Obstetricians and Gynaecologists
 Salisbury Vineyard Christian Fellowship
 Science and Technology Policy Research
 Scottish Christian Party
 Scottish Council on Human Bioethics
 Somerset CCG
 South Coast Church
 South Devon and Torbay CCG
 Spectrum Family Resources
 Spire Healthcare
 Springs Christian Fellowship
 Society for the Protection of the Unborn Child
 St James Surgery Dover
 St John and Elizabeth Hospital Westminster
 St Mary Star of Tea Church
 St Paul's Church, Salisbury
 St Peter's Church
 Taverham Evangelical Church
 Tees Valley Community Church
 The Common Good Party
 The Fire Thorn Trust
 The Maltings Surgery
 The Moat House Surgery
 The Salvation Army
 The Vineyard Life Church
 The Way Evangelical Church
 The Zygos Partnership
 UHMB Trust
 Union Chapel Christian Fellowship
 Union of Catholic Mothers
 University Hospitals Coventry & Warwickshire
 University of Liverpool
 University of Oxford
 VCSM School
 Voice for Justice UK
 W&P Ltd
 West Isles Pregnancy Crisis Support
 Wirral Christian Centre
 Women's Health and Equality Consortium
 1283 individuals responded

Annex B

Further background

1. All termination of pregnancy providers must be registered with the Care Quality Commission (CQC) and meet current essential standards of quality and safety as set out in Part 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. In light of the Francis Inquiry Report, these regulations are set to change later in 2014. A new set of fundamental standards have been developed and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 will be revoked. The CQC will continue, under the new regulations, to register the service provider of the regulated activity once they can demonstrate that they meet the requirements of registration. CQC may also place conditions on the registration, for example, about where the regulated activity may be carried out. CQC will be developing new guidance about providing services that meet the requirements set out under the new regulations. The following link explains the changes in more detail:

<http://www.cqc.org.uk/public/about-us/our-performance-and-plans/our-strategy-and-business-plan>

2. Places where the regulated activity or termination of pregnancy is carried out are subject to 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.

3. Prior to the publication of the interim RSOPs in July 2012, the last update of requirements for independent sector places took place in 1999. In July 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 made some additional amendments to the RSOPs, since the interim version was issued, to bring it in line with current policies and guidance, and on which we based our consultation. The consultation did not seek views on whether the Secretary of State should continue to approve independent sector places, any aspect of abortion legislation nor the ethics of abortion.