

# Interim Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy (Abortion)



# Procedures for approval of independent sector places in the private sector for termination of pregnancy under the Abortion Act 1967, as amended



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# Introduction

- 1 The Secretary of State for Health has a responsibility under Section 1(3) of the Abortion Act 1967, as amended by Section 37 of the Human Fertilisation and Embryology Act 1990, to approve places (other than places exempt by this section) for the purpose of treatment for termination of pregnancy (abortion). All places operated by non-NHS bodies must be approved. The Secretary of State also maintains a register of Pregnancy Advice Bureaux. Unless they hold a relevant NHS contract, approved places may only accept patients referred from Bureaux on the register
- 2 The Secretary of State will consider the approval of places for the purposes of section 1(3) of the Abortion Act 1967 if proprietors undertake to comply with:
  - The Abortion Act 1967 and Regulations made under the Act – Abortion Regulations 1991
  - The requirements set out in regulations under the Health and Social Care Act 2008 (these are set out in the CQC guidance about compliance *Essential Standards of Quality and Safety* (March 2010))
  - The Required Standing Operating Procedures (RSOPs) in Section 2, and
  - Any conditions on which the Secretary of State's approvals rest. These will be clearly set out in writing and made available to those wishing to apply for approval of a place to carry out termination of pregnancy under the Abortion Act 1967
- 3 Only after having registered with the CQC and on receipt of written approval from the Secretary of State for Health will private healthcare providers be able to provide termination of pregnancy. Once registered, the CQC will continually monitor compliance with the Health and Social Care Act 2008 and regulations made under it.
- 4 Failure to comply with the requirements of the Health and Social Care Act 2008, RSOPs or any conditions on which the approval rests may lead to withdrawal of Secretary of State approval. The CQC may also take independent enforcement action under the Health and Social Care Act 2008, which includes the power to suspend or cancel registration and pursue prosecution.
- 5 A copy of the application form for the approval of places may be obtained from the Department of Health's Sexual Health Team (details follow). The Department will consider all applications. This process may include visits (and if appropriate unannounced visits) to the premises by CQC staff. The CQC has the power to carry out inspections on an announced or unannounced basis, but once a provider is registered, it normally carries out unannounced inspections, unless there is a good reason to let the service know it is coming.

If you have any enquiries arising from this document, please contact the:

Sexual Health Team  
Department of Health  
6th Floor  
Wellington House  
133-155 Waterloo Road  
London SE1 8UG  
Telephone: 020 7972 3988

# 1 The Department of Health's code of practice for abortion under the Abortion Act 1967 (as amended)

The Department of Health's overall aims are to ensure that we give effective help and advice to those providing abortion services to help them comply with the requirements of the Abortion Act and the Required Standard Operating Procedures (RSOPs).

*How the Department of Health will help organisations providing services in connection with the Abortion Act*

You are entitled to expect the Department of Health

To be objective

- By handling enquiries fairly
- By treating all our providers impartially

To help you

- To understand how and when the regulations and the 'principles' apply to you and how we may consult you
- By providing you with clear and unequivocal advice in reply to general or specific enquiries about the requirements of the Abortion Act 1967 and the 'principles'

To provide an efficient service by dealing with your enquiries promptly and accurately; by keeping your enquiries strictly confidential and by requiring compliance with regulations, 'principles' and issued guidance

If you are not satisfied

- You can ask us to look at your complaint and for it to be examined at a senior level elsewhere in the Department
- You can ask your MP to put your case to the Parliamentary Ombudsman

General or specific enquiries, written or oral, about the requirements of the Abortion Act will be acknowledged within 5 working days and dealt with as quickly as possible by named officials. We can be contacted at Room 621 Wellington House, 133-155 London Road SE1 8UG or by phone on 020 7972 3988.

The conditions on which the Secretary of State's approval rest will be clearly set out in writing and made available to those wishing to apply for approval to carry out termination of pregnancy under the Abortion Act, It will be made clear to all applicants that failure to comply with any of those conditions could lead to withdrawal of the Secretary of State's approval.

The applicant will be notified of the Secretary of State's decision within two working days of the decision being taken and in writing within 14 days. Notification of the Secretary of State's decision following application for re-approval or re-registration will be sent before the start of the new period of approval.

A CQC visit may form part of the registration procedure and will be arranged for a time and date mutually convenient to the applicant and the visiting teams. Once registration is granted by CQC, it will continually monitor compliance with the Health and Social Care Act 2008 and regulations made under that Act. Locations (places where the regulated activity of termination of pregnancy is carried out, and in some cases managed from) and satellite clinics managed by that location will also be subject to unannounced inspection by CQC staff, unless there is a good reason to let the service know they are coming.

## 2 Regulatory framework

- 2.1 The Abortion Act 1967 (see Annex A for more details on the requirements of the Act) requires that treatment for the termination of pregnancy must be carried out at an NHS hospital or at a place approved by the Secretary of State for Health. Wherever that approval is provided, it must be based on a set of core 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
- 2.2 All providers of regulated activities must be registered with the CQC and meet essential standards of quality and safety. 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.

### Required Standard Operating Procedures

In addition to compliance with the CQC requirements set out in section 2 paragraph 2, proprietors must comply with the RSOPs set out below.

#### RSOP1 **Compliance with the Abortion Act – Completion of Forms**

The Abortion Act 1967 (as amended) regulates the provision of abortion services in England, Wales and Scotland. If an abortion is performed, which does not comply with the terms of the Act, then an offence will have been committed under the Offences Against the Person Act 1861 and/or the Infant Life (Preservation) Act 1929.

The law dictates that, except in emergencies (as set out in S1(4) of the Abortion Act), two doctors must certify that in their opinion a request for an abortion meets at least one and the same grounds set out in the Act. They must be able to certify that they agree for the abortion to go ahead given the information that they have about the woman's circumstances. If there is evidence that a certifying doctor has not formed an opinion in good faith, then the doctor performing the termination

is not protected by the Act and has potentially committed a criminal offence by terminating the pregnancy. We consider it good practice that one of the two certifying doctors has seen the woman, though this is not a legal requirement.

The Abortion Regulations 1991 (amended in 2002) require timely completion of abortion forms. Completion of Abortion Act forms is the responsibility of the registered medical practitioner who certifies that in their opinion a termination is necessary (HSA1 or 2) or who carries out a termination (HSA4). It is a legal requirement that abortion notification forms (HSA4) be submitted either electronically or by post to the Chief Medical Officer (CMO) within 14 days of the termination taking place.

HSA1 – Must be completed and signed by two doctors before an abortion is performed under S1(1) of the Abortion Act 1967. The HSA1 form must be kept with the patient notes for 3 years from the date of termination.

HSA2 – Completed within 24 hours of an emergency abortion and kept by the abortion provider for 3 years

HSA4 – Must be sent to the Chief Medical Officer (CMO) within 14 days (by post or electronically). This form is used by the Department to ensure compliance with the Abortion Act.

The HSA1 and HSA2 can be photocopied using a PDF of the form, which can be obtained from the website address below.

[http://www.dh.gov.uk/en/Publichealth/Healthimprovement/Sexualhealth/Sexualhealthgeneralinformation/DH\\_4063863](http://www.dh.gov.uk/en/Publichealth/Healthimprovement/Sexualhealth/Sexualhealthgeneralinformation/DH_4063863)

[www.orderline.dh.gov.uk](http://www.orderline.dh.gov.uk)

HSA4 forms can be submitted electronically or via the post. Copies of HSA4 forms can be obtained via the above link.

## RSOP2

### **Medical Terminations including Early Medical Abortion (EMA) – Delegation of Duties and Protocols**

The Abortion Act requires that a registered medical practitioner (RMP) only may carry out an abortion. However, provided the RMP personally decides upon, initiates and takes responsibility throughout the process, the protection provided by the Act will apply to the RMP and to any other person participating in the termination under his or her authority (e.g. registered midwives and nurses).

The RMP is not required to personally perform every action. Certain actions may be undertaken by registered nurses or midwives (who are not RMPs) provided they are fully trained and agreed protocols are in place.

This does not affect the rights, provided under Section 4 of the Act, of those with a conscientious objection not to participate in treatment authorised by the Act unless that treatment is immediately necessary to save life or prevent grave permanent physical or mental injury to the pregnant woman.

Under Section 1(3) of the Abortion Act 1967, treatment for early medical abortion can only take place in an NHS hospital or approved independent sector place. Both drugs must be taken on the premises. Women may be given the choice to stay on the premises or to go home soon after taking the second tablet, to be in the privacy of their own home for the expulsion. A protocol should be in place governing the care of women who choose this option.

### Follow-ups

All women having an abortion should be able to choose to return for routine follow-up and post-abortion counselling, if they so wish. Women should be informed of the most common physical symptoms following an abortion and a 24-hour telephone helpline should be available for use after the procedure.

### Confidentiality

All women seeking abortion have the right to confidentiality from all clinical and ancillary staff. Measures must be in place to safeguard patient confidentiality and all staff must be familiar with them. Only in exceptional circumstances, where the health, safety or welfare of a minor or other persons is at risk, should information be disclosed to a third party. Similarly, if a minor is a ward of court or in care disclosure may be considered appropriate. The Department of Health published *Confidentiality; NHS Code of Practice* in 2003. This document and subsequent supplementary guidance sets out required practice for those who work within or under contract to NHS organisations.

## RSOP3

### Notification of Change of Provider

All prospective providers must undertake to inform the CQC and the Department of any change in the ownership of the controlling business or premises. This is because a new approval is required in every case where the ownership of an approved place changes. Nominated Individuals (or registered managers) must also notify any significant deviation from the design, layout or operation of the premises or business details applicable when the approval was granted (e.g. changes of senior management).

## RSOP4

### Service Provision for Children, Vulnerable Children and Adults

The CQC is responsible for interpreting and implementing the regulatory framework set out in the regulations and has issued *Guidance about Compliance*, which explains in more detail how providers can comply with the registration requirements. This guidance is not enforceable in its own right, but providers must have regard to it in complying with the registration requirements and it must be taken into account by the CQC when any decision about registration is taken.

The *Guidance about Compliance* includes the following prompts relevant to termination of pregnancy, which set out that children, vulnerable children and adults should be:

- Fully informed of their care, treatment and support.
- Able to take partfully in decision making.
- Asked if they agree for their parents or guardians to be involved in decisions they need to make.
- Able to benefit from an environment that is appropriate to their age and individual needs.
- Treated by staff who are appropriately trained to provide care, treatment and support for children, including Children's Workforce Development Council Induction standards.
- Confident that they are treated by staff who carry out sufficient levels of activity to maintain their competence, including in relation to specific anaesthetic and surgical procedures for children, taking account of guidance from relevant expert or professional bodies.
- Receive care, treatment and support by staff registered by the Nursing and Midwifery Council on the parts of their register that permit a nurse to work with children, or the advice of such a nurse can be accessed at any time that it is needed. Providers will also need to make robust and practical arrangements for children's nursing advice to be accessed at any time.

#### Girls aged under 13

Under Section 5 of the Sexual Offences Act 2003 a girl under 13 is not considered capable of giving her consent to sexual intercourse. The total number of abortions performed on this age group is very small (under 10 a year) and the majority are undertaken in NHS hospitals. It is essential that very vulnerable children's medical,

psychological and social needs are met in an appropriate environment. In addition, there are safeguarding issues that need to be considered and protocols should be in place to ensure appropriate referral to the police and social services.

## Safeguarding

Managing suspected child abuse, incest, or abuse more generally (e.g. sexual violence) in abortion services can be complex. The need for a decision on an abortion may be urgent because of advanced gestation and both the girl/woman and any accompanying adult may attempt to conceal the truth from assessing staff. The young person may have travelled away from her home area to assist with the concealment. Staff must be alert to the possibility of abuse, particularly if a young woman refuses to involve her parents or general practitioner, or is accompanied by an adult such as a male relative who wishes to remain particularly close to her.

It is recommended good practice that all services should designate a small number of doctors and counsellors, with child protection training, to assess all girls under 16 years. Within the terms of confidentiality, it is their responsibility to liaise with the appropriate children's social care team in the Local Authority when it is thought that a girl has been abused or when other children are likely to be at risk. Guidance on this is contained within *Working Together to Safeguard Children*, published in 2010. Particular paragraphs of interest are 5.25-5.31 and 6.2-6.4. Similar considerations can arise in the case of vulnerable adult women because of a learning disability or other issue that relates to their capacity to consent. Under the revised *Working Together to Safeguarding Children*, commissioning bodies are required to notify the CQC on the initiation of a serious case review. The CQC has also developed an operating protocol for staff and this may be helpful guidance for stakeholders on the role of the CQC in local safeguarding procedures:

<http://www.cqc.org.uk/public/what-are-standards/safeguarding-people>

The duty of a doctor who learns of such an allegation or has other reason to suspect abuse is to protect the child and secure the best possible outcome for that child. Where a doctor believes that a child may be the victim of abuse or neglect, the patient's interests are paramount, and will usually require a doctor to disclose information to children's social care team in the Local Authority. In the case of children, healthcare professionals' responsibilities are set out in *What to do if you're worried a child is being abused*, published in 2006.

Disclosure is not invariably required but it is usual in order that the interests of the child, which are paramount, may be protected. A doctor may be called upon to justify before the court or the statutory professional body, the GMC, the action that he or she has taken. When such concerns arise in the context of abortion, whether during counselling or subsequently, the duty of the doctor is clear, and

those who practise in this field should ensure that they are familiar with the procedures to be observed. Health professionals should also bear in mind that other children in a family may be in need of protection.

## Consent

Consent is also covered under Regulation 18 of the CQC's (Registration) Regulations 2009.

### **Adult women: aged 18 or over:**

- Must have sufficient capacity to understand the nature and purpose of the procedure(s) and its alternatives
- Consent must be voluntary and made without undue pressure on the woman to accept or refuse treatment
- Decision must be based on sufficient and accurate information

### **Women aged 16 -17 years**

Young women aged 16 and 17 are presumed to be able to consent to their own medical treatment if given voluntarily in an appropriately informed way. However, the refusal of a competent person aged 16 or 17 years may, in certain circumstances, be overridden by a person with parental responsibility or by a court. To establish whether the woman has the capacity to consent to an intervention, the same criteria as for adults is used. If requirements for valid consent are met, it is not legally necessary to obtain consent from a person with parental responsibility. It is good practice to involve, with her consent, the woman's parent[s], guardian or person with parental responsibility in the decision-making process, unless the woman specifically wishes to exclude them.

### **Young people aged under 16 years**

Legally a doctor or health professional is able to provide contraception, sexual and reproductive health advice and treatment, including abortion, without parental knowledge or consent, provided that they are satisfied that the following conditions are met:

- The young person understands all aspects of the information and advice related to the treatment.
- The medical professional cannot persuade the young person to inform her parents or to allow the medical professional to inform the parent that their child is seeking advice and/or treatment on sexual matters. In the case of abortion, if the young person cannot be persuaded to involve a parent, every effort should be made to help them to find another adult (such as a family member or specialist youth worker) to provide support.

- The young person is very likely to begin or continue having sexual intercourse with or without contraceptive treatment or requires treatment for sexually transmitted infections.
- Unless the young person receives advice and treatment on the relevant sexual matter, her physical or mental health or both is likely to suffer.

In considering this requirement, the medical professional will take into account all aspects of the young person's health and act in the best interest of the young person without parental consent or notification. As highlighted, every effort should be made to persuade the girl to involve her parents or another adult. Where a young person lacks the capacity to consent, consent can be given on their behalf by a person with parental responsibility who must act in the child's best interests. That person must themselves have capacity and, if under 18, have the capacity to consent. The courts can overrule a refusal by a person with parental responsibility. Where a child is a ward of court, the court must give consent to important decisions in respect of the child e.g. to approve a termination.

The principles of good practice which all registered medical practitioners are expected to follow when seeking patients' informed consent to examination or treatment are set out in more detail in the GMC's guidance *Consent: patients and doctors making decisions together*, published in 2008. The BMA's guidance on *Law and Ethics of Abortion*, updated in 2007, and the Department of Health's comprehensive reference guide to consent for examination or treatment (2009) also set out good practice in this area. The Mental Capacity Act 2005 generally only applies to people aged 16 or over and provides a statutory framework to empower and protect people who may lack capacity to make some decisions for themselves.

## RSOP5

### Gestational Limits

All providers should indicate which gestations and which methods they intend to offer as part of the application process to both the CQC to carry out a regulated activity and to DH to be an approved place. Chapter 7, page 61 of the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines on *The Care of Women Requesting an Induced Abortion* (2011) summarises the methods considered to be appropriate for women presenting at different gestations.

The purpose of the requirements is to ensure that practice is in keeping with the appropriate physical environment and clinical expertise available. Every service provider registered with the CQC is required by law to have a statement of purpose. The statement of purpose should provide information about services and their locations, to a level of detail that enables the CQC to understand what

actually happens in the location and who the service is provided for. For example, this might state: “We undertake both medical and surgical abortion including late abortions for women and young people under the age of 18 years.”

## RSOP6 Professional Guidelines

Clinical practice and good quality care is guided by authoritative clinical guidelines and professional opinion such as that provided by relevant Royal Colleges, in particular guidelines published by RCOG and the National Institute of Health and Clinical Excellence (NICE), and the CQC's *Guidance about Compliance*. Further guidance on good practice is set out in more detail in Section 3 and a reference list is attached at Annex B. In particular, and in line with guidelines from RCOG, abortion care should be delivered within a robust clinical governance framework to assure accessibility, clinical quality and patient safety. Health professionals working within the service must be appropriately trained and experienced. Clinical appraisal/revalidation procedures ensure that staff keep up to date with the continuing professional development requirements set down by their professional body and registered persons must monitor compliance to these standards.

## RSOP7 Access to Timely Abortion Services

Available evidence suggests that the earlier the termination takes place in the pregnancy, the lower the risk of complications. Therefore, for reasons of safety, terminations should always be performed as early as possible after having received the woman's informed consent to the procedure being performed.

In order to minimise delays, good practice is that service arrangements should be in place so that:

- Women are offered an appointment within 5 working days of referral or self-referral
- Women are offered the abortion procedure within 5 working days of the decision to proceed, and
- The total time from access to procedure should not exceed 10 working days

Women can choose to delay appointments/booked procedures and this should always override issues of timeliness.

Appointments should be expedited for women who present beyond 12 completed weeks or require abortion for urgent medical reasons, to minimise further risk to health.

For all gestations, women should be given a choice of surgical and medical terminations up to the legal limit as part of a pathway of care. Gestational limits should be included in the statement of purpose.

Services that provide abortions only up to a certain gestation should ensure rapid transfer of these women to appropriate providers via robust care pathways.

Where women are having an abortion for medical reasons, e.g. pre-existing medical condition such as heart disease, then the provider must ensure that there are clinical pathways in place for access to appropriate medical back-up services, if needed.

## RSOP8

### Information for Women

Women must be given impartial evidence-based information (verbal and written) covering the following:

- Alternatives to abortions (including adoption and motherhood)
- Abortion methods appropriate to gestation
- The range of emotional responses that may be experienced during and following an abortion
- What to expect, during and after the abortion (to include potential side effects, complications and any clinical implications)
- Full discussion of contraception options and supply of chosen method
- Testing for sexually transmitted infections

Information should be available in a variety of languages and formats (e.g. braille, audiovisual) to maximise accessibility. Women should be given the opportunity to take the information away with them, to inform their decision-making, if they so wish.

On discharge, women should be given details of a 24-hour helpline to obtain further support and advice if needed and a letter that includes sufficient information about the procedure to allow another practitioner, elsewhere, to deal with any complications/ongoing care etc.

Providers should make women aware that the contents of the HSA4 form used to inform the CMO of abortions will be used for statistical purposes by the Department of Health. The data published is anonymised.

## RSOP9

### Contraception and Sexually Transmitted Infections (STI) Screening

Providers should be able to supply all methods of contraception, including Long Acting Reversible methods (LARCs). Before the woman is discharged, future contraception should have been discussed and the chosen method initiated immediately. Particular attention should be given to women who have had repeat conceptions and abortions. Women who choose not to start a contraception method immediately should be given information about local contraception providers in addition to their general practitioner. Providers should have an agreed pathway of care to local community sexual health services.

All women should be tested for chlamydia and undergo a risk assessment for other STIs (e.g. HIV, Syphilis etc.) and tested as appropriate. A system for partner notification and follow-up or referral to a sexual health service should be in place. This may trigger the need to be registered with the CQC for the regulated activity of diagnostics and screening.

Tests that will fall into the regulated activity of diagnostics and screening include:

- Chlamydia testing
- HIV testing

Tests that fall outside of the scope include:

- Taking swabs

## RSOP10

### Counselling

A person trained and experienced in counselling in this field must be available to attend clinics/hospitals if required. Counselling must be offered to women who request it or appear to need help in deciding on the management of the pregnancy or who are having difficulty in coping emotionally. Counselling should be offered to women under 16 and to those with a history of psychiatric illness, who lack social or emotional support or whom their partner, family or employer is possibly coercing into having an abortion. RCOG's 2011 clinical guideline *The Care of Women Requesting Induced Abortion* highlights that "all women attending an abortion service will require a discussion to determine the degree of certainty of their decision and their understanding of its implications as part of the process of gaining consent. Careful and sensitive enquiry as to the reasons for requesting an abortion should be made, with the opportunity for further discussion, especially where women express any doubts or suggestion of pressure or coercion."

Any woman who remains ambivalent after counselling can be given a provisional appointment for admission but must be told that the procedure can be postponed or cancelled and that she remains free to continue with the pregnancy, if she so wishes.

Clinicians caring for women requesting abortion should try to identify those who require more support in decision-making than can be provided in the routine clinic setting (e.g. young women, those with a pre-existing mental health condition, those who are subject to sexual violence or poor social support, or where there is evidence of coercion). Care pathways for additional support should be available.

## RSOP11

### Disposal of Fetal Tissue

The Human Tissue Authority (HTA) regulates activities concerning the removal, storage use and disposal of human tissue. It has issued practical guidance to professionals carrying out activities which lie within its remit to help establishments develop appropriate policies.

The HTA's Code of Practice (Code 5) on *Disposal of Human Tissue* applies to all those involved in the disposal of human tissue and is suitable for developing policies on the disposal of fetal tissue resulting from a number of different pregnancy losses, including ectopic pregnancies, miscarriages, early intrauterine fetal deaths and termination of pregnancy.

RCOG has produced the good-practice guidance *Disposal Following Pregnancy Loss Before 24 Weeks Gestation (2005)* (Good Practice No 5), which provides a further source of information if required.

Stillbirths and Neonatal Deaths Society (SANDS) (2007) guidelines for professionals also argue the need for sensitive disposal.

Women should be made aware that information on disposal options for later medical and surgical abortions is available. Any personal wishes expressed should be met wherever possible.

Women may decide to arrange disposal themselves and they are free to do so. The Royal College of Nursing's (RCN) *Sensitive Disposal of All Fetal Remains: Guidance for nurses and midwives* (2007) highlights the options.

## RSOP12

### Performance Standards and Audit

All providers should have in place clear locally agreed standards against which performance can be audited with specific focus on outcomes and processes. These should be guided by appropriate national standards, for example RCOG's *Guidelines on Audit*. However, it is important that local standards are agreed, applied and audited. Subjects which providers may wish to audit could include:

- Waiting times.
- The consultation process. For example: the outcome of consultations; the number of women who do not proceed to a termination.
- The qualifications and expertise of those responding to requests for advice and support from women. The availability of expert advisors; the nature of the calls received; the number of calls requiring further action.
- The provision of services for women with significant medical conditions. For example: the availability of trained counsellors for those women at risk of particular psychological or emotional difficulties or those with pre-existing mental health conditions. Efforts should be made to ensure the availability of a female doctor for women who wish to consult a woman – especially those from certain cultural backgrounds and ethnic minorities, with arrangements for non-English-speaking women.
- The number of staff competent to provide all methods of contraception.
- Patient choice across the range of service provision to include follow-ups, contraception and abortion methods, and completion of EMA at home.
- Indicators of good practice could include locally developed strategies for minimising avoidable morbidity, which could include: the number of 'incidents' and the number of women known to require repeat surgical procedures within four weeks of the procedure; the use of local anaesthesia where this is clinically indicated; medical complications; or the use of ultrasound equipment.
- The number of women who have had repeat abortions and whether they left the service with suitable contraception.
- The number of women leaving the clinic/hospital soon after receiving the second drug for a medical abortion. What are their experiences?

Registered managers should also be aware of the requirements of the National Abortion Specification.

## RSOP13

### **Patient Feedback and Complaints**

**This guidance should be read in conjunction with Regulation 19 of the CQC (Registration) Regulations 2009**

Providers must recognise the rights of women to confidentiality. Nevertheless, all places should undertake post-care patient satisfaction surveys and feedback aimed at identifying women's experiences and views on the treatment they have received. A registered person, provider or director should monitor these and take

appropriate action to address any issues raised. Providers should be prepared to make the results of these surveys available to the Department for Health on a confidential basis. All information would, for reasons of confidentiality, be aggregated and anonymised.

There must be a recognised and clearly defined complaints policy and a procedure that is made known to all clients. A senior manager, director or proprietor must regularly monitor complaints and take action where appropriate.

## RSOP14 **Staffing and Emergency Medical Cover**

There should be a sufficient number of staff with the right competencies, knowledge, qualification, skills and experience to meet the routine and non-routine needs of women who use the service.

Procedures and protocols must be underpinned by regular training in emergency procedures – especially basic resuscitation. Evidence must be available that training has taken place.

Immediate medical cover must be provided by the residential medical officer or (in an emergency) any other full registered medical practitioner. The National Consultants Contract in England (Schedule 12 paragraph 2) states that “A consultant is required to reside within a distance of 30 minutes or 10 miles by road from their principal place of work, unless an employing organisation agrees that they may reside at a greater distance. In addition, they must be contactable by telephone.”

The aim should be to stabilise the patient and, when safe, to transfer to a specialised unit where, if needed, there is immediate access to intensive care, laboratory services and other specialist disciplines.

Anaesthetic emergencies are a special problem. These often arise quickly and require immediate attention. Therefore, it must be possible to contact a consultant anaesthetist with appropriate current experience immediately by telephone. All relevant staff must be aware of the emergency call system. An anaesthetist must be present in the recovery room while there is a patient who does not fulfil the criteria to discharge.

Subject to clinical duties, proprietors of premises should assist CQC inspectors to have access to clinical staff (medical, nursing and midwifery) on duty at the time of a visit (including unannounced visits).

## RSOP15 **Duty Records**

Records of duty and shift rotas must be kept for four years after the year to which they relate. A named senior manager should be responsible for ensuring that these are complete and accurate and that staff attend according to the rota.

## RSOP16 **Confirmation of Professional Status**

A named senior manager, director or proprietor must be responsible for ensuring that qualifications, experience and GMC registration/UKCC PIN reference are confirmed for all medical, midwifery and nursing staff. The senior manager, director or proprietor should also be responsible for ensuring that all medical, midwifery and nursing staff have their qualifications, knowledge and skills reviewed on a regular basis to ensure that they are kept up to date with current practice.

## RSOP17 **Risk Management**

All providers should have in place a formal risk management system and keep a risk register to identify and minimise any risks to patients and staff within their premises. Protocols should exist on action to be taken should incidents occur. There should be opportunities for medical, midwifery and nursing staff to contribute to risk appraisal. Service provision can be improved by learning from adverse events, incidents, errors and near misses that happen, the outcome of comments and complaints, and advice of the CQC and other expert bodies where this information shows the service is not fully compliant.

## RSOP18 **Maintenance of Equipment**

**This is covered in Regulation 16 of the CQC (Registrations) Regulations 2009**

Risks and emergencies can be minimised through a programme of regular checking and servicing of equipment. All equipment should be properly maintained and suitable for its purpose. This is particularly the case with anaesthetic and patient monitoring equipment. Guidelines for checking anaesthetic machines are available from the Association of Anaesthetists (<http://www.aagbi.org/publications/guidelines/docs/checklista404.pdf>).

## RSOP19 **Death of a Patient**

Arrangements must be in place to immediately inform the CQC and the Department of Health in the event of the death of a patient. A record must be kept of the date, time, cause and place of death. Verbal information must be confirmed in writing to the Department of Health within 24 hours of receiving verbal confirmation.

**Further information about how to notify the CQC can be found here:**

**<http://www.cqc.org.uk/contact-us>**

## RSOP20 **Payment of Fees**

Women must be free from any fear of exploitation when accessing termination of pregnancy services. Fees should not be demanded or accepted by a registered provider for an abortion either directly or indirectly until two certificates of opinion necessary for a legal abortion under the Act have been given on form HSA1. This is also set out in Regulation 20(2)(b) of the Care Quality Commission (Registration) Regulations 2009. The registered provider must provide the woman with a written statement specifying the terms and conditions in respect of the services to be provided as far as reasonably practicable prior to the commencement of the service as set out in Regulation 19 of the Care Quality Commission (Registration) Regulations 2009. Where the abortion provider has a contract to provide abortion services on behalf of the NHS, the woman should be informed and should therefore not be charged a fee.

## RSOP21 **Referrals from Bureaux**

Premises approved for the termination of pregnancy should not accept patients from any bureau that is not on the register of approved Pregnancy Advisory Bureaux. NHS-funded patients can access services through those routes agreed via local commissioning arrangements.

## 3 Maintaining standards

- 3.1 The approval process will provide a framework for maintaining the safety and quality of care in a fully integrated independent sector abortion service. In keeping with the concept of clinical governance, the Department for Health and the CQC will be responsible for ensuring that these are maintained through a system of monitoring and, where appropriate, inspection visits carried out by, the CQC.
- 3.2 Within the NHS, clinical practice will be increasingly influenced by guidance such as that issued by the National Institute of Health and Clinical Excellence (NICE) alongside professional bodies.
- 3.3 It is the responsibility of local practitioners, in consultation with providers, to develop good clinical practice within their local setting, reflecting evidence-based guidelines from relevant professional bodies. In addition, consideration should be given to the contents of the National Abortion Specification, which supports wider NHS delivery.

### Abortions beyond 9 weeks gestation

- 3.4 Abortions beyond 9 weeks gestation require additional training and particular skills for medical, midwifery and nursing staff. Therefore, they must be conducted by practitioners who can demonstrate that they have sufficient regular and recent experience to ensure that their specialist skills are maintained.
- 3.5 Abortions after 20 weeks gestation raise particular public and professional concern because of the possibility of a viable birth. Therefore, premises wishing to carry out terminations at 20 weeks gestation or more must have separate approval from the Secretary of State. No procedures for the termination of pregnancy must be carried out after the end of the 24th week of gestation. In addition to meeting all the relevant RSOPs outlined in Section 2, premises must demonstrate that all medical, midwifery and nursing staff involved in the care of patients undergoing late terminations have appropriate recent experience and skills.

### Fetal awareness and abnormality

- 3.6 RCOG released two working-party reports in March 2010: *Fetal Awareness* and *Termination of Pregnancy for Fetal Abnormality*. The first updates the previous report published in 1997, while the latter replaces the 1996 report. Both documents were commissioned by the Department of Health, following recommendations by the House of Commons Science and Technology Committee in 2008. The two reports contain information for clinicians,

researchers and healthcare professionals. The report on *Fetal Awareness* also includes practical information and advice to women and parents. The main findings from each document are listed below.

## **Fetal awareness**

- The fetus cannot feel pain before 24 weeks because the connections in the fetal brain are not fully formed.
- Evidence examined by the Working Party showed that the fetus, while in the chemical environment of the womb, is in a state of induced sleep and is unconscious.
- The Working Party concluded that because the 24-week-old fetus has no awareness nor can it feel pain, the use of analgesia is of no benefit.
- More research is needed into the short- and long-term effects of the use of fetal analgesia post 24 weeks.

## **Abortion for fetal abnormality**

- The Working Party concluded that it is unrealistic to produce a definitive list of conditions that constitute 'serious' handicap since accurate diagnostic techniques are yet unavailable. Likewise, the consequences of abnormality are difficult to predict.
- The Working Party recommends that the NHS Fetal Anomaly Screening Programme is centrally linked so that specific congenital abnormalities are monitored over time and programmes across the country can be evaluated.
- Appropriate information and support should be offered to all women undergoing antenatal screening.
- In the case of a possible abortion, all staff caring for the mother must adopt a non-directive, non-judgemental and supportive approach.

3.7 The two reports should be read together as the subject matters are inter-related.

## Feticide

- 3.8 The RCOG report on *Fetal Awareness* (March 2010) recommends that feticide be performed before delivery, unless the fetal abnormality is lethal, on abortions performed after 21 weeks and six days gestation to avoid the possibility of a live birth. Feticide can also be used prior to medical abortion of pregnancy after 21 weeks and six days gestation or for selective reduction of multiple pregnancies, either where one fetus has an abnormality or where the number of fetuses increases the risk of maternal morbidity or pregnancy complications to an unacceptable level.

## Informing the general practitioner

- 3.9 It is recommended that, wherever possible, the woman's GP should be informed about any treatment for abortion. Then, in the event of a woman requiring care in the longer term, the GP would be aware of all treatments provided and be in a better position to determine the appropriate therapy. All women should be told of their right to confidentiality and their decision respected if they do not want their GP to be informed.

## Nursing and midwifery staff

- 3.10 One first-level registered general nurse or registered midwife should be on duty in the clinic/hospital at all times. The person in charge of each shift throughout the 24-hour period should be a first-level registered nurse or registered midwife able to accept professional responsibility for the smooth running of the clinic, of other staff and of patients.
- 3.11 The first-level nurse or registered midwife should at all times be supported by at least one other first- or second-level registered nurse or registered midwife. Nursing and midwifery staff levels should reflect factors such as:
- The anticipated throughput of patients and abortion methods to be used
  - The incidence of complications (which must be routinely assessed/reassessed)
  - The support required for dealing with a patient
  - Other emergencies that may arise as well as the continued observation of patients
  - The residence or otherwise of a medical officer
- 3.12 Particularly where late (i.e. 20 to 24 weeks gestation) terminations are being undertaken, staffing levels should be calculated with reference to case mix, anaesthesia used, room layouts and skill mix. The particular emotional and psychological support of women undergoing these late terminations should not be overlooked. As a guide, there should be at least one midwife for up to every five patients available from the time treatment commences to the time treatment ends. Midwifery and nursing staff must be competent in the use of all the equipment required to be available in places approved for late terminations.

- 3.13 Each nurse or midwife should have the appropriate knowledge and training on which to base observations and to detect deviations from normal progress and to carry out medical instructions. Each nurse or midwife should have the ability to professionally assess a patient's condition and describe this accurately to a doctor.
- 3.14 Each nurse or midwife should have the appropriate knowledge, training and confidence to initiate immediate action in the event of an emergency and before medical help arrives.
- 3.15 Midwives and nurses should not be asked to undertake duties for which they are not clinically competent.
- 3.16 Nursing or maternity support workers are not nurses or midwives and should not be expected to carry out duties or responsibilities in excess of their capabilities or competence or which are those of a registered nurse or midwife. Arrangements must also be in place to ensure that all auxiliary and support staff are aware of the principles of good quality care and the need to respect patient confidentiality.
- 3.17 All nursing and midwifery staff are expected to undertake continuing professional education and training to retain skills and gain familiarity with ongoing clinical developments.

## Pregnancy Advice Bureaux

- 3.18 Women may obtain advice on pregnancy matters and access to abortion services through general practitioners, sexual and reproductive healthcare clinics, genito-urinary medicine clinics, or a Pregnancy Advice Bureau (PAB).
- 3.19 PABs are registered by the Secretary of State and are defined as "places that provide advice and help to women who may be pregnant". Services include pregnancy testing, medical advice, assessment, counselling, contraceptive advice and sexually transmitted infection services.
- 3.20 Separate approval is required of places wishing to be registered as a PAB. Further information on the criteria for registration as a PAB can be found in the guidance *Procedures for the Registration of Pregnancy Advice Bureaux*, obtainable from the Department of Health.

## 4 Annex A

### Abortion Act 1967 (as amended)

Grounds for abortion under the Act

(1) Subject to the provisions of this section, a person shall not be guilty of an offence under the law relating to abortion when a pregnancy is terminated by a registered medical practitioner if two registered medical practitioners are of the opinion, formed in good faith –

- (a) that the pregnancy has not exceeded its twenty-fourth week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman or existing children of her family; or
- (b) that the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman; or
- (c) that the continuance of the pregnancy would involve risk to the life of the pregnant woman, greater than if the pregnancy were terminated; or
- (d) that there is substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped.

(2) In determining whether the continuance of a pregnancy would involve such risk of injury to health as is mentioned in paragraph (a) or (b) of subsection (1) of this section, account may be taken of the pregnant woman's actual or reasonably foreseeable environment.

The Act permits an abortion to be performed in an emergency on the basis of the opinion formed in good faith of the doctor performing the procedure. The Abortion Regulations permit the doctor in such cases to sign the certificate of opinion before or within 24 hours after the termination if it is not reasonably practicable to complete and sign a certificate before treatment commences. The emergency grounds are:

- (e) To save the life of the woman.
- (f) To prevent grave and permanent injury to the physical or mental health of the woman.

## 5 Annex B

### References

#### **Abortion Act 1967**

<http://www.legislation.gov.uk/>

#### **Abortion Regulations 1991**

<http://www.legislation.gov.uk/uksi/1991/499/contents/made>

#### **Abortion (Amendment)(England) Regulations 2002**

<http://www.legislation.gov.uk/uksi/2002/887/contents/made>

#### **Better Prevention, Better Services, Better Sexual Health – The National Strategy for Sexual Health and HIV**

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4003133](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4003133)

#### **British HIV Association – UK National Guidelines for HIV Testing 2008**

<http://www.bhiva.org/HIVTesting2008.aspx>

#### **Care Quality Commission**

<http://www.cqc.org.uk/>

#### **Department of Health ‘You’re Welcome’ quality criteria**

[www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_097571](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_097571)

#### **Equality and Human Rights Commission**

<http://www.equalityhumanrights.com/>

## **Faculty of Sexual and Reproductive Healthcare**

<http://www.ffprhc.org.uk/>

## **Guidance on Abortion Notification Forms**

[http://www.dh.gov.uk/en/Publichealth/Healthimprovement/Sexualhealth/Sexualhealthgeneralinformation/DH\\_4063863](http://www.dh.gov.uk/en/Publichealth/Healthimprovement/Sexualhealth/Sexualhealthgeneralinformation/DH_4063863)

<http://www.orderline.dh.gov.uk>

## **Human Tissue Authority – Disposal of Fetal Tissue**

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code5disposal.cfm>

## **Medical Foundation for AIDS and Sexual Health (MEDFASH) Standards**

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4106273](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4106273)

## **Moving Forward: Progress and Priorities – Working Together for High-Quality Sexual Health**

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/H\\_103090](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/H_103090)

## **National Institute for Health and Clinical Excellence (NICE) – Long Acting Reversible Contraception (LARC) guidance**

<http://www.nice.org.uk/guidance/index.jsp?action=byID&r=true&o=10974>

## **Reference Guide to Consent for Examination and Treatment**

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_103643](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643)

## **Royal College of Anaesthetists – guidance on post-operative care**

<https://www.rcoa.ac.uk/system/files/CSQ-GPAS4-Postop.pdf>

## **Royal College of Nursing – Abortion Care**

[http://www.rcn.org.uk/\\_\\_data/assets/pdf\\_file/0005/194261/003270.pdf](http://www.rcn.org.uk/__data/assets/pdf_file/0005/194261/003270.pdf)

## **Royal College of Obstetricians and Gynaecologists – guidance on foetal abnormalities**

<http://www.rcog.org.uk/termination-pregnancy-fetal-abnormality-england-scotland-and-wales>

## **Royal College of Obstetricians and Gynaecologists – The Care of Women Requesting Induced Abortions**

<http://www.rcog.org.uk/womens-health/clinical-guidance/care-women-requesting-induced-abortion>

## **Royal College of Psychiatrists – Induced Abortion and Mental Health**

[http://www.nccmh.org.uk/reports/ABORTION\\_REPORT\\_WEB%20FINAL.pdf](http://www.nccmh.org.uk/reports/ABORTION_REPORT_WEB%20FINAL.pdf)

## **Safeguarding Children and Young People: roles and competencies for healthcare staff (intercollegiate document, September 2010)**

[http://www.rcn.org.uk/\\_\\_data/assets/pdf\\_file/0004/359482/REVISED\\_Safeguarding\\_03\\_12\\_10.pdf](http://www.rcn.org.uk/__data/assets/pdf_file/0004/359482/REVISED_Safeguarding_03_12_10.pdf)

## **Science & Technology Committee Report**

<http://www.publications.parliament.uk/pa/cm200607/cmselect/cmsctech/1045/104502.htm>

## **Sexual Health – Confidentiality for Under 16s**

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4086960](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086960)

## **Working Together to Safeguard Children (2010)**

Note: the Government is consulting on a revised version of this guidance in 2012.

<https://www.education.gov.uk/publications/standard/publicationdetail/page1/DCSF-00305-2010>

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