Department of Health

ANNEX C

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

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

Prepared by:

Sexual Health Team

Department of Health

Room 124

Richmond House

79 Whitehall

London SW1A 2NS Telephone: 020 7210 6375

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Introduction

The Secretary of State for Health has a power under section 1(3) of the Abortion Act 1967[1] to approve places where treatment for termination of pregnancy (abortion) may be carried out. All places other than NHS hospitals must be so approved. The Secretary of State also maintains a register of Pregnancy Advice Bureaux. Unless they hold a NHS contract, approved places may only accept patients referred from Bureaux on the register.

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 1992[2]
- The requirements set out in regulations under the Health and Social Care Act[3]; and
- The Required Standard Operating Procedures (RSOPs) in Section 3 of this document;

Only after having registered with the CQC and on receipt of written approval from the Secretary of State for Health will independent healthcare providers be able to carry out a termination of pregnancy. Once registered, the CQC will continually monitor compliance with the Health and Social Care Act 2008 and regulations made under it.

Failure to comply with the requirements of the Health and Social Care Act 2008 or the RSOPs may lead to withdrawal of Secretary of State's approval. The CQC may also take independent enforcement action under the Health and Social Care Act

[1] Section 1 was amended by s.37(2) of the Human Fertilisation and Embryology Act 1990 to insert subsection (3A), which extends the power under s.1(3) to enable approval for a class of places.

[2] Abortion Regulations 1991, S.I. 1991/499.

[3] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 S.I. 2010/781 and the Care Quality Commission (Registration) Regulations 2009 S.I. 2009/3112.

2008, which includes the power to suspend or cancel registration and pursue prosecution.

A copy of the application form for the approval of places may be obtained from The Department of Health, Sexual Health Team (details below). The Department will consider all applications. The application process may include visits (and if appropriate unannounced visits by CQC to carry out an inspection for the purpose of its own registration functions) to the premises by CQC staff. CQC has the powers 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:

Sexual Health Team
Department of Health
Room 124
Richmond House
79 Whitehall
London SW1A 2NS Telephone: 020 7210 6375

Section 1 - Working with Termination of Pregnancy Providers

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 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
- treating all our providers impartially

To help you

- understand how and when the Abortion Act 1967 and regulations, and the RSOPs apply to you and how we may consult you.
- provide you with clear advice in reply to general or specific enquiries about the requirements of the Abortion Act 1967 and the RSOPs

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 Commissioner for Administration (the Ombudsman)

- General or specific enquiries, written or oral, about the requirements of the Abortion Act will be acknowledged within five working days and dealt with as quickly as possible by named officials. We can be contacted at Room 124 Richmond House, 79 Whitehall, London SW1A 2NS or by phone on 0207 210 6375.

- 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 will be sent before the start of the new period of approval.

- A CQC visit may form part of the CQC 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 be also subject to unannounced inspection by CQC staff unless there is a good reason to let the service know they are coming.

Section 2 - Regulatory Framework

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 a NHS hospital or at a place approved by the Secretary of State for Health. In granting any approval the Secretary of State takes into account a set of core principles the aims of which are to:

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

Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, provides that the termination of pregnancy is a regulated activity. All providers of regulated activities must be registered with the CQC and meet essential standards of quality and safety as set out in Part 4 to the 2010 regulations. DH is in the process of updating the quality and safety requirements that all providers have to meet. The new requirements and guidance will come into force from April 2014 for the NHS. They may commence later for other sectors. The CQC will update their guidance about meeting these requirements.

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

The Health and Social Care Act 2008 states that all providers must have a registered manager. The exceptions to this are:

- Where the service provider is an individual who is in day-to-day management of the service and who is fit to carry on the service.
- NHS trusts:

Each regulated activity is required to be supervised by a registered manager, and the Act specifies that the registered manager must be assessed for their fitness to do so. Further guidance and details of the application process are available on the CQC website. See link below.

http://www.cqc.org.uk/organisations-we-regulate/registering-first-time

Required Standard Operating Procedures

In addition to compliance with CQC requirements, the Secretary of State will take into account whether proprietors will comply with the Required Standard Operating Procedures (RSOPs), set out below, as part of the approval process.

RSOP1: Compliance with the Abortion Act

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[4], two doctors must certify that in their opinion, which must be formed in good faith, a request for an abortion meets at least one and the same grounds set out in the Act.

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, although this is not a legal requirement. The expectation is 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". Members of a multi-disciplinary team (MDT) can play a role in seeking information from the woman. However, the Abortion Act places the responsibility for reaching a decision in good faith on the two doctors alone.

[4] See section 1(4) of the Act which enables a termination to be carried out where a registered medical practitioner is of the opinion, formed in good faith, that the terminations is immediately necessary to save the life or to prevent grave permanent injury to the physical or mental health of the pregnant woman.

The Abortion Regulations 1991 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 falls within one of the lawful grounds (HSA1 or 2) or who carry 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 section 1(1) of the Abortion Act 1967. The HSA1 form must be kept with the patients 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 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.

https://www.orderline.dh.gov.uk/ecom_dh/public/home.jsf

HSA4 forms can be submitted electronically or sent by 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 only a registered medical practitioner (RMP) 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 the provider has agreed protocols in place. For example, in practice a nurse or midwife may administer the drugs used for medical abortions, once these have been prescribed by a doctor.

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 the life or prevent grave permanent physical or mental injury to the pregnant woman.

Under Section 1(3) of the Abortion Act 1967, treatment for EMA can only take place in an NHS hospital or approved independent sector place. Both drugs for the medical abortion must therefore be taken in the hospital or approved place. 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 the latter option.

RSOP 3: 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.

RSOP 4: 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. However, where the health, safety or welfare of a minor, or other persons is at risk, information should 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. This code is currently being updated.

https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice

RSOP 5: Notification of Change of Provider

All prospective providers must undertake to inform 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. Prospective providers 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).

RSOP 6: Compliance with CQC Regulatory Framework

The CQC is responsible for implementing the regulatory framework set out in the regulations made under the Health and Social Care Act 2008 and has issued *Guidance about Compliance*[5], which explains in more detail how registered providers and registered managers can comply with the registration requirements. This guidance in not in itself enforceable, 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.

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

The *Guidance about Compliance* includes prompts relevant to termination of pregnancy, which sets out that children, vulnerable children and adults (where appropriate) should be:

Children[6]:

- 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

Adults and Children[7]:

- 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 , taking account of guidance from relevant expert or professional bodies.
- Receive care, treatment and support by staff registered by the Nursing and Midwifery Council 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.

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[5] See CQC `Essential Standards of Quality and Safety'

[6] Outcome 4 – Care and Welfare of People who use services ` Essential Standards of Quality and Safety'

[7] See Outcome 14 – Supporting Workers CQC Essential Standards of Quality and Safety.

- Fully informed of their care, treatment and support.
- Able to take part fully in decision making.

Girls aged under 13

Under Section 5 of the Sexual Offences Act 2003 sexual intercourse with a girl under the age of 13 is a criminal offence. 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 – Under 16s and other vulnerable groups

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 of age. Within the scope of their confidentiality duties, 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 August 2013), which replaces previous guidance published in 2010.

http://www.education.gov.uk/aboutdfe/statutory/g00213160/working-together-to-safeguard-children

Disclosure is not always required but it is usual in order that the interests of the child, which are paramount, are protected. A health professional may be called upon to justify before the court or their statutory professional body, such as the General Medical Council and Nursing and Midwifery Council 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 health professional to safeguard the child 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.

Similar considerations can arise in the case of vulnerable women because of a learning disability or other issue that relates to their capacity to consent. Under the revised Working Together to Safeguard Children guidance, commissioning bodies are required to notify the CQC on the initiation of a serious case review arising from a safeguarding issue so they can feed relevant information into their regulatory activities. In addition, the CQC has developed an operating protocol for its staff to describe their role in safeguarding both children and adults. It covers all the relevant health and social care sectors for which CQC has regulatory responsibility and provides the principles for how CQC will work to help make sure people are protected.

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

Consent

Adult Women

Adult women aged 18 or over are presumed to be able to consent to their own medical treatment.

Consent must:

- be provided voluntarily and without undue pressure on the woman to accept or refuse treatment.
- be based on sufficient and accurate information (informed consent)

An adult will lack the capacity to consent where they are unable[8] to make the decision because of an impairment of, or disturbance in the functioning of, the mind or brain; and where they are unable to:

- understand the information relevant to the decision;
- retain that information;
- use or weight that information as part of that process; or
- communicate their decision by any means (section 2 Mental Capacity Act 2005)

[8] See section 2 Mental Capacity Act 2005.

Women aged 16 -17 years

Consent to termination provided by a woman aged 16 or 17 years must also be provided on the basis of appropriate information and given voluntarily. Such consent has the same legal effect as consent provided by an adult[9].

As for adults, a woman aged 16 or 17 will lack capacity if she does not meet the test set out under section 2 of the Mental Capacity Act (see above).

Young Women 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 the young woman has sufficient understanding and intelligence to enable her to understand fully what is being proposed; in other words she must be "*Gillick"* competent[10].

As a matter of best practice a medical professional should also have regard to the following factors before providing treatment:

- whether the young person can be persuaded to inform her parents or to allow the medical professional to inform the parents 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

- whether the young person does not receive advice and treatment on the relevant sexual matter, her physical or mental health or both is likely to suffer.

- whether the relationship is mutually agreed and whether there may be any coercion or abuse.

Where a young person is not Gillick competent and therefore cannot consent to a termination, consent can be given on their behalf by a proxy (anyone with parental responsibility or the court). A person with parental responsibility must act in the child's best interests when consenting or refusing consent to treatment. The courts

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[9] See section 8 Family Law Reform Act 1969.

[10] The case of *Gillick v West Norfolk and Wisbech (1986) AC 112* established that a child under the age of 16 can consent to treatment if they have "sufficient understanding and intelligence to enable him or her to understand fully what is proposed" (189 per. Lord Scarman)

can overrule a refusal by a person with parental responsibility where this is in the child's best interests.

The principles of good practice, which all healthcare professionals 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.

In addition, the GMC have published two documents: `0-18 Years: Guidance for all doctors' (2007) (Para 70-72, page 29) provides information for doctors dealing with young people and abortion and `Protecting Children and Young People' – The responsibility of all doctors (2012). The BMA's guidance on "Law and Ethics of Abortion" and the Department of Health's comprehensive reference guide to consent for examination or treatment (2009) also set out good practice in this area.

Consent requirements for providers of regulated activities are also set out under regulation 18 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and in a Supporting Note "Consent to Treatment and Care.

http://www.cqc.org.uk/sites/default/files/media/documents/rp_poc1b_100476_20110331_v1_00_sn_consent_updated_for_publication.pdf

RSOP8: Gestational Limits

All registered providers should indicate which gestations and 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 requirement to specify gestation and methods is to ensure that what is being proposed is in keeping with the physical environment and clinical expertise available. In addition 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'.

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RSOP9: Professional Guidelines

Good quality clinical practice is guided by authoritative clinical guidelines and professional opinion such as that provided by relevant Royal Colleges. In relation to abortion, the guidelines published by the Royal College of Obstetricians and Gynaecologists; National Institute of Health and Clinical Excellence (NICE) and CQC's Guidance about compliance are of particular relevance. Further guidance on good practice is set out in more detail in Section 3 to this document and in the documents listed in the references attached at Annex 2.

In particular, and in line with guidelines from the RCOG[11], 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 with these standards.

RSOP10: Access to Timely Abortion Services

Available evidence[12] 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 five working days of referral or self-referral
- Women are offered the abortion procedure within five working days of the decision to proceed, and
- The total time from access to procedure should not exceed ten working days

[11] RCOG Guideline ` Care of Women Requesting Induced Abortion (2011)

[12] RCOG Guideline – Care of Women Requesting Induced Abortion (2011)

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 care pathway.

Services that provide abortions only up to a certain gestation should ensure rapid transfer of women to appropriate providers via robust care pathways. Gestational limits should be included in the statement of purpose.

Where women are having an abortion under the grounds of risk to physical health e.g. where a pre-existing medical condition may exist, then the provider must ensure that there are clinical pathways in place for access to appropriate medical back up services, if needed.

RSOP11: Information for Women

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

- Alternatives to abortions (for instance 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 the supply of chosen method
- Testing for sexually transmitted infections including HIV.

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

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/on-going care etc.

Providers should make women aware that the contents of the statutory 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.

RSOP12: Contraception and Sexually Transmitted Infections (STI) Screening

Providers should be able to supply all methods of contraception, including Long Acting Reversible methods (LARC). Before the woman is discharged, future contraception should have been discussed and the chosen method should be 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 offered testing for Chlamydia, offered a risk assessment for other STI's (e.g. HIV, Syphilis etc.), and tested as appropriate. This may trigger the need to be registered with the CQC for the regulated activity of diagnostics and screening. A system for partner notification and follow up or referral to a sexual health service should also be in place.

RSOP13: Counselling

A person trained and experienced in counselling in this field must be available to attend clinics/hospitals if required. All women requesting an abortion should be offered the opportunity to discuss their options and choices with a trained counsellor and this offer should be repeated at every stage of the care pathway. Post abortion counselling should also be available for those women who require it.

The RCOG's 2011[13] clinical guideline 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."

[13] To see recommendation 4-11 (page 31) `Care of Women Requesting Induced Abortion (2011)'

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 be able 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.

RSOP14: 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 fall 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.

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

Women should be made aware that information on disposal options for later medical and surgical abortions are 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) document, Sensitive Disposal of All Fetal Remains (2007) highlights the options.

RSOP15: 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 Guidelines on Audit[14]. However, it is important that local standards are agreed, applied and

[14] See RCOG Clinical Governance Advice No.5 – October 2003

audited. Subjects which providers and commissioners 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.
- 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.
- 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 for experiences of women who have returned home after taking the 2nd drug for a medical abortion.
- 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.

RSOP16: Patient Feedback and Complaints

This guidance should be read in conjunction with Regulations 10 and 19 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

All approved places should have systems in place to undertake post-care patient satisfaction surveys and feedback aimed at identifying women's experiences and

views on the treatment they have received. These should be monitored by the provider who should take appropriate action to address any issues raised.

Registered 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.

RSOP17: Staffing and Emergency Medical Cover

This guidance should be read in conjunction with Regulation 22 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

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

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

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 to the ward.

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).

Nursing and Midwifery Staff

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.

The first level nurse or registered midwife should be supported by appropriately qualified registered nurses or midwives. 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.

Particularly where late (i.e. 20 to 24 week 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.

There should be an adequate number of appropriately trained and competent nurses/midwives available from the time treatment commenced to the time treatment ended. Midwifery and nursing staff must be competent in the use of all the equipment required to be available in places approved for late terminations.

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.

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.

Midwives and nurses should not be asked to undertake duties for which they are not clinically competent.

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 need to respect patient confidentiality.

All nursing and midwifery staff are expected to undertake continuing professional education and training to retain skills and gain familiarity with on-going clinical developments.

RSOP18: 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.

RSOP19: Confirmation of Professional Status

This guidance should be read in conjunction with Regulation 21 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

A named senior manager, director or proprietor must be responsible for ensuring that qualifications, experience, GMC registration / NMC 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.

RSOP20: Risk Management

This guidance should be read in conjunction with Regulation 10 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

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 as well as from the outcome of comments and complaints and regulatory findings of the CQC and findings of advice from expert bodies where this information shows the service is not fully compliant.

RSOP21: Maintenance of Equipment

This requirement is also covered by Regulation 16 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

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) .

RSOP22: Death of a Patient

See also regulations 16 and 20 Health and Social Care (Registration) Regulations 2009

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 should be confirmed in writing to the Department of Health within 24 hours of receiving verbal confirmation. The regulations about notifications changed in June 2012. CQC has issued guidance for non-NHS trust providers on how to notify them of a death of a patient. Further information can be found at:

Notifications for non-NHS trust providers/Care Quality Commission

RSOP23: Payment of Fees

Women must be free of any fear of exploitation when accessing termination of pregnancy services. Fees should not be demanded or accepted 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 (Registration) Regulations 2009. The manager of the service must also 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 (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.

RSOP23: 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 routes agreed via local commissioning arrangements.

Section 3 - Maintaining Standards

RSOP24: Maintaining Standards

The approval process provides 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 CQC will be responsible for ensuring that the requirements under the Health and Social Care Act 2009 are maintained through a system of monitoring and where appropriate inspection visits.

The CQC takes account of the RSOPs when interpreting the requirements on providers of terminations and there is also overlap between the requirements meaning that the Department is able to monitor compliance with the RSOPs through a programme of communication with the CQC. Providers are also asked to provide evidence of continued compliance and monitoring of compliance with the RSOPs as part of the re approval process.

Within the NHS, clinical practice will be increasingly influenced through guidance such as that issued by the National institute of Health and Clinical Excellence (NICE) alongside professional bodies.

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.

RSOP 25: Abortions beyond 9 weeks gestation

Abortions beyond 9 weeks gestation require additional training and particular skills for medical, midwifery and nursing staff. Therefore, they must be conducted by healthcare professionals who can demonstrate that they have sufficient regular and recent experience to ensure that their specialist skills are maintained.

Abortions after 20 weeks gestation raise particular public and professional concern because of the possibility of a live birth. We therefore recommend that premises wishing to carry out terminations at 20 weeks gestation and over should notify the Secretary of State. Under the Health and Social Care Act registration regulations, registered providers not part of the NHS may not carry out terminations beyond 24 weeks 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.

RSOP 25: Fetal Awareness and Abnormality

The Royal College of Obstetricians and Gynaecologists (RCOG) released two working party reports in March 2010:

- Fetal Awareness, and
- Termination of Pregnancy for Fetal Abnormality.

The first updates a previous report published in 1997, while the latter replaces a 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.

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

Feticide

The RCOG report on Fetal Awareness (March 2010) recommends that feticide be performed before delivery, unless the fetal abnormality is lethal, on medical abortions performed after 21 weeks and six days gestation to avoid the possibility of a live birth.

Feticide can also be used prior to abortion 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.

RSOP26: Informing the General Practitioner and Pregnancy Advisory Bureaux

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.

Pregnancy Advisory Bureaux

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 Advisory Bureau (PAB)

PABx 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.

Separate approval is required of places wishing to be registered as a standalone PAB (not one that is co-located within a clinic). Further information on the criteria for

registration as a PAB can be found in the guidance Procedures for the Registration of Pregnancy Advisory Bureaux, obtained from the Department of Health.

Annexes

Annex 1

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.

Annex 2

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.legistlation.gov.uk/uksi/2002/887/contents/made

British HIV Association - UK National Guidelines for HIV Testing 2008
http://www.bhiva.org/HIVTesting2008.aspx

Care Quality Commission
http://www.cqc.org.uk/

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
https://www.gov.uk/government/publications/abortion-notification-forms-for-england-and-wales

A Framework for Sexual Health Improvement in England
https://www.gov.uk/government/publications/a-framework-for-sexual-health-improvement-in-england

Human Tissue Authority (HTA) - 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

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

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 (2nd edition)

https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

Royal College of Nursing's publication "Abortion Care"
www.rcn.org.uk

Royal College of Obstetricians and Gynaecologists (RCOG) - "The Care of Women Requesting Induced Abortions",
http://www.rcog.org.uk/womens-health/clinical-guidance/care-women-requesting-induced-abortion

Royal College of Obstetricians and Gynaecologists – guidance on fetal abnormalities
http://www.rcog.org.uk/termination-pregnancy-fetal-abnormality-england-scotland-and-wales

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http://www.nccmh.org.uk/reports/ABORTION_REPORT_WEB520FINAL.pdf

Working Together to Safeguard Children (2013)
http://www.education.gov.uk/aboutdfe/statutory/g00213160/working-together-to-safeguard-children

GMC - Protecting Children and Young People: The responsibilities of all doctors (2012)
http://www.gmc-uk.org/guidance/ethical_guidance/13257.asp

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

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http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086960

Mental Health Review – Royal College of Psychiatrists
http://www.nccmh.org.uk/reports/ABORTION_REPORT_WEB%20FINAL.pdf

Safeguarding Children and Young People: roles and competencies for healthcare staff Intercollegiate Doc Sept 2010
http://www.rcn.org.uk/__data/assets/pdf_file/0004/359482/REVISED_Safeguarding_03_12_10.pdf

Confidentiality: NHS Code of Practice (2003)
https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice