Department of Health & Social Care

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

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Introduction

The Secretary of State for Health and Social Care has a power under section 1(3) of the Abortion Act 1967 to approve places where treatment for termination of pregnancy ("abortion") may be carried out.

The Secretary of State will consider the approval of places for the purposes of section 1(3) of the Abortion Act 1967 if providers undertake to comply with:

- The Abortion Act 1967 and regulations made under that Act – currently the Abortion Regulations 1991
- The requirements set out in regulations made under the Health and Social Care Act 2008; and
- The Required Standard Operating Procedures ("the RSOPs") set out in this document.

Independent healthcare providers will only be able to carry out termination of pregnancy if they are registered with the Care Quality Commission ("the CQC") to carry out that regulated activity and have received written approval from the Secretary of State for Health and Social Care. Once registered, the CQC will monitor a provider's compliance with the relevant requirements of the Health and Social Care Act 2008 and regulations made under that Act.

Failure to comply with the requirements of the Abortion Act 1967 (and associated Regulations), the Health and Social Care Act 2008 (and associated regulations) and/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 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 and Social Care, Healthy Behaviours Team (details below). The Department will consider all applications. The application process may include visits to the premises by CQC staff.

Department of Health and Social Care, Healthy Behaviours Team, 39 Victoria Street, London SE1H 0EU. Email: healthybehaviours@dhsc.gov.uk

Section 1 - Working with Termination of Pregnancy Providers

The Department of Health and Social Care aims to give effective help and advice to those providing abortion services to comply with the requirements of the Abortion Act 1967 and the RSOPs**.**

Schedule 1 to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 provides that the termination of pregnancy is a regulated activity. All providers of regulated activities must be registered with the CQC and meet fundamental standards of quality and safety as set out in Part 3 to the 2014 regulations. Registered providers must also meet the requirements set out in The Care Quality Commission (Registration) Regulations 2009. 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. CQC registration must be in place before the Secretary of State will consider an application for approval. It is unlawful for an independent provider to carry out termination of pregnancy without the approval of the Secretary of State for Health and Social Care.

You are entitled to expect the Department of Health and Social Care,

To help you:

- Understand how and when the Abortion Act 1967, the Abortion Regulations 1991 and the RSOPs apply to you.

- By providing you with clear advice in response to general or specific enquiries relating to the requirements of the Abortion Act 1967, the Abortion Regulations 1991 and the RSOPs.

- By clearly setting out the principles which the Secretary of State will take into account as part of the approval process and making this policy available to those wishing to apply for approval to carry out treatment for termination of pregnancy under the Abortion Act 1967. All applicants should know that failure to comply with any of those principles could lead to withdrawal of the Secretary of State's approval.

- By notifying applicants 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.

To be objective by:

- Handling enquiries fairly.

- Treating all providers impartially.

- General or specific enquiries, written or oral, about the requirements of the Abortion Act 1967 will be acknowledged within five working days and dealt with as quickly as possible by named officials.

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.

- Your MP to put your case to the Parliamentary Commissioner for Administration (the Ombudsman).

Section 2 - Regulatory Framework

The Abortion Act 1967 (see Annex 1 for more details on the requirements of that Act) requires that treatment for the termination of pregnancy must be carried out in an NHS hospital or in a place approved by the Secretary of State for Health and Social Care. This includes where treatment is provided in NHS hospitals by independent sector providers. 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, and
- Provide sound management, organisational and clinical governance arrangements.

The CQC registers the service provider of the regulated activity (in this case termination of pregnancy) once they can demonstrate that they meet the requirements of registration. CQC may also place conditions on the registration, for example, about where the regulated activity may be carried out or managed from.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 set out the quality and safety requirements that all providers have to meet.

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 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 in day-to-day management of the service and who is fit to carry on the service; and
- In most cases, NHS trusts.

Where it is the case that a Registered Manager is required, the registered manager is responsible for managing the carrying out of the regulated activity. 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.

Required Standard Operating Procedures

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

Approval can be removed at any time if evidence of non-compliance with the RSOPs comes to the Department's attention. Decisions will be based on the facts and circumstances of each individual case.

RSOP1: Compliance with the Abortion Act

All providers must comply with the Abortion Act 1967 and regulations made under that Act (currently the Abortion Regulations 1991, S.I. 1991/499 as amended).

The Abortion Act 1967 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.

Section 1(4) of the Act provides that, except in emergencies, two doctors must certify that in their opinion, which must be formed in good faith, at least one and the same grounds for abortion set out in the Act is met - see the form in Part 1 to Schedule 1 and regulation 3(ii)(d) of the Abortion Regulations 1991.

The Department of Health and Social Care issued guidance on 23rd May 2014 which sets out its interpretation of the law on abortion (reproduced at Annex 2). All approved places must comply with this guidance.

The Schedule to the Abortion Regulations 1991 set out the forms for the purpose of certifying the opinion of a registered medical practitioner ("RMP") under the Act (forms HSA1 and HSA2). The regulations also set out the form for notification of abortions to the Chief Medical Officer ("the CMO") (form HSA4). Completion of these forms is the responsibility of the RMP.

HSA1 – Must be completed and signed by two doctors before an abortion is performed. The HSA1 form must be kept for 3 years from the date of termination.

HSA2 – Completed before an abortion is performed or, if that is not reasonably practicable, within 24 hours of an emergency abortion and kept for 3 years from the date of termination.

As a matter of best practice, we expect forms HSA1 and HSA2 to be kept with the patient's notes.

HSA4 – Must be sent to the CMO within 14 days (by post or electronically). This form is used by the Department to check compliance with the Abortion Act. DHSC would strongly encourage the use of electronic reporting as this is a more secure system and reduces the risk of lost or misplaced forms or missing data. For further information on accessing and using the online system, please contact HSA4@dhsc.gov.uk

The HSA1 and HSA2 forms can be photocopied using a PDF of the form which can be obtained from the abortion notification forms for England and Wales section of the gov.uk website.

Supplies of HSA4 forms are available to order from:

Health and Social Care, PO Box 777, London SE1 6XH or by phoning 0300 123 1002 or from www.healthpublications.gov.uk

RSOP2: Provision of Terminations at different gestations including Early Medical Abortion, delegation of duties and protocols

All providers should have protocols and procedures in place covering the services they deliver (covering both methods of abortion and gestation bands). In particular, policies should be in place covering the delegation of duties in relation to medical abortions, the follow up of women who go home after an Early Medical Abortion (EMA), and the management of conscientious objections.

Medical Termination of Pregnancy - legal position

The Abortion Act 1967 enables a RMP to carry out an abortion in certain circumstances. However, in relation to medical terminations the courts have decided that, 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. The RMP is not required to personally perform every action. Certain actions may therefore be undertaken by registered nurses or midwives provided they are fully trained, and where the provider has agreed protocols in place. For example, a nurse or midwife may administer the drugs used for medical abortions once these have been prescribed by a doctor.

Early Medical Abortion – legal position

Under Section 1(3) of the Abortion Act 1967 treatment for Early Medical Abortion (EMA) can only take place in an NHS hospital or approved independent sector place. Both drugs (mifepristone and misoprostol) for the medical abortion must be taken in the hospital or approved place. In 2018, the Government approved women's homes as a "class of place" for the second stage of EMA. Home is defined as the place where a pregnant woman has her permanent address or usually resides. Home use must be carried out in line with the criteria set out in the approval and clinical guideline published and issued by the Royal College of Obstetricians and Gynaecologists.

Conscientious Objection – legal position

Section 4 of the Abortion Act 1967 allows those with a conscientious objection to refuse to participate in treatment authorised by the Act unless that treatment is immediately necessary to save the life, or to prevent grave permanent injury to the physical or mental health, of a pregnant woman.

RSOP 3: Post Procedure

All providers should have protocols in place covering the support that should be in place for women following an abortion procedure.

Women should be informed of the most common physical and emotional/psychological symptoms following an abortion. Information provided to women should include what to do in an emergency situation. A 24-hour dedicated support line which specialises in post abortion support and care, staffed by individuals trained in offering support in this speciality, should also be made available.

Irrespective of method or gestation all women having an abortion should be able to opt for routine follow up and/ or post-abortion support or counselling. This does not have to be face to face with a counsellor or provided directly by the abortion provider. Pathways to further post-abortion counselling should be available for any woman who may require additional emotional support or whose mental health is perceived to be at risk.

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 post-abortion emergency care or related 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 must be respected if they do not want their GP to be informed.

RSOP 4: Notification of Change of Provider

All providers must undertake to inform the DHSC of any change in the ownership of the controlling business or in the premises.

This is because a new approval is required in every case where the ownership of an approved place changes. Providers must also notify any significant deviation from the design, layout or operation of the premises or business arrangements applicable when the approval was granted (e.g. changes of senior management).

RSOP 5: Compliance with CQC Regulatory Framework

Providers must comply with the regulatory framework set out in the Health and Social Care Act 2008 and accompanying regulations and guidance.

The CQC is responsible for implementing the regulatory framework set out in the regulations made under the Health and Social Care Act 2008. It is the responsibility of registered providers and registered managers to comply with the registration requirements and keep up to date with guidance on compliance issued by the CQC.

RSOP 6: Confidentiality

Providers must have measures in place to safeguard patient confidentiality and all staff must be familiar with them.

As a matter of law women seeking an abortion have the right to confidentiality from all clinical and ancillary staff. The Department published "Confidentiality; NHS Code of Practice" in 2003. It is recommended that providers consider this document and any subsequent supplementary guidance, which sets out required practice for those who work within or under contract to NHS organisations in their policies.

We recognise that aggregated, anonymised patient information needs to be shared with commissioners and public health staff to inform the planning and commissioning of abortion services. However, information disclosed for these purposes must not include any information which could identify a patient.

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

All providers must comply with legal requirements and have regard to any statutory guidance relating to children, young people and vulnerable adults. All providers must have policies and protocols in place for dealing with these groups.

Children and young people aged under-16

A doctor or health professional is able to provide contraception, sexual and reproductive health advice and treatment, including abortion, without parental knowledge or consent, to a young person aged under 16 years, provided that the doctor or health professional is satisfied that the conditions set out in the Fraser Guidelines are met. As a matter of best practice every effort should be made to encourage women aged under 16 to involve their parents (a parent is someone with legal parental responsibility). If they cannot be persuaded to do so then they should be assisted to find another adult (such as another family member or specialist youth worker) to provide support.

Safeguarding, including young women aged 16 and 17

The Sexual Offences Act 2003 provides a framework of offences to protect children of all ages from sexual abuse. The law makes clear that the age of consent is 16, and that sexual activity involving children under 16 is not lawful.

Managing suspected child abuse or exploitation in abortion services can be complex. The need for a decision on an abortion may be urgent because of advanced gestation. However, managing the clinical aspects of care must not prevent staff from being alert to the possibility of abuse. This may be relevant particularly where 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 that providers use the pro forma, developed by the British Association for Sexual Health and HIV and Brook, to help clinicians and other staff working in sexual health services to identify young people who are suffering or may be at risk of child sexual exploitation.

Providers should have regard to the statutory guidance Working Together to Safeguard Children. This guidance is issued under section 11 of the Children Act, which places duties on a range of organisations and individuals to ensure their functions, and any services that they contract out to others, are discharged having regard to the need to safeguard and promote the welfare of children. These duties extend to NHS England, clinical commissioning groups, NHS trusts and NHS foundation trusts. NHS England and CCGs are accountable for the services they commission from all provider organisations. The guidance sets out obligations on healthcare and other professionals who work with children, and how various agencies and organisations involved should work together in the interests of the child NHS England's Safeguarding Vulnerable People in the Reformed NHS:

Accountability and Assurance Framework complements the statutory guidance.
All health providers are required to have effective arrangements in place to safeguard vulnerable children and to assure themselves, regulators and their commissioners that these are working. These arrangements include safe recruitment; effective training of all staff, effective supervision arrangements, working in partnership with other agencies and identification of a named doctor and a named nurse for safeguarding children, who should work closely with the organisation's safeguarding lead.

Health professionals are required to be competent in child protection and are expected to participate in regular training to update their skills. All clinical staff working in abortion services should be trained to at least level 3 of the intercollegiate framework, Safeguarding Children and Young people: roles and competences for health care staff

Under 13s

The total number of abortions performed on girls aged under 13 years of age tends to be very small (under 10 a year) and the majority are undertaken in NHS Hospitals. It is essential that the medical, psychological and social needs of such children are met in an appropriate environment. Account should also be taken of guidance to doctors from the GMC (paragraph 60) that "you should usually share information about sexual activity involving children under 13, who are considered in law to be unable to consent. You should discuss a decision not to disclose with a named or designated doctor for child protection and record your decision and the reasons for it".

Guidance

The General Medical Council provides guidance on providing healthcare services (including sexual health services), to young people under the age of 18, safeguarding, and how to deal with confidentiality issues, including disclosing information without consent. We expect providers to have regard to this guidance.

Vulnerable adults

Considerations around safeguarding may arise in the case of adult women who may be vulnerable to abuse because of a range of issues. These may include a learning disability, dementia, mental health problem or other difficulty. Those women without strong support networks or who are socially isolated are particularly vulnerable to abuse. These may include women who have been raped or suffered domestic violence and/or intimate partner abuse. Providers must ensure that all staff are trained in recognising the signs of potential abuse in adult women and know how to respond. Providers must have written guidance that staff are aware of and can easily refer to. Staff should have easy access to a named lead in the organisation for guidance and advice. It is important that Providers understand that they have key responsibilities in this area.

Protocols should be in place for onward referral to specialist services. Providers must follow agreed inter agency policies and procedures developed by the Safeguarding Adult Board, where they have reason to suspect someone has experienced abuse.

RSOP 8: Consent

Providers should have protocols in place for obtaining consent and pathways and support for all women who lack capacity to consent.

Adult women and young women aged 16 or 17 are assumed to have capacity to consent to their own medical treatment unless it is established that they do not, see section 1(2) of the Mental Capacity Act 2005.

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).

Consent provided by a 16 or 17 year old woman has the same legal effect as consent provided by an adult, see section 8 Family Law Reform Act 1969.

An adult will lack the capacity to consent where they are unable to make the decision because of an impairment of, or disturbance in the functioning of, the mind or brain, see section 2 of the Mental Capacity Act 2005.

A person is unable to make a decision where they are unable to:

- Understand the information relevant to the decision

- Retain that information

- Use or weight that information as part of the process of making the decision; or

- Communicate their decision by any means (see section 3 of the Mental Capacity Act 2005)

If a woman has learning disabilities this does not automatically mean that she is unable to make a decision and to consent. Professionals have to provide information and support to assist her to understand and weigh up the issues. Where she nevertheless remains unable to consent, then a capacity assessment needs to be carried out. If she is found to lack the capacity to make the decision, then a decision about abortion needs to be made by the Court of Protection. The Court has its own website with information about how to make an application; it also has procedures for urgent applications. Neither family members nor professionals such as social workers or doctors can consent on behalf of a person who lacks capacity.

As for adults, a woman aged 16 or 17 will lack capacity if she does not meet the test set out above.

As set out in RSOP 7, a young woman who is under 16 years of age can consent and be provided with advice and treatment, including an abortion, without parental consent or knowledge, provided she meets the requirements following assessment under the Fraser Guidelines. This assessment should be undertaken by health professionals with appropriate training and experience in working with this age group.

Guidance

We expect providers to have regard to the guidance set out below.

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.

It is expected that providers will also have regard to GMC publications: `0-18 Years: Guidance for all doctors' (updated 2018) (Para 63-65), which 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 "The law and ethics of abortion - BMA views" (November 2014 - updated June 2017) 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 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Providers offering online counselling and preventive services must comply with the General Data Protection Regulation (GDPR) and the Data Protection Bill which came into force on 25 May 2018.

RSOP9: Gestational Limits

The Abortion Act 1967 (as amended) permits termination of pregnancy performed under Grounds C or D where the pregnancy has not exceeded its twenty-fourth week. The Department has sought legal and clinical advice on this issue and set out that our interpretation is that this equates to pregnancies up to and including 23 weeks + 6 days gestation. All stages of the abortion procedure should be completed by 23 weeks +6 days.

Regulation 20 of the Care Quality (Registration) Regulations 2008 sets out that the registered person who (a) carries on or manages the regulated activity consisting of the termination of pregnancies; and (b) is not an English NHS body, must ensure that no termination of a pregnancy is undertaken after the 24th week of gestation (i.e. 23 weeks and 6 days).

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 DHSC, to be an approved place.

NICE guidelines on abortion care detailed recommendations on conducting abortions at different gestational stages are also included, to ensure that women get the safest and most effective care possible.

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 abortions at

gestations between 20 weeks and 23 weeks + 6 days for women and young people under the age of 18 years'.

Services that do not provide abortions at all gestations up to 23 weeks and 6 days should ensure arrangements are in place to quickly transfer women to appropriate providers via robust care pathways.

RSOP10: Professional Guidelines

Providers should have regard to relevant clinical and professional guidance.

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, Royal College of Anaesthetists and the National Institute for Health and Care Excellence (NICE) are of particular relevance. Further guidance is set out in the documents listed in the references attached at Annex 3.

In particular, and in line with guidelines from the NICE, abortion care should be delivered within a robust clinical governance framework to assure accessibility, clinical quality and patient safety in line with CQC regulations. Health professionals working within the service must be appropriately trained and experienced. Clinical appraisal/revalidation procedures also 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.

RSOP11: Access to Timely Abortion Services

Providers should have arrangements in place to minimise delays in women accessing services and a choice of method should be provided at all gestations.

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:

- once deemed suitable for treatment women are offered an appointment within five working days.
- 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.

The planning and scheduling of appointments should be responsive to women's needs. Women can choose to delay appointments/booked procedures, and this should always override issues of timeliness.

Appointments, care and treatment should only be cancelled or delayed by the provider when absolutely necessary. Women should be supported to access care and treatment again as soon as possible.

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 do not provide abortions at all gestations up to 23 weeks and 6 days should ensure arrangements are in place to quickly transfer women to appropriate providers via robust care pathways.

Where a pre-existing physical or mental health 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.

RSOP12: Information for Women

Women must be given impartial, accurate and evidence-based information (verbal and written) delivered neutrally and 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 and strategies in place for infection prevention

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. Services should make use of the patient information and tailored local information.

As set out in RSOP3, 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.

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 and Social Care. The data published are anonymised.

Woman should be made aware that there are options for disposal of pregnancy remains and given verbal or written information about the options.

RSOP13: Contraception and Sexually Transmitted Infections (STI) Screening

Providers should be able to supply all reversible methods of contraception, including Long Acting Reversible methods (LARC) which are the most effective and offer testing for STIs as appropriate.

Health professionals fitting LARC methods should have appropriate training and qualifications, i.e. the Faculty of Sexual and Reproductive Health Care's Diploma or equivalent. Before the woman is discharged, future contraception should have been discussed and, as far as possible, the chosen method should be initiated immediately. Failing this, an interim method should be provided. Particular attention should be given to the young and 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 GP. Providers should have an agreed pathway of care to local community sexual health services for initiation or continuation of contraception in the community. Other local pathways will also be relevant, for example assertive outreach for support and review for teenagers or those who have had repeat presentations.

All women should be offered testing for Chlamydia, offered 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 also be in place. Where providers are unable to offer NHS funded STI screening, women should be provided with information and clear pathways to be able to access sexual health testing services.

RSOP14: Counselling

Women are not required to have compulsory counselling or compulsory time for reflection before the abortion. However, counselling should be provided or refer women for support to make a decision if they request this.

A trained pregnancy counsellor is someone trained to Diploma level or equivalent. Counselling must be non-directive and non-judgemental and should not create barriers or delays. Counsellors should undergo continuous professional development and training similar to other professionals.

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. Care pathways to antenatal services for those who choose to continue their pregnancy, and for women considering adoption, should be in place

Post abortion counselling should also be available for those women who require it. They should tell women that this support is available if they need it.

Clinicians caring for women requesting abortion should be able to identify those who require more support than can be provided in the routine abortion service setting, for example 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. For the minority of women who require formal, therapeutic counselling, services should have referral pathways in place with access to trained counsellors with appropriate expertise.

RSOP15: Disposal of Pregnancy Remains

All providers should have policies on disposal of pregnancy remains which take account of relevant guidance detailed below. Information about disposal should be available for women setting out their choices.

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. To inform policies and procedures governing the disposal of pregnancy remains resulting from pregnancy loss or termination of pregnancy in a clinical setting, including NHS and independent hospitals and abortion clinics, the HTA has issued updated guidance on the disposal of pregnancy remains following pregnancy loss or termination. Regulation 20 (11) of the CQC (Registration) Regulations 2008 sets out that the registered person must prepare and implement appropriate procedures to ensure that fetal tissue is treated with respect;

In addition, the Stillbirths and Neonatal Society 2016 guidelines for professionals on pregnancy loss and the death of a baby also highlight the need for sensitive disposal:

"The sensitive nature of pregnancy remains, and their disposal is highly important and must be borne in mind at all times. Women should be made aware that there are disposal options available to them. The wishes of the woman regarding disposal, and her understanding of the options open to her, are of paramount importance and should be respected and acted upon".

Women may decide to arrange disposal themselves and they are free to do so. The Royal College of Nursing's document, Managing the disposal of pregnancy remains highlights the options.

RSOP16: Performance Standards and Audit

In addition to national clinical standards, all providers should have in place clear locally agreed standards against which performance can be audited, with specific focus on outcomes and processes. These local standards are generally agreed with local commissioners.

RSOP17: Patient Feedback and Complaints

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. Surveys and feedback are generally agreed with local commissioners.

RSOP18: Staffing and Emergency Medical Cover

Providers should ensure there is a sufficient number of staff with the right competencies, knowledge, qualifications, skills and experience to safeguard the health, safety and welfare of all who use the service and meet their routine and non-routine needs.

NHS funded care is expected to meet guidance on staffing levels provided by the National Quality Board where this is applicable. In addition, staff at all levels should be able to demonstrate awareness of the recommendations in relevant NICE guidance.

Procedures and protocols must be in place to deal with emergencies underpinned by regular training in emergency procedures, especially basic resuscitation. Evidence must be available that training has taken place. Protocols should also cover transfer to specialist services including intensive care and dealing with anaesthetic emergencies. Anaesthetics and conscious sedation must be administered in line with guidance from the Royal College of Anaesthetists'. The NICE recommend that for surgical abortion, consider local anaesthesia alone, conscious sedation with local anaesthesia, deep sedation or general anaesthesia.

From an organisational point of view, this has favourable implications on costs, and most importantly, it reduces risks for women and improves their recovery after the procedure. The monitoring of patients under sedation or anaesthetic must be undertaken in line with national guidance.

Medical Staff

Registered medical practitioners should take account of guidance published by professional bodies and the appropriate Royal Colleges. In the case of general anaesthesia being administered or intravenous sedation, this should include guidance issued by the Royal College of Anaesthetists.

Nursing and Midwifery Staff

One first level registered general nurse or registered midwife should be on duty in the clinic/hospital at all times when there are patients who will need their care. 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.

Where 20 to 23 week + 6 days gestation terminations are being undertaken the particular emotional and psychological support required by women undergoing terminations at these gestations should not be overlooked.

There should be an adequate number of appropriately trained and competent nurses/ midwives 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 they may be called upon to use as part of their duties.
Each nurse or midwife should have the appropriate knowledge, training and confidence to initiate immediate action in the event of an emergency and before further 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 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.

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

A named senior manager or director must be responsible for ensuring that qualifications, experience, GMC registration / NMC PIN reference are confirmed for all medical, midwifery, nursing staff and counsellors.

The senior manager or director should also be responsible for ensuring that all medical, midwifery, nursing and counselling staff have their qualifications, knowledge and skills reviewed on a regular basis to ensure that they are kept up to date with current practice.

Robust methodologies should be in place to ensure professional requirements are met.

RSOP20: 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 as well as from the outcome of comments and complaints and regulatory findings of the CQC and findings of advice from expert bodies.

All providers should have a governance structure in place that identifies and mitigates risk and ensures that lessons are learnt from incidents that occur.

Providers should have a risk management system in place and keep a register to identify and minimise the risk to patients and staff. There should be opportunities for medical, midwifery and nursing staff to contribute to risk appraisal. The provider should have oversight of risk within their service.

Providers should have an adverse event reporting system so that recurring themes can be addressed across their service. 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.

Providers should have a system of learning from regulators findings and from reports from professional bodies. Providers should ensure that there are systems in place to review such reports and to identify learning across the service provided.

RSOP21: Maintenance of Equipment

Providers should minimise risks and emergencies 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.

RSOP22: Notification of Death of a Patient

Arrangements must be in place to immediately notify the CQC and the Department of Health and Social Care in the event of the death of a patient.

A record must be kept of the date, time, cause and place of death. If the notification has been provided verbally over the telephone, information should be confirmed in writing to the Department of Health and Social Care within 24 hours.

CQC has issued guidance for non-NHS trust providers on how to notify them of a death of a patient.

In addition regulation 20(10) of the Care Quality (Registration) Regulations 2008 require that the registered person must give notice in writing the Care Quality Commission if they receive information concerning the death of a service user who has undergone termination of a pregnancy during the period of 12 months ending on the date on which the information is received and has reason to believe that the service user's death may be associated with

the termination. The registered person must give notice in writing to the Commission of that information, within the period of 14 days beginning on the day on which the information is received.

RSOP23: Payment of Fees

Providers must not request fees are paid for an abortion either directly or indirectly until two certificates of opinion necessary for a legal abortion under the Act have been provided.

This requirement ensures that women are free of any fear of exploitation when accessing termination of pregnancy services. 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.

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 2008 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 can 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.

It is the responsibility of providers, in consultation with their commissioners, to develop good clinical practice within their local setting, reflecting evidence-based guidelines from relevant professional bodies.

RSOP 25: Abortions beyond 9 weeks gestation

Providers should ensure that staff performing abortions beyond nine weeks gestation have the relevant skills and training.

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.

Under Regulation 20(5) of the Care Quality Commission (Registration Regulations 2009), registered providers which are not an English NHS body must ensure that no terminations of pregnancy are carried out after the 24th week (23 weeks and 6 days) of gestation.

RSOP 26: Fetal Awareness and Abnormality

Providers should have in place policies and procedures to manage the specific needs of patients seeking abortion for fetal abnormality which reflect guidance from the Royal College of Obstetricians and Gynaecologists (RCOG).

The RCOG published two working party reports in March 2010:

- Fetal Awareness, and

- Termination of Pregnancy for Fetal Abnormality

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. Abortion for fetal abnormality is more commonly performed in specialist NHS centres. However, providers should have in place policies and procedures to manage the specific needs of patients seeking abortion for fetal abnormality which reflect the RCOG guidance. There should also be a designated care pathway and referral arrangements to specialist support organisations. All staff caring for the mother must adopt a non-directive, non-judgemental and supportive approach. While in most cases the abnormalities will have been detected and confirmed in other settings, if scanning for abnormalities is performed, appropriate training should be undertaken by all staff involved.

Feticide

The RCOG report on Fetal Awareness 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.

Annex I – Requirements of 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.

3. Except as provided by subsection (4) of this section, any treatment for termination of pregnancy must be carried out in a hospital vested in (the Secretary of State for the purposes of his functions under the National Health Service Act 1977 or the National Health Service (Scotland) Act 1978 (or in a hospital vested in a National Health Service Trust) or in a place approved for the purpose of this section by the Secretary of State.)

3(a) The power made under subsection (3) of this section to approve a place includes power in relation to treatment consisting primarily in the use of such medicines as may be

specified in the approval and carried out in such manner as may be so specified, to approve a class of places.

4. Subsection (3) of this section, and so much of subsection (1) as relates to the opinion of two registered medical practitioners shall not apply to the termination of a pregnancy by a registered medical practitioner in a case where he is of the opinion, formed in good faith, that the termination is immediately necessary to save the life or to prevent grave permanent injury to the physical or mental health of the woman

Annex II - Guidance in relation to requirements of the abortion Act 1967

1. The Chief Medical Officer (“CMO”) wrote to all Registered Medical Practitioners (RMPs) on 23 February 2012 and 22 November 2013 stressing the need for full compliance with the requirements of the Abortion Act 1967 (“the Abortion Act”). In the letter of 22 November, it was announced that the Department of Health would provide more detailed guidance to doctors in relation to the Abortion Act.

2. It is acknowledged that there have been advances in abortion care since the passage of the Abortion Act. Increasingly, abortions are provided through medical rather than surgical methods, at earlier gestations and there is generally multidisciplinary team (“MDT”) involvement. However, apart from amendments made in 1990, the Abortion Act remains unchanged. It is essential that all those involved in commissioning and providing abortion care, including those managing services, should understand the legal requirements placed on RMPs to ensure that their practice is lawful.

3. Abortion is an area in which people can hold very strong views. All those involved in abortion care, particularly clinicians, can be faced with working in a sometimes difficult and challenging environment with a number of vulnerable clients. This guidance is intended to support all those involved in commissioning, providing and managing abortion services to provide a high quality, legal service that meets the needs of women.

Background

4. Following the decision by the CPS in August 2013 not to prosecute two doctors investigated for certifying abortions based on the gender of the fetus, the CPS highlighted the lack of guidance for doctors about abortion law. In particular, the statement made by the CPS in relation to those cases highlighted that “there is no guidance on how a doctor should go about assessing the risk to physical or mental health, no guidance on where the threshold of risk lies and no guidance on a proper process for recording the assessment carried out”.

5. In response, the Department of Health and Social Care agreed to produce guidance on these issues. The guidance does not, and indeed cannot, change the law in relation to abortion, which is governed by the criminal law and the Abortion Act and is ultimately a matter for Parliament and the courts to determine. However, the intention is to provide support for doctors by setting out how the law is interpreted by the Department of Health and Social Care. More detailed guidance for health professionals on abortion is also available from the General Medical Council (GMC), British Medical Association (BMA), Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Nursing (RCN).

6. Although there is no legal requirement for at least one of the certifying doctors to have seen the pregnant woman before reaching a decision about a termination, the Department’s view is that it is good practice for this to be the case. It is recognised however that, with technological advances, this may well mean that a doctor does not physically see the woman, e.g. there could be a discussion by phone or over a webcam.

This paragraph should also be read in conjunction with paragraphs 20 and 21 of this guidance.

Abortion legislation

7. The Offences Against the Person Act 1861 makes it a criminal offence to intentionally unlawfully procure a miscarriage, including for a woman to procure her own miscarriage. The Infant Life (Preservation) Act 1929 makes it an offence to intentionally kill a child, capable of being born alive, before it has a life independent of its mother. The Abortion Act creates exceptions to these offences in certain limited circumstances.

8. The Abortion Act makes abortion legal where the pregnancy is terminated by an RMP and, except in emergencies, where two RMPs are of the opinion formed in good faith that one of the lawful grounds specified in the Act are met.

Forming an opinion in good faith

9. If there is evidence that either certifying doctor has not formed their opinion in good faith then the doctor performing the termination is not protected by section 1(1) of the Abortion Act and has potentially committed a criminal offence by terminating the pregnancy. It is also possible that the doctor could be acting contrary to their professional duties.

10. Practices have come to light recently which call into question whether doctors have acted in accordance with their legal obligations under the Abortion Act. These practices include the signing of HSA1 forms by doctors before a woman has been referred, and doctors signing forms relying solely on decisions made about the woman in question by other doctors or members of the multi-disciplinary team without any other information.

Abortion certification

11. Regulation 3 of The Abortion Regulations 1991 states form HSA1 must be completed, signed and dated by two RMPs before an abortion is performed and that the HSA1 form must be kept with the patient notes for 3 years from the date of termination. The form must be completed by both RMPs certifying their opinion, formed in good faith that at least one and the same ground for abortion in section 1(1) of the Abortion Act exists. The certification takes place in the light of their clinical opinion of the circumstances of the pregnant woman's individual case. The lawful grounds for abortion are set out in Annex A.

Assessing risk to physical or mental health, the threshold of risk and recording how the assessment is carried out

12. Whilst there is no statutory requirement for either doctor to have seen and/or examined the woman, it is the Department's interpretation of the law that both doctors should ensure that they have considered sufficient information specific to the woman seeking a termination to be able to assess whether the woman satisfies one of the lawful grounds under the Abortion Act.

13. This assessment will include consideration of any risk to the woman's physical or mental health as one of the lawful grounds. The identification of where the threshold of risk

to the physical or mental health of the woman lies is a matter for the clinical opinion for each of the doctors.

14. Although the burden of proof would be on a prosecutor to show that an opinion was not formed in good faith, DHSC recommend that RMPs should be prepared to justify how they considered information specific to the woman when forming their opinion, for example by recording in the patient record that they have assessed the relevant information and reached the conclusion based on this information. This is in line with guidance from the GMC (see Annex B).

15. It should be noted that ultimately, if challenged, the question as to whether an individual doctor formed an opinion in good faith would be for a court to decide based on the facts in the individual case.

What is pre-signing of HSA1 forms?

16. In February 2012, CQC inspectors identified a number of cases where signatures on HSA1 certificates predated the referral and assessment of women in a clinic. For example, one woman was referred to the clinic on 20 December and assessed on the 22 December. The certificate reflected that a doctor at the clinic had seen the woman and signed the form on 22 December. However, the signature of the second doctor, also a practitioner at the clinic, was dated 19 December. Therefore, on the information provided, the second doctor had certified the abortion before being assigned the case, and before having any opportunity to consider the clinical files or other specific information to the woman.
The pre-signing of HSA1 forms calls into question whether a doctor could turn his or her mind to a specific woman's circumstances and form a good faith opinion about which, if any, of the lawful grounds under the Abortion Act might apply (see Annex A). In subsequent investigations the CQC identified a further 14 services where there was clear evidence of pre-signing of HSA1 forms. Poor practice identified included photocopying of signatures on forms. DHSC considers pre-signing of forms (without subsequent consideration of any information relating to the woman) to be incompatible with the requirements of the Abortion Act.

Signing HSA1 forms based on the decisions of another doctor

17. It has also come to light that, in some cases, the second RMP might simply sign an HSA1 based on the decision of the first RMP, relying solely on that doctor's judgment to provide a second signature without considering any information specific to the woman concerned.

18. An example of where this situation could arise would be where an "on-call" doctor is asked to sign an HSA1 form without access to the patient records to form their opinion in good faith with no other information specific to the woman being available. Junior doctors, in particular, may feel under pressure to comply with such a request.

19. The purpose of the requirement that two doctors certify the ground(s) for termination is to ensure that the law is being observed; this provides protection for the woman and for the doctors providing the termination. One of the two certifying doctors may also be the doctor that terminates the pregnancy. The clear intention of the Act is for each doctor to consider the woman's circumstances in forming a good faith opinion. This is reflected in

the recognition that the doctors may find that different grounds are met (although they must both find the same ground is met for the abortion to be lawful). Treating certification by one or either doctor as a 'rubber stamp' exercise is therefore contrary to the spirit of the Act and calls into question whether that doctor is in fact providing an opinion that they have formed themselves in good faith rather than relying solely on a colleague's opinion, however trusted that colleague's judgement may be. DHSC considers the signing of forms without consideration of any information relating to the woman to be incompatible with the requirements of the Abortion Act.

The role of the MDT

20. It is acknowledged that the MDT, including nurses and counsellors (it is possible that the MDT would include a midwife where a congenital abnormality has been diagnosed antenatally) plays an important role in supporting women seeking an abortion and in obtaining information from women. RMPs can rely on information obtained by members of the MDT but it is DHSC's interpretation of the law that the RMPs should themselves review the information before reaching an opinion, for example by considering the paperwork or speaking to members of the team. The RMP must be satisfied that they can justify how they reached their decision in good faith if later challenged. The opinions required under the Act are clearly those of the RMP, not of any other member of an MDT, however experienced or trusted. DHSC does not think that the Act can be read to enable the opinion required to be that of another person entirely, or the opinion of a team as a whole. An RMP may, of course, take into account the opinions and views of colleagues in forming an opinion and it is often important to do so, but the opinion provided must be their own.

Faxing of HSA1 forms

21. If the first doctor signs and dates a HSA1, which is faxed to the second doctor who then signs and dates the faxed copy certificate then, although they will have technically signed and dated two separate certificates, in DHSC's view the doctors will have complied with the requirements as to certification set out in the Abortion Regulations 1991 ("the Abortion Regulations). However, as set out above, it is still expected that both doctors should take positive steps to obtain information specific to the woman seeking a termination as part of reaching their decision as to whether there are grounds under the Abortion Act.

22. As the certificate will contain sensitive personal data, it must be processed (transmitted, stored, disposed of etc.) in accordance with the Data Protection Act 1998 (DPA). The DPA permits the "sensitive personal" data to be transmitted from one doctor to another if the patient explicitly consents, or the processing is necessary for medical purposes and is undertaken by a health professional or by someone who is subject to an equivalent duty of confidentiality. Data Protection Principle 7 requires that: 'Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data'.

23. There are some recent examples of fines being imposed by the Information Commissioners Office (ICO) where faxes containing sensitive personal data were sent to the wrong fax number. For example an NHS Trust in London was fined £90,000 for persistently committing this error. Abortion providers therefore need to consider whether

fax is a sufficiently secure method of transmitting the forms. Providers' should consider the ICO's guidance about the use of faxes:
http://www.ico.org.uk/for-organisations/guide-to-data-protection/encryption/scenarios/fax/

Abortion on the ground of gender

24. Abortion on the grounds of gender alone is illegal. Gender is not itself a lawful ground under the Abortion Act (see Annex A for the lawful grounds under Section 1(1)). However, it is lawful to abort a fetus where two RMPs are of the opinion, formed in good faith, "that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped", and some serious conditions are known to be gender-related.

Completion of Form HSA4

25. Section 2 of the Abortion Act requires all RMPS terminating a pregnancy to give notice to the Chief Medical Officer (CMO). It is a criminal offence for RMPs not to notify the CMO of every termination they perform. In England, the Abortion Regulations require that Form HSA4 be submitted to the CMO within 14 days of the procedure. This notification is used by the Department of Health and Social Care as an aid to checking that terminations are carried out within the law.

26. Form HSA4 requires detailed information relating to the procedure, including the names and addresses of the doctors who certified there were lawful grounds under the Abortion Act, gestation, method used and place of termination. Every form is checked and monitored by DHSC officials authorised by the CMO. Data derived from the forms is used to publish annual statistics on abortion. It is crucial that all abortions performed are notified to the CMO, both as a matter of law and for there to be appropriate public and Parliamentary scrutiny and trust in the data that are published.

27. Forms can be submitted electronically or using the paper based system would strongly encourage the use of electronic reporting as this is a more secure system and reduces the risk of lost or misplaced forms or missing data.

28. Currently, around 10% of paper HSA4 forms received are returned to RMPs because of missing, incomplete or invalid data. The main errors that occur are missing doctors' names on page one, missing gestation and missing ground information, both on page four. Incomplete forms will be returned to either the RMP terminating the pregnancy or to the place of termination. If an amended form is not returned within 6 weeks, reminders will be sent until the information is received. Incomplete forms are a financial burden; they generate additional work for those completing the forms and for those who process them on behalf of the CMO. The MDT may have a role in filling in the detail of the form but the RMP terminating the pregnancy is the person legally responsible for giving notice to the CMO. DHSC therefore recommends that RMPs always check the form before signing it and returning it to the CMO. Clinics and hospitals should have protocols and processes in place to ensure that HSA4 forms are being returned in a timely and accurate manger. Reporting an abortion for fetal abnormality to a fetal abnormality register does not negate the legal requirement for RMPs to also notify the CMO.

Role of the RMP in abortion procedures

29. For medical abortions, the Courts have determined that provided the RMP personally decides upon and initiates the process of medical induction and takes responsibility for it throughout the termination, the protection under the Act applies to both the RMP and any other person participating in the termination under his or her authority. The nurse or midwife would not be responsible for leading or directing the procedure or care, or taking the overall decisions, this is firmly the responsibility of the doctor. The Nursing and Midwifery Council's (NMC) Code will apply to all actions taken or decisions made by the nurse or midwife.

Place of termination

30. Unless performed in an emergency, the Abortion Act states that all abortions must take place in an NHS hospital or a place approved by the Secretary of State. Within the NHS, abortions have traditionally been carried out in gynaecology wards and day care units. Independent sector hospitals or clinics which are outside the NHS must obtain the Secretary of State's approval and have agreed to comply with the Required Standard Operating Procedures set out in the Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy.

31. The Care Quality Commission (CQC) is responsible for implementing the regulatory framework set out in the Regulations made under the Health and Social Care Act 2008. It is the responsibility of registered providers and registered managers to comply with the registration requirements and keep up to date with guidance on compliance issued by the CQC.

Counselling

32. Guidance on the provision of non-judgemental counselling was included in the Government's Framework for Sexual Health Improvement published in March 2013. Patients should be able expect impartial advice from the NHS and CCGs and NHS providers should be accountable for the services they recommend.

Annex III - Grounds for Abortion under Section 1 of the Abortion Act

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 that:

- A. The continuance of the pregnancy would involve risk to the life of the pregnant woman greater than if the pregnancy were terminated, Abortion Act 1967 as amended, section 1(1)(c)

- B. The termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman, section 1(1)(b)

- C. 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, section 1(1)(a)

- D. 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 any existing children of the family of the pregnant woman, section 1(1)(a)

- E. There is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped, section 1(1)(d)

Or, in an emergency, certified by the operating practitioner as immediately necessary:

- F. To save the life of the pregnant woman, section 1(4)

- G. To prevent grave permanent injury to the physical or mental health of the pregnant woman, section 1(4)

In determining whether the continuance of a pregnancy would involve such risk of injury to health account may be taken of the pregnant woman’s actual or reasonably foreseeable environment.

Annex IV - Relevant Guidance from Good Medical Practice, General Medical Council (2013)

(1) Section 19: “Documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events you are recording or as soon as possible afterwards.”

(2) Section 35: “You must work collaboratively with colleagues, respect their skills and contributions”

(3) Section 71: “You must be honest and trustworthy when writing reports, and when completing or signing forms, reports and other documents. You must make sure that any documents you write or sign are not false or misleading.

- You must take reasonable steps to check the information is correct.

- You must not deliberately leave out relevant information.”