GENERAL SCHEME OF THE

Protection of Life during Pregnancy Bill 2013

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Head 1 Interpretation

(1) In this Act-

"Appropriate location" means any premises which is carried on by the Executive or by a person with whom the Executive has entered into an arrangement for the provision of a health and personal social service under section 38 of the Health Act 2004 and which are, either wholly or partly, used for the care and treatment of

- (a) pregnant women in relation to pregnancy, childbirth and post-partum care, and
- (b) neonates.

"Executive" means the Health Service Executive;

"implantation" means implantation in the womb of woman;

"medical procedure" includes the provision of any drug or any medical treatment:

"midwife" means a person whose name is registered in the midwives division of the register of nurses and midwives established under section 46 of the Nurses Act 2011;

"Minister" means the Minister for Health;

"neonate" means a baby who is 4 weeks old or younger;

"nurse" means a person whose name is registered in the nurses division of the register of nurses and midwives established under section 46 of the Nurses Act 2011;

"obstetrician/gynaecologist" means a medical practitioner who is registered in the Specialist Division of the register of medical practitioners established under section 43(2)(b) of the Medical Practitioners Act 2007 under obstetrics/gynaecology;

"psychiatrist" means a medical practitioner who is registered in the Specialist Division of the register of medical practitioners established under section 43(2)(b) of the Medical Practitioners Act 2007 under psychiatry;

"reasonable opinion" means an opinion formed in good faith which has regard to the need to preserve unborn human life as far as practicable;

"registered medical practitioner" means a medical practitioner whose name is entered in the register of medical practitioners established under section 43(1) of the Medical Practitioners Act 2007:

"relevant specialty" means a medical specialty listed in the Specialist Division of the register of medical practitioners established under section 43(2)(b) of the Medical Practitioners Act 2007, and relevant to the threat to the life of the pregnant woman;

"review committee" means a committee established under head 7;

"unborn" as it relates to human life means following implantation until such time as it has completely proceeded in a living state from the body of the woman.

"woman" means a female person of any age.

Explanatory Notes

Subhead (1) provides the necessary definitions.

"Appropriate location"

The Minister believes that the State's constitutional obligation and its responsibility to act in the common good demand that, provision of terminations of pregnancy be only allowed in health care facilities providing obstetric and mental health services and where relevant specialists are attached, that can be duly monitored and investigated, should the need arise.

At present the regulation of obstetric units falls under the Registration of Maternity Homes Act 1934 and the Health Act 2007. The 1934 Act provides for a system of registration for maternity homes and for the keeping of certain records, administered by the Health Service Executive (HSE). It is due to be repealed under the proposed modern licensing system for all acute hospitals. In the meantime, under Section 8 of the Act, HIQA sets standards on safety and quality in relation to services directly provided by the HSE and bodies funded by the HSE to provide services on its behalf (i.e. the public health service). It is the Minister's view that the 2007 Act offers scope for oversight of terminations of pregnancy permitted under the Bill and consistent with our obligations under Article 40.3.3.

The relevant medical treatment, therefore, may only be provided in public obstetric units except in emergencies for the following reasons:

- 1) HIQA can monitor their compliance with standards on safety and quality
- 2) HIQA can carry out investigations as to the safety, standards and quality of public obstetric units
- 3) The Minister can request HIQA to carry out investigations as to the safety, standards and quality of public obstetric units

There are currently 19 public obstetric units across the country. Sixteen of them are managed by the Health Service Executive, and three are voluntary maternity hospitals. The HSE has responsibility for the management and delivery of health and personal social services under the Health Act 2004. It delivers services itself and it can also, under section 38 of the Act, enter into an arrangement with other agencies to provide services on its behalf. This would include the three voluntary maternity hospitals.

The HSE and agencies providing services under section 38 on behalf of the HSE come within HIQA's remit and the remit of the Mental Health Commission.

"Implantation" means implantation in the womb of a woman. This definition aims to exclude the treatment of ectopic pregnancies and emergency contraception from the scope of this Bill.

Other than in emergency situations, doctors who can certify in regard to a real and substantial risk to the woman of loss of life that can only be averted by a medical procedure in the course of which or as a result of which unborn human life is ended must be registered by the Medical Council in its Specialist Division. "Relevant speciality", "obstetrician/gynaecologist" and "psychiatrist" are terms used in the Bill in connection with the certification process. "Relevant specialty" is defined with reference to specialist knowledge to ensure doctors involved in the certification process have a high level of knowledge and skills but it is not further limited in order to ensure that all clinical specialities that might be relevant are included in the definition. In relation to the definitions of "obstetrician/gynaecologist" and "psychiatrist", again it is considered that Specialist registration is required in order to ensure that all doctors involved in certification procedures fulfil precise and formal criteria as regards levels of knowledge and skills. Further detail on certification is given in Head 2, 3, and 4.

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"Reasonable opinion"

The definition of "reasonable opinion" requires that this opinion must be formed in good faith and must have regard to protect and preserve unborn human life where practicable. The registered medical practitioner(s) will be obliged to record this opinion in writing if certifying a procedure that will end unborn human life. This definition is intended to place a duty on certifying medical practitioners to preserve the life of the unborn as far as practicable, and is influenced by the Twenty-fifth Amendment of the Constitution (Protection of Human Life in Pregnancy) Bill 2001 (section 1).

The Bill provides that terminations permitted under the Bill may only be carried out by registered medical practitioners. "Registered medical practitioner" means a doctor registered by the Medical Council, under the Medical Practitioners Act 2007, which indicates a person permitted by law to practice as a medical practitioner in the State. In the performance of their professional activities, all such medical practitioners are, as a matter of law, subject to the ethical and professional control of the Medical Council. It is not intended that it should be possible for a person other than a qualified doctor to undertake the procedures involved in this Bill.

'Unborn' The definition suggested above is based on the Supreme Court judgment in *Roche v Roche & Others*¹ which deemed that embryos acquire legal protection under Article 40.3.3 of the Constitution only from the moment of implantation. This definition of 'unborn' protects the foetus from implantation until birth, including a foetus in the course of being born, thereby closing off a potential legal irregularity in legislation identified by the Expert Group in its report on the *A,B,C v Ireland* Judgement.

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¹ [2012] IRRM 411.

Head 2 Risk of loss of life from physical illness, not being a risk of self destruction

Provide that

- (1) It is not an offence to carry out a medical procedure, in accordance with this head, in the course of which or as a result of which unborn human life is ended, where
 - (a) that procedure is carried out by a registered medical practitioner at an appropriate location, and
 - (b) two medical practitioners, have, in accordance with this head, jointly certified in good faith that
 - (i) there is a real and substantial risk of loss of the pregnant woman's life other than by way of self-destruction, and
 - (ii) in their reasonable opinion this risk can be averted only by that medical procedure.
- (2) One of the two medical practitioners referred to in *paragraph* (b) of *subhead* (1) shall be an obstetrician/gynaecologist, who must be employed at that location, and one shall be a medical practitioner who is registered on the Specialist Division of the register of medical practitioners established under section 43(2)(b) of the Medical Practitioners Act 2007 under a relevant specialty.
- (3) (a) In forming their opinion, at least one of the two medical practitioners referred to in paragraph (b) of subhead (1) shall consult with the pregnant woman's general practitioner where practicable.
- (b) In forming the aforesaid opinion both medical practitioners should examine the woman.
- (4) Where two medical practitioners referred to in *subhead* (2) have jointly certified an opinion referred to in *paragaph* (b) of *subhead* (1), the certifying obstetrician/gynaecologist referred to in subhead (2) shall forward the certificate to a location referred to in paragraph (a) of subhead (1) and shall make arrangements for carrying out the procedure at that location.
- (5) It will always be a matter for the patient to decide if she wishes to proceed with a termination following a decision that it is permissible under this Act.

Explanatory Notes

Head 3 provides that it is not an offence to carry out a medical procedure in the course of which or as a result of which unborn human life is ended. The criteria are those laid out in the *X* case judgment, where a termination of pregnancy is permissible if it is established as a matter of probability that:

- 1) there is a real and substantial risk to the life of the mother; and
- 2) this risk can only be averted by the termination of her pregnancy.

Under subhead (1), a termination is lawful if each of the following requirements is met:

- (1) the termination is carried out in an appropriate location, i.e. a public obstetric unit. There are currently 19 public obstetric units around the country.
- (2) the procedure is undertaken by a registered medical practitioner

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(3) two registered medical practitioners qualified to act under the legislation have jointly certified their opinion that there is a real and substantial risk to the life of the mother arising from a physical illness, not being a risk of self-destruction, and this risk can only be averted by the termination of her pregnancy.

The Supreme Court judgment in the X case indicated that it is not necessary for medical practitioners to be of the opinion that the risk to the woman's life is inevitable or immediate, as this approach insufficiently vindicates the pregnant woman's right to life.

Looking to other areas of medical practice, the case of involuntary detention under the Mental Health Act 2001 provides guidance in that, given the serious consequence arising from the medical assessment, the opinion of more than one doctor is required. In light of the fundamental constitutional rights involved in this clinical decision-making process, i.e. the right to life of the pregnant woman and of the unborn, subhead (1) provides that two doctors will be required to form an opinion and jointly certify that a termination of pregnancy is required to avert a real and substantial risk to the life of the mother. Subhead (2) provides that one doctor must be an obstetrician/gynaecologist, while the other medical practitioner must be of a specialty relevant to the clinical assessment of the woman. One of these medical practitioners must be employed at the location where the termination is due to take place.

The Bill does not specify that the two doctors examine the woman together or that they examine the woman at the same location. It is expected that a decision would be reached following a multi-disciplinary discussion in accordance with medical best practice.

In light of this approach, the general scheme is silent on how the certification may come about. Clinical scenarios where the *X* case criteria might apply are bound to be complex. Due to the unpredictability and complexity of these rare medical cases it was felt not desirable to provide in legislation for a specific referral pathway. Rather, it is deemed that standard medical practice will provide an appropriate mechanism for the process through which an assessment would be accessed.

In this regard, it is important that professional guidance is developed by the relevant professional Colleges for their members on the operation of this legislation. In order to facilitate this and to ensure its timely development, the Department of Health will support and work very closely with all the relevant professional bodies (particularly, the Institute of Obstetrics and Gynaecology, the Royal College of Physicians and the Irish College of General Practitioners) in developing guidelines for their members on the implementation of the legislation following enactment of the Protection of Life during Pregnancy Bill. Steps have already been taken to establish the willingness of these Professional Medical bodies to work with the department on such guidance.

As mentioned in the Interpretation, it is considered that Specialist registration is required to ensure that all doctors involved in certification procedures fulfil precise and formal criteria as regards their levels of knowledge and skills.

Subhead 2 provides details on the professional expertise of the relevant certifying medical practitioners. Except in emergency circumstances, an obstetrician/gynaecologist will always be one of the certifying medical practitioners. This provision is deemed appropriate for two reasons. Firstly, in accordance with current clinical practice, an obstetrician/gynaecologist is obliged to care for the pregnant woman and the foetus and, therefore has a duty of care to both patients and to have regard to protecting the right to life of the unborn and to bring that to bear on the care of the woman and her unborn child. Secondly, a termination of pregnancy will most likely be carried out by, or under the care of, an

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obstetrician/gynaecologist, and therefore their inclusion here should be central in accessing services and ensuring patient safety.

As the Expert Group's Report indicated General Practitioners often have a long-term relationship with their patients and, therefore, it may be appropriate that GPs are consulted as a matter of best practice in the course of the diagnostic process. This would provide access to their knowledge of the patient and establish continuity of care for the woman after the treatment has been delivered.

The aim of subhead (4) is to ensure that following certification of medical opinion, a woman can then access this treatment in the usual way, i.e. through referral by the appropriate specialist.

Subhead (1)(b)(ii) refers to a 'reasonable opinion'. This is defined in the Interpretation to mean an opinion formed in good faith, which has regard to the need to preserve unborn life where practicable. Again, as outlined earlier, this definition is intended to place a duty on certifying medical practitioners to preserve the life of the unborn as far as practicable, and is influenced by the Twenty-fifth Amendment of the Constitution (Protection of Human Life in Pregnancy) Bill 2001 (section 1). This emphasis on preserving unborn human life as far as practicable governs the actual medical procedure – the termination of pregnancy only and not whether there is a real and substantial risk to the life of the mother.

In circumstances where the unborn may be potentially viable outside the womb, doctors must make all efforts to sustain its life after delivery. However, that requirement does not go so far as to oblige a medical practitioner to disregard a real and substantial risk to the life of the woman on the basis that it will result in the death of the unborn.

Essentially the decision to be reached is not so much a balancing of the competing rights-rather, it is a clinical assessment as to whether the mother's life, as opposed to her health, is threatened by a real and substantial risk that can only be averted by a termination of pregnancy.

Head 3 Risk of loss of life from physical illness in a medical emergency

Provide that

- (1) It is not an offence to carry out a medical procedure, in accordance with this head, in the course of which or as a result of which unborn human life is ended, where
 - (a) that procedure is carried out by a medical practitioner,
 - (b) he or she in good faith believes that there is an immediate risk of loss of the pregnant woman's life other than by way of selfdestruction, and
 - (c) the medical procedure is, in his or her reasonable opinion, immediately necessary to save the life of the woman.
 - (2) The opinion referred to in *subhead (1)* shall be certified by the registered medical practitioner referred to in *subhead (1)* in the form and manner prescribed by the Minister.

Explanatory Notes

The Bill must also take account of medical emergencies, while setting clear and appropriate parameters. These provisions apply in cases where the risk to the life of the woman is immediate and are limited to risks arising from physical conditions.

The requirements are set out in subhead 1 and are that:

- (1) a registered medical practitioner is of the opinion that the termination is immediately necessary to save the life of the pregnant woman, and issues a certificate to that effect, and
- (2) the termination has been undertaken by a registered medical practitioner.

Doctors should not be prevented from saving a woman's life in a situation of acute emergency, because, for example, the required numbers of doctors are not available to certify or the woman in question arrives at a health facility that is not covered as an appropriate location under this Bill i.e. not a public obstetric unit. Therefore, in emergency circumstances, the reasonable opinion of one medical practitioner is required to certify that the termination is immediately necessary to save the life of a pregnant woman, but the medical practitioner who carries out the procedure will be required to certify the reasons for his/her actions, and notification of all emergency terminations will be sent to the Minister. Again, this opinion must be formed in good faith and have regard to the need to preserve unborn life where practicable. Because of its emergency nature, this termination may be carried out in a location other than a public obstetric unit.

Head 4 Risk of loss of life from self-destruction

Provide that

- (1) It is not an offence to carry out a medical procedure, in accordance with this head, in the course of which or as a result of which unborn human life is ended, where
 - (a)that procedure is carried out by a registered medical practitioner at an appropriate location.
 - (b) one obstetrician/gynaecologist, who must be employed at that location, and two psychiatrists, both of whom shall be employed at a centre which is registered by the Mental Health Commission, and one of whom shall be attached to an institution where such a procedure is carried out, in accordance with this head, jointly certified in good faith that –
 - (i) there is a real and substantial risk of loss of the pregnant woman's life by way of self-destruction, and
 - (ii) in their reasonable opinion this risk can be averted only by that medical procedure.
- (2) (a) At least one of the three medical practitioners referred to in paragraph (b) of subhead (1) shall consult with the pregnant woman's general practitioner where practicable.
 - (b)In forming the aforesaid opinion, the medical practitioners should examine the woman.
- (3)Where three medical practitioners referred to in this head have jointly certified an opinion referred to in *paragraph* (b) of *subhead* (1), the certifying obstetrician/gynaecologist referred to in paragraph (b) shall forward the certificate to a location referred to in *paragraph* (a) of *subhead* (1) and shall make arrangements for the carrying out of the procedure at that location.
- (4) It will always be a matter for the patient to decide if she wishes to proceed with a termination following a decision that it is permissible under this Act.

Explanatory notes

Head 4 is concerned with risk of loss of life from self destruction. The criteria are again based on the judgment in the *X* case, this time focusing on cases where a termination of pregnancy is permissible if it is established as a matter of probability that:

- 1) there is a real and substantial risk to the life of the mother arising from suicide intent; and
- 2) this risk can only be averted by the termination of her pregnancy.

It is not necessary for medical practitioners to be of the opinion that the risk to the woman's life is inevitable or immediate as this approach insufficiently vindicates the pregnant woman's right to life.

This head provides that three doctors are required to form an opinion and jointly certify that a termination is required to avert a real and substantial risk to the life of the mother. This provision arises from the recognised clinical challenges in accurately assessing suicidal intent, and the absence of objective clinical markers. In these cases the Bill provides that the

opinion will be jointly certified by an obstetrician/gynaecologist and two psychiatrists. Both of these psychiatrists must be employed in a hospital or other in-patient facility for the care and treatment of persons suffering from mental Illness or mental disorder registered by the Mental Health Commission under the Mental Health Act 2001. Also, one of these shall be attached to the institution where such a procedure is carried out.

The Bill does not specify that the three doctors examine the woman together or that they examine the woman at the same location. It is expected that a decision would be reached following a multi-disciplinary discussion in accordance with medical best practice.

In light of this approach, the general scheme is silent on how the certification may come about. Clinical scenarios where the *X* case criteria might apply are bound to be complex. Due to the unpredictability and complexity of these rare medical cases it was felt not desirable to provide in legislation for a specific referral pathway. Rather, it is deemed that standard medical practice will provide an appropriate mechanism for the process through which an assessment would be accessed.

As mentioned in the Interpretation, it is considered that Specialist registration is required to ensure that all doctors involved in certification procedures fulfil precise and formal criteria as regards their levels of knowledge and skills.

As the Expert Group's Report indicated General Practitioners often have a long-term relationship with their patients and therefore have in-depth knowledge of a patient's personal circumstances. The GP may be able to provide valuable insight into her clinical history; knowledge which might be particularly useful when assessing a real and substantial risk to life through suicide. Therefore, it may be appropriate that GPs are consulted as a matter of best practice in the course of the diagnostic process. This would provide access to their knowledge of the patient and establish continuity of care for the woman after the treatment has been delivered. In this regard, it is important that professional guidance is developed by the relevant professional Colleges for their members on the operation of this legislation. In order to facilitate this and to ensure its timely development, the Department of Health will support and work very closely with all the relevant professional bodies (particularly the Irish College of Psychiatry, the Institute of Obstetrics and Gynaecology, and the Irish College of General Practitioners) in developing guidelines for the their members on the implementation of the legislation following enactment of the Protection of Life during Pregnancy Bill. Steps have already been taken to establish the willingness of these Professional Medical bodies to work with the department on such guidance.

The aim of subhead (3) is to ensure that following certification of medical opinion, a woman can then access this treatment in the usual way, i.e. through referral by the appropriate specialist.

Subhead (1)(b)(ii) refers to a 'reasonable opinion'. This is defined in the Interpretation to mean an opinion formed in good faith, which has regard to the need preserve unborn life where practicable. Again, as outlined earlier, this definition is intended to place a duty on certifying medical practitioners to preserve the life of the unborn as far as practicable, and is influenced by the Twenty-fifth Amendment of the Constitution (Protection of Human Life in Pregnancy) Bill 2001 (section 1). This emphasis on preserving unborn human life as far as practicable governs the actual medical procedure – the termination of pregnancy only and not whether there is a real and substantial risk to the life of the mother.

In circumstances where the unborn may be potentially viable outside the womb, doctors must make all efforts to sustain its life after delivery. However, that requirement does not go

so far as to oblige a medical practitioner to disregard a real and substantial risk to the life of the woman on the basis that it will result in the death of the unborn.

Essentially the decision to be reached is not so much a balancing of the competing rights-rather, it is a clinical assessment as to whether the mother's life, as opposed to her health, is threatened by a real and substantial risk that can only be averted by a termination of pregnancy.

Head 5 Medical opinion to be in the form and manner prescribed by the Minister

(1) A medical opinion referred to in *heads 2*, 3, *or 4* shall be given in the form and manner prescribed by the Minister.

Explanatory Notes

This head provides that medical opinions in heads 2, 3, or 4 must be certified in the form and manner prescribed by the Minister. This is intended to allow proper documentation of the certification process.

Head 6 Formal Medical Review Procedures

- (1) Where a medical practitioner qualified to certify in accordance with head 2 or as the case may be head 4 has been consulted by a pregnant woman in relation to whether there is a real and substantial risk of loss to her life that can only be averted by a medical procedure in the course of which or as result of which unborn human life may be terminated and the practitioner is not of an opinion referred to in head 2 or head 4, he or she shall inform the pregnant woman that she may make an application as set out in *subhead* (2) of this head.
- (2) A pregnant woman or a person on her behalf with her consent may apply in writing to the HSE in the form and manner prescribed by the Minister to have her case reviewed if she has consulted a medical practitioner qualified to certify in accordance with head 2, or as the case may be, head 4, and the medical practitioner is not of the opinion referred to in those heads or has not given an opinion in relation to the matter.
- (3) The Executive shall establish and maintain a panel of medical practitioners meeting the requirements in relation to certification under head 2 and head 4 and of sufficient size and composition for the purposes of a review referred to in *subhead* (2) on the nomination of
- (a) Institute of Obstetricians and Gynaecologists
- (b) Irish College of Psychiatry
- (c) Royal College of Surgeons in Ireland
- (d) Royal College of Physicians of Ireland
- (4)The Executive shall appoint and authorise one or more of its employees with appropriate qualifications and experience for the purposes of establishing and convening a committee in accordance with subhead 5.
- (5) As soon as possible but no later than 7 days after receiving a completed written application in accordance with subhead (2), an authorised person referred to in subhead (4) shall establish and convene a committee drawn from the panel established and maintained by the Executive under subhead (3).
- (6) As soon as possible but no later than 7 days after having been convened in accordance with subhead (5), the committee shall review the case and shall form an opinion in good faith as to whether or not there is a real and substantial risk of loss of life of the pregnant woman that can only be averted by a termination of her pregnancy.
- (7) Notification in the form and manner prescribed by the Minister of the outcome of the committee's review shall be given to
 - (a) the woman who made the application and if applicable the person who made the application on her behalf and
 - (b) the Executive.
- (8) A medical practitioner may not be a member of a committee established and convened under *subhead* (5) to review a case where he or she has previously been consulted by the woman who is the subject of the application in relation to whether there is a real and substantial risk of loss of her life that can only be averted by a medical procedure in the course of which or as a result of which unborn human life is ended.

Explanatory Notes

The establishment of a formal framework providing for an accessible, effective and timely medical review mechanism is one of Ireland's obligations under the judgment in *A*, *B* and *C v Ireland*. This formal review pathway is in addition to and not in substitution for the option of the woman seeking a second opinion as with normal medical practice.

The European Court of Human Rights in this judgment emphasised the necessity for a review mechanism in cases in which there is a difference of medical opinion as to whether a woman requires an abortion or when the woman disputes the medical diagnosis. The Court stated that there must a be 'framework' whereby

"...any difference of opinion between the woman and her doctors or between different doctors consulted, or whereby an understandable hesitancy on the part of a woman and her doctor, could be examined and resolved through a decision which would establish as a matter of law whether a case presented a qualifying risk to a woman's life such that a lawful abortion might be performed".

The judgment in *Tysiąc v Poland* is of particular relevance in setting out the detailed requirements envisaged by the Court. The Court indicated that a right to legal abortion must be supported by procedural safeguards to ensure the law is correctly applied, and the need for such safeguards is particularly acute in cases where there is a disagreement as to whether the preconditions for a legal abortion are satisfied.

The Court stated that 'in such situations the applicable legal provisions must, first and foremost, ensure clarity of the pregnant woman's position'³. It continued

'In this connection, the Court reiterates that the concepts of lawfulness and the rule of law in a democratic society command that measures affecting fundamental human right be, in certain cases, subject to some form of procedure before an independent body competent to review the reasons for the measures and the relevant evidence... In ascertaining whether this condition has been satisfied, a comprehensive view must be taken of the applicable procedures.. In circumstances such as those in issue in the instant case, such a procedure should guarantee to a pregnant woman at least the possibility to be heard in person and to have her views considered. The competent body should also issue written grounds for its decision.

In this connection the Court observes that the very nature of the issues involved in decisions to terminate a pregnancy is such that the time factor is of critical importance. The procedures in place should therefore ensure that such decisions are timely so as to limit or prevent damage to a woman's health which might be occasioned by a late abortion.⁴

In light of the above it would appear that the review mechanism put in place must have, *inter alia*, the following attributes. It must be:

- independent,
- <u>competent</u> to review (i) the reasons for the decision and (ii) the relevant evidence,
- the procedures should include the possibility for the woman to be <u>heard</u>
- it should issue written opinion
- decisions must be timely.

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² A, B and C v Ireland at paragraph 253.

³ Tysiąc v Poland at paragraph 116.

⁴ Tysigc v Poland at paragraph 117.

The aim of Head 6 is to make provisions to fulfil the judgment's requirement to set up a formal mechanism to allow a woman to seek a review of her case. The purpose of the review committee is to provide a formal mechanism to review the clinical assessment made by the original treating doctor or team to the effect that a woman does not require a termination in line with the *X* case criteria, or when she has been unable to obtain an opinion in this regard. A duty is placed on the relevant medical practitioner to inform the woman of this formal review option in subhead 1.

Subhead 2 clarifies that recourse to the formal review process should usually be at the request of the woman only but may be initiated on her behalf with her consent. It should also be noted that the intention of the Bill is to confer procedural rights on the person most centrally involved, namely a woman who believes she has a life-threatening condition, so that she can have certainty as to whether or not she requires this treatment. Conferring these procedural rights upon her does not deprive any other person of any right they may enjoy and any person who believes they may have a right to take action will be free to exercise their right of access to the courts to challenge a decision which they believe to be wrong.

Subhead 3 provides for the HSE to establish a panel of relevant experts for the purposes of a formal medical review. Members will be nominated by the Institute of Obstetricians and Gynaecologists, the Irish College of Psychiatry, the Royal College of Surgeons in Ireland, and the Royal College of Physicians of Ireland. The HSE will draw from this panel when it needs to establish a review committee to consider an application made under this Head.

Subhead 4 provides that the HSE must appoint one or more of its employees to act as a Convenor of the formal review process.

Subheads 5 and 6 provide for a response to occur in a timely manner when a request for a medical review is received.

Subhead 8 is intended to ensure that a doctor who has already given an opinion on the case or has been consulted by the pregnancy woman in regard to the case cannot be part of the review of that case.

Head 7 Review where risk arises from physical illness, not being a risk of self destruction

- (1) In the case of a pregnant woman who believes there may be a real and substantial risk of loss of her life other than by way of self-destruction, a committee established by an authorised person shall consist of an obstetrician/gynaecologist who must be employed at an appropriate location and one medical practitioner who is registered on the Specialist Division of the register of medical practitioners established under section 43(2)(b) of the Medical Practitioners Act 2007 under a relevant specialty.
- (2) As soon as possible but no later than 7 days after receiving a completed written application in accordance with *subhead* 7(2), an authorised person referred to in *subhead* 7 (4) shall establish and convene a committee drawn from the panel established and maintained by the Executive under *subhead* 7(3).
- (3) As soon as possible but no later than 7 days after having been convened in accordance with subhead (5), the committee shall review the case and shall form an opinion in good faith as to whether or not there is a real and substantial risk of loss of life of the pregnant woman that can only be averted by a termination of her pregnancy.
- (4) Notification in the form and manner prescribed by the Minister of the outcome of the committee's review shall be given to
 - (a) the woman who made the application and if applicable the person who made the application on her behalf, and
 - (b) the Executive.
- (5) Where a committee referred to in *subhead* (1) forms an opinion referred to in head 2, the committee shall jointly certify this opinion in the form prescribed by the Minister and the certifying obstetrician/gynaecologist shall make arrangements for the procedure to be carried out in an appropriate location.
- (6) The procedures set out in this Head are without prejudice to Head 3, which shall apply where there is a material deterioration in the health of a pregnant woman such that there is an immediate risk of loss of her life other than by way of self destruction, and thereupon the provision of Head 3 shall apply irrespective of review procedures which are in train.

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Head 8 Review in case of risk of loss of life through self-destruction

- (1) In the case of a pregnant woman who believes there may be a real and substantial risk of loss of her life arising from self-destruction the committee shall consist of one obstetrician/gynaecologist who must be employed at an appropriate location and two psychiatrists both of whom shall be employed at a centre which is registered by the Mental Health Commission and one of whom shall be employed at an appropriate location.
- (2) As soon as possible but no later than 7 days after receiving a completed written application in accordance with *subhead* 7(2), an authorised person referred to in *subhead* 7 (4) shall establish and convene a committee drawn from the panel established and maintained by the Executive under *subhead* 7(3).
- (3) As soon as possible but no later than 7 days after having been convened in accordance with subhead (5), the committee shall review the case and shall form an opinion in good faith as to whether or not there is a real and substantial risk of loss of life of the pregnant woman that can only be averted by a termination of her pregnancy.
- (4) Notification in the form and manner prescribed by the Minister of the outcome of the committee's review shall be given to
 - (b) the woman who made the application and if applicable the person who made the application on her behalf and
 - (b) the Executive.
- (5) Where a committee referred to in *subhead* (1) forms an opinion referred to in head 4, the committee shall jointly certify this opinion in the form prescribed by the Minister and the certifying obstetrician/gynaecologist shall make arrangements for the procedure to be carried out in an appropriate location.

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Head 9 General provisions for Committee

- (1) A committee established under head 6 to review a case, or an authorised person at its request, may direct in writing any relevant medical practitioner to produce to the committee any document or thing in his or her possession or control that is specified in the direction.
- (2) The committee or an authorised person at its request may direct in writing any medical practitioner to attend before it on a date and at a time and place specified in the direction.
- (3) At her request, the committee shall enable
 - (a) a woman who has made an application or on whose behalf an application has been made, or
 - (b) a person on her behalf,

to be present at a meeting of the Committee to present her case to the committee.

- (4) A person who -
 - (a) having been directed under *subhead* (2) to attend before the committee without just cause or excuse disobeys the direction,
 - (b) fails or refuses to send any document or things legally required by the committee under *subhead* (1) to be sent to it by the person without just cause or excuse,

shall be guilty of an offence and shall be liable on summary conviction to a class C fine (not exceeding €2,500).

- (5) Summary proceedings for an offence under *subhead* (3) may be brought and prosecuted by the HSE.
- (6) A member of a committee established under head 6(5) shall be paid by the Executive out of funds at its disposal, remuneration and allowances for expenses, if any determined under *subhead* (8).
- (7) A medical practitioner who attends a review committee under subhead (2) shall be paid by the Executive out of funds at its disposal, remuneration and allowances for expenses, if any determined under *subhead* (8).
- (8) With the consent of the Minister for Public Expenditure and Reform, the Minister may determine the remuneration and allowances for expenses, if any, payable to members of a review committee and medical practitioners attending a review committee under *subhead* (2).

Explanatory Notes

Head 9 aims to empower the review committee to obtain whatever manner of clinical evidence it requires to reach a decision, and to call any relevant medical practitioners to give evidence in person and to vindicate a woman's right to present her case at the meeting of the Review Committee or someone authorised on her behalf. The wording in this head has been adapted from the Mental Health Act 2001. The penalties for not complying with any direction issued by the Review Committee have also been adapted from the Mental Health Act 2001 and the corresponding penalties for not complying with directions issued in relation to a mental health tribunal contained therein. It is intended that bringing of prosecutions in this regard would be a matter for the HSE.

Head 10 Formal medical review reports to Minister

- (1) The Executive shall in each year, at such times and in such manner as the Minister may determine, provide the Minister with a general report on applications made during the previous year indicating
- (a) the total number of applications received
- (b) the number of reviews carried out
- (c) in the case of reviews carried out, the reason why the review was sought
- (d) the outcome of the review and
- (e) any other information specified by the Minister.

Explanatory Notes

Head 10 provides that the Executive will have a duty to report annually on the workings of the formal medical review process to the Minister. This information is required to monitor the implementation of the legislation to ensure that the principles and requirements of the system are being upheld. Furthermore, if it were to transpire that all terminations that had taken place had gone through the formal review process, this might indicate that further guidance is required from the professional bodies.

Head 11 Notifications

- (1) The person in charge of an appropriate location or other establishment, at which a medical procedure permitted under this Bill is carried out, shall keep a record in the form and manner prescribed by the Minister.
- (2) Where a medical procedure permitted under this Bill has been carried out, the person carrying on the business of the premises at which the procedure is carried out, shall, no later than 28 days after the medical procedure has been carried out, notify the Minister of the such procedure and such notification shall include any information as maybe prescribed for this purpose.
- (3) No notification under this head shall give the name or address of the woman in respect of whom the termination was carried out.
- (4) The Freedom of Information Act 1997 shall not apply to any record under this head.

Explanatory Note

There is a need to keep records on the terminations carried out and the medical reasons that gave rise to the treatment for clinical purposes. This is provided for in *subhead* (1). The intention is that *subhead* (1) will encompass all terminations carried out under the Bill including any terminations carried out in an emergency situation.

Information is also required to inform policy, as well as to ensure that the principles and requirements of the system are being upheld. The Minister must receive notification of all terminations carried out under this Bill.

It is not intended that the Freedom of Information Act 1997 will apply to these records.

Regulation under the Bill will provide that notification of all terminations carried out under this Bill will include the following details:

- Location
- Grounds for termination
- Names of medical Practitioners involved
- Gestation

Head 12 Conscientious Objection

Provides that

- (1) Nothing in this Bill shall be construed as obliging any medical practitioner, nurse or midwife to carry out, or to assist in carrying out, a lawful termination of pregnancy.
- (2) Nothing in subhead (1) shall affect any duty to participate in treatment under Head 4.
- (3) No institution, organisation or third party shall refuse to provide a lawful termination of pregnancy to a woman on grounds of conscientious objection.
- (4) In the event of a doctor or other health professional having a difficulty in undertaking a required medical procedure, he or she will have a duty to ensure that another colleague takes over the care of the patient as per current medical ethics.

Notes

Article 9(1) of the European Convention on Human Rights states that: "everyone has the right to freedom of thought, conscience and religion...". An individual's right to conscientious objection is provided for in most ethical guidelines and has existed with good reason for many centuries. The Medical Council *Ethical Guidelines* state:

- '10.2 If you have a conscientious objection to a course of action, you should explain this to the patient and make the names of other doctors available to them.
- 10.3 Conscientious objection does not absolve you from responsibility to a patient in emergency circumstances. 55

Similarly, the *Code of Conduct for each Nurse and Midwife* makes reference to an entitlement to conscientious objection that may be relevant to professional practice⁶.

However, an individual's right to conscientious objection is not absolute and often has limitations. This is because the right to conscientious objection must be balanced against someone else's competing rights, for example, the right to life in the case of a medical emergency. The balance is reflected by the provisions of the European Convention on Human Rights in which freedom of conscience is qualified by Article 9(2), "Freedom to manifest one's religion or beliefs shall be subject only to such limitations as are prescribed by law and are necessary in a democratic society in the interests of public safety, for the protection of public order, health or morals, or for the protection of the rights and freedoms of others".

Subhead 1 provides a right to conscientious objection but clarifies that this right only applies to medical and nursing personnel and pharmacists. It is adapted from section 3 of the Twenty-fifth Amendment of the Constitution (Protection of Human Life in Pregnancy) Bill 2001 as passed by Dáil Éireann. The effect of this provision is that a medical or other health professional will not be obliged to carry out a procedure to which he or she has a conscientious objection, even though it may not constitute an offence under the Bill. In the event of a doctor or other health professional having a difficulty in undertaking a required medical procedure, he or she will have a duty to ensure that another colleague took over the care of the patient as per current medical ethics.

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⁵ Medical Council: 2009, pg. 16.

⁶ An Bord Altranais, 2000.

Subhead (3) refers to the fact that the right to conscientious objection is a human right and, as such, applies only to individuals and not institutions.

Head 13 Travel and Information

- (1) This Act does not limit freedom to travel between the State and another state or freedom to obtain or make available in the State, in accordance with conditions for the time being laid down by law, information relating to services lawfully available in another state.
- (2) This Act does not operate to restrict any person from travelling to another state on the ground that his or her intended conduct there would, if occurred in the State, constitute an offence under head 19 of this Act.

Notes

It was decided to include the subheads above 'for the avoidance of doubt'.

Subhead 1 reaffirms the freedom to travel and freedom to information which the People voted to insert into Article 40.3.3 of the Constitution in 1992. The Thirteen and Fourteenth Amendments to the Constitution added a second and third paragraph to Article 40.3.3 of the Constitution so as to ensure that the Article would not be invoked in order to limit either freedom to travel to another state or to obtain or make available, in the State, subject to such conditions as may be laid down by law, information relating to services lawfully available in another state.

Subhead 2 provides that the Bill does not restrict a person from travelling to another state on grounds that their conduct would be illegal, if it occurred in Ireland. Its intention is to address any concerns that a person could be prevented from travelling outside the State to have an abortion, on the grounds that such an abortion would not be legal in Ireland.

Head 14 Regulations

- (1) The Minister may make regulations that the Minister considers necessary or expedient for purposes under this Act.
- (2) Without limiting the generality of subhead (1), the Minister may make regulations -
 - (a) for any purpose in relation to which regulations are provided for in this Act,
 - (b) prescribing any matter or thing referred to in the act as prescribed or to be prescribed, and
 - (c) generally for the purpose of giving effect to this Act.
- (3) A regulation under this head may contain such consequential supplementary and ancillary provisions as the Minster considers necessary or expedient.

Note

This is a standard provision in regard to Ministerial powers to make regulations.

Head 15 Regulations respecting certification of opinions referred to in this Act

- (1) Without limiting the generality of head 14, the Minister shall make regulations
 - (a) respecting the written form and manner in which an opinion referred to head 2, 3 or 4, and
 - (b) respecting the notification where the review committee is not of the opinion referred to in head 2 or 4.
- (2) Without limiting the generality of subhead (1), regulations under paragraphs (a) and (b) of that subhead shall specify that certifications shall indicate the clinical reason or reasons for the opinion referred to in head 2, 3 or 4.

Explanatory note

This head requires that certain regulations must be made. Under heads 3 and 19, a termination of pregnancy is not an offence where two or three relevant medical practitioners, as specified, have certified that in their reasonable opinion there is a real and substantial risk of loss of life of a pregnant woman and this risk can only be averted by the termination of her pregnancy. In an emergency situation, (head 3) a termination is not an offence when carried out by a medical practitioner when he or she is of the reasonable opinion that the procedure is immediately necessary to save the life of the pregnant woman. This does not apply in situations where the threat to life arises from self destruction. The Minister will be required to make regulations prescribing the form and manner in which these opinions are to be certified by the relevant doctors, or by the doctor acting in an emergency. Regulations will require certificates to indicate the clinical grounds (physical / self-destruction) for the opinion.

The Minister will also be required to make regulations regarding the notification to be given where the review committee is not of the opinion that there is a real and substantial risk of loss of life to a pregnant woman that can only be averted by the termination of her pregnancy.

Head 16 Regulations respecting notifications to the Minister

(1) Without limiting the generality of head 14, the Minister shall make regulations respecting the form and manner information is notified to the Minister under head 10.

Head 17 Laying of regulations before Houses of the Oireachtas

- (1) The Minister shall ensure that every regulation made by the Minister under this Act other than an order under head 11 is laid before each House of the Oireachtas.
- (2) Either House of the Oireachtas, by resolution passed within 21 sitting days after the day on which a regulation is laid before it under this head, may annul the regulation.
- (3) The annulment of a regulation under subhead (2) takes effect immediately on the passing of the resolution concerned, but does not affect the validity of anything done under the regulation before the passing of the resolution.

Note

This is a standard provision in relation to regulations.

Head 18 Repeal and Consequential Amendments

Provide that

(1) Sections 58 and 59 of the Offences Against the Person Act 1861 are hereby repealed.

Notes

This head provides for the repeal of Sections 58 and 59 of the Offences Against the Person 1861 Act, as they are replaced by the provisions in Head 2 of this Bill.

Section 58 provides for an offence of unlawfully using drugs or instruments to procure a miscarriage. Section 59 provides for an offence of unlawfully supplying or procuring poison or instruments for the purpose of procuring a miscarriage.

In so far as we are aware there is no extant common law offence of abortion which requires abolition.

The need for consequential amendments is being considered. Section 19 of the Health (Family Planning) Act 1979 provides *inter alia* that nothing in the 1979 Act shall be construed as authoring the procuring of an abortion, or the doing of any other thing the doing of which is prohibited by section 58 or 59 of the 1861 Act. The reference to the 1861 Act will require amendment to refer to the current piece of legislation.

Additional subhead being prepared in regard to consequential amendments

Head 19 Offence

Provide that

- (1) It shall be an offence for a person to do any act with the intent to destroy unborn human life.
- (2) A person who is guilty of an offence under this head is liable on conviction on indictment to a fine or imprisonment for a term not exceeding 14 years or both.
- (3) Where an offence under this Act—
 - (a) is committed by a body corporate, by a person purporting to act on behalf of a body corporate or by an individual or an unincorporated body of persons, and (b) is proved to have been committed with the consent or approval of, or to have been attributable to any neglect or connivance on the part of, any person who, when the offence was committed, was—
 - (i) a director, member of the committee of management or other controlling authority of the body concerned, or
 - (ii) the manager, secretary or other officer of the body concerned,

that person shall also be deemed to have committed the offence and may be proceeded against and punished accordingly.

(4) A prosecution for an offence under this head may be brought only by or with the consent of the Director of Public Prosecutions.

Explanatory Notes

This section restates the general prohibition of abortion in the State in clear, modern terms. It seeks to bring legal clarity to the existing situation; it does not confer any new substantive rights to a termination of pregnancy. Its provisions will replace and update those in sections 58 and 59 of the Offences against the Person Act 1861.

Subhead (1) protects the right to life of the unborn by prohibiting any act that would intentionally destroy unborn human life in a pregnant woman.

Penalties are provided for in subhead (2). There is a penalty of up to 14 years in prison or an unlimited fine, or both, for a person who intentionally performs or effects an abortion. Due to the gravity of the crime a maximum of 14 years in prison is considered an appropriate penalty. Other offences subject to a maximum of 14 years include the offence of assisting the commission of a suicide (Criminal Law (Suicide) Act 1993), and assaults causing serious harm (section 4 of the Non-fatal Offences against the Person Act 1997).

The penalty of up to 14 years imprisonment may apply to any person, including the pregnant woman. While it is recognised that the potential criminalisation of a pregnant woman is a very difficult and sensitive matter, this provision reflects the State's constitutional obligation arising from Article 40.3.3. It would also be inequitable to have, as a matter of course, a significant penalty for the person performing a termination but none at all for the woman undergoing the procedure. The sentence to be applied in any particular case is a matter for the Court involved.

The offence applies to an individual and to a body corporate or company. In addition, in the case of a company or body corporate, subhead (3) provides for offences by directors and members of the committee of management or other controlling authority of the body concerned, or the manager, secretary or other officer of the body concerned.

Subhead (4) provides that a prosecution may be brought only by or with the consent of the Director of Public Prosecutions. This is to ensure that frivolous or mischievous cases cannot be brought before the Courts.

Head 20 Commencement – with short title

- (1) This Act comes into operation on such day or days as the Minister may appoint by order.
- (2) Different days may be appointed under this head for different purposes or different provisions of this Act.

Note

This head is included on the assumption at this stage that the Act is not to come into force on enactment.