Statutory Document No. 2019/0215

Abortion Reform Act 2019

ABORTION REFORM (RECORDS AND NOTICES) REGULATIONS 2019[1]

Approved by Tynwald:	*22 May 2019*
Coming into Operation:	*24 May 2019*

The Department of Health and Social Care makes the following Regulations under section 17(1) of the Abortion Reform Act 2019.

1 Title

These Regulations are the Abortion Reform (Records and Notices) Regulations 2019.

2 Commencement

If approved by Tynwald, these Regulations come into operation on 24 May 2019[1].

3 Interpretation

In these Regulations **"the Act"** means the Abortion Reform Act 2019.

4 Recording the reasons for action

(1) Where, in accordance with the provisions of the Act—

(a) a registered medical practitioner or other relevant professional or pharmacist terminates a pregnancy; or

(b) a relevant professional or pharmacist supplies a person with a relevant product, otherwise than in fulfilment of a prescription issued by another person,

the reasons for, and the circumstances of, the termination or the supply must be recorded.

(2) The record must contain the information specified in Schedule 1 and be in the form specified in that Schedule.

[1] Tynwald approval is required by section 17(1) of the Abortion Reform Act 2019.

(3) Any record of the reason for—

(a) a surgical termination; or

(b) a medical termination, except the supply of a relevant product otherwise than in fulfilment of a prescription issued by another person,

must be made by a registered medical practitioner or other relevant professional or pharmacist before the commencement of the treatment for the termination of the pregnancy to which it relates.

(4) Any record of the reason for the supply of a relevant product, otherwise than in fulfilment of a prescription issued by another person must be made by the relevant professional or pharmacist before he or she supplies the relevant product.

(5) Despite paragraphs (3) and (4), if a termination or supply of a relevant product is necessary to prevent a substantial risk of serious injury to the woman's life or health, the record of the reason may be made within 24 hours from the termination or supply of the relevant product, but no later.

(6) The registered medical practitioner, relevant professional or pharmacist who completes the record must preserve that record for a period of at least 3 years, beginning with the date of the termination of the pregnancy or supply of the relevant product.

5 Notifications

(1) A registered medical practitioner or other relevant professional or pharmacist who—

(a) terminates a woman's pregnancy; or

(b) supplies a person with a relevant product, otherwise than in fulfilment of a prescription issued by another person,

must give notice of the termination or supply of the relevant product to the Director of Public Health.

(2) The notice must contain the information specified in Schedule 2 and be in the form specified in that Schedule.

(3) Any notice must be sent to the Director of Public Health within 14 days from the date of the termination or supply of the relevant product, by one of the following means—

(a) in a sealed envelope; or

(b) by e-mail to an e-mail address used solely by the Director of Public Health for the transfer of confidential information to him or her.

(4) The Director of Public Health must preserve, for a period of at least 3 years, beginning with the date of termination or supply of the relevant product, any information given to him or her under paragraph (1).

6 Restriction on disclosure of information

The Director of Public Health must not disclose any information furnished or document given to him or her under these Regulations, except in the following cases.

Case 1

In statistical form or in a summary or collection of information framed in such a way that the identity of any person to whom the information relates is not ascertainable.

Case 2

To an officer of the Department of Health and Social Care authorised by the Director of Public Health, for the purpose of carrying out his or her duties.

Case 3

To an individual authorised by the Director of Public Health who is engaged in setting up, maintaining or supporting a computer system for the purpose of recording, processing and holding information disclosed to the Director of Public Health under these Regulations.

Case 4

To the Attorney General or an authorised member of his or her staff, for the purpose of the Attorney General carrying out his or her duties in relation to offences under the Act or the law relating to abortion.

Case 5

To a police officer not below the rank of chief inspector or to a person authorised by him or her, for the purpose of investigating whether an offence has been committed under the Act, the law relating to abortion or offences against the person.

Case 6

Under a court order, for the purpose of proceedings which have begun.

Case 7

For the purpose of bona fide scientific research, subject to the information being provided in such a way that the identity of the woman to whom the information relates is not ascertainable.

Case 8

To the registered medical practitioner or other relevant professional or pharmacist who terminated the pregnancy or supplied the relevant product, otherwise than in fulfilment of a prescription issued by another person.

Case 9

To a registered medical practitioner or other relevant professional or pharmacist with the consent in writing of the woman —

(a) whose pregnancy was terminated; or

(b) who was supplied with a relevant product, otherwise than in fulfilment of a prescription issued by another person.

Case 10

For the purpose of investigating whether the fitness to practice of a registered medical professional, relevant professional or pharmacist (as the case may be) is impaired to—

(a) the Chief Executive and Registrar of the General Medical Council or a member of its staff authorised by him or her;

(b) the Chief Executive and Registrar of the Nursing and Midwifery Council or a member of its staff authorised by him or her; or

(c) the Chief Executive and Registrar of the General Pharmaceutical Council or a member of its staff authorised by him or her.

Case 11

To the woman whose pregnancy was terminated or who was supplied with a relevant product otherwise than in fulfilment of a prescription issued by another person, on her supplying sufficient evidence as to her identity to the Director of Public Health.

MADE 25 APRIL 2019

SCHEDULE 1

[Reg. 4]

FORM ARA1

ABORTION REFORM ACT 2019

RECORD OF THE REASONS FOR AN ABORTION

A. This form is to be completed to record the reasons for, and the circumstances of:

i. the termination of a pregnancy; and

ii. the supply of a relevant product to a woman otherwise than in fulfilment of a prescription issued by another person.

B. Unless paragraph C. applies, this record must be completed before the termination of a pregnancy is commenced or the relevant medicinal product is supplied.

C. If a termination or the supply of a relevant product is necessary to prevent substantial risk of serious injury to the woman's life or health, this record must be completed within 24 hours from the termination or supply of the relevant product.

D. This record must be preserved for at least 3 years from the date of the termination or the supply of the relevant product.

E. Please use block capitals and numerals for dates throughout.

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1. MEDICAL PROFESSIONAL/PHARMACIST

I, …….....

[Name of the medical professional/pharmacist]

……..

[Qualifications]

of……..

……..

[Permanent address]

Have/have not* seen/and examined* the pregnant woman to whom this record relates

at……..

*delete as appropriate

……..

……..

[The address at which the patient was seen/examined]

on…….

[The date on which the patient was seen/examined]

2. SPECIALIST MEDICAL ADVICE

This section is only to be completed in cases where the 24th week of the gestation period has commenced and the practitioner deemed it appropriate to take specialist medical advice.

……..

[Name of the Specialist]

……..

[Qualifications]

……..

……..

[Permanent address]

Have/have not* seen/and examined* the pregnant woman to whom this record relates

at……..

…….

[The address at which the patient was seen or examined]

on……

[The date on which the patient was seen or examined]

3. CERTIFICATION

I/we* certify that I am/we* are of the opinion, to the best of my/our* knowledge and belief, that in the case

of……..

[Full name of the patient]

*delete as appropriate

of……..

…….

[Permanent address of the patient]

3.1 Reasons

(Ring the appropriate letters/numerals)

A. The pregnancy has NOT exceeded the 14th week of the gestation period and abortion services have been requested by or on behalf of the patient.

B. The pregnancy is in the period commencing with the beginning of the 15th week and ending at the end of the 23rd week of the gestation period, abortion services have been requested by or on behalf of the patient, and one or more of the following applies in her case:

a. the continuation of the pregnancy would pose a substantial risk of serious injury to the patient's life or health;

b. there is a substantial risk that the foetus is or will be affected by a significant physical or mental impairment which will have a seriously debilitating effect on the child or will result in the death of the foetus in the womb;

c. according to the patient the pregnancy resulted from rape, incest or other unlawful intercourse; or

d. according to the patient there are serious social grounds justifying the termination of the pregnancy.

C. The start of the 24th week of the gestation period has commenced, abortion services have been requested by or on behalf of the patient and, having taken such specialist medical advice as appeared appropriate:

a. the termination is necessary to prevent grave long-term injury to her health;

b. the continuance of the pregnancy would involve risk to her life, greater than if the pregnancy were terminated;

c. there is a substantial risk that because of its physical or mental condition the foetus would die before or during labour; or

d. there is a substantial risk that, were the child born alive—

i. the child would die shortly after birth because of severe foetal developmental impairment; or

ii. the child would suffer a serious impairment which is likely to limit both the length and quality of the child's life.

3.2 Section 13 of the Act and consent

a. the termination of the pregnancy does not contravene section 13 of the Abortion Reform Act 2019 and the patient freely consents to the termination of her pregnancy and has not been coerced into doing so*;

b. section 9(2) or (4) (women under disabilities) applies.*

*delete as appropriate

…….. ……

Signature – Practitioner Date

…… ……

Signature – Specialist (if required) Date

SCHEDULE 2

[Reg. 5]

FORM ARA2

ABORTION REFORM ACT 2019

ABORTION NOTIFICATION

Notes

1. This form is to be completed by the registered medical practitioner, other relevant professional or pharmacist who:
   a. terminated the pregnancy; or
   b. supplied the woman with a relevant product, otherwise than in fulfilment of a prescription issued by another person.
2. This form is to be sent to the Director of Public Health within 14 days of the date of the termination or the supply of a relevant medicinal product otherwise than in accordance with a prescription issued by another person.
3. This form can either be:
   a. posted or hand delivered in a sealed envelope marked "Private and Confidential" to:

      Director of Public Health

      Department of Health and Social Care, Public Health Directorate

      Cronk Coar

      Noble's Hospital

      Douglas

      IM4 4RJ; or

   b. sent electronically, marked "Private and Confidential" to [an e-mail address identified by the Director of Public Health].
4. When completing this form please use block capitals and numerals for dates throughout.

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1. MEDICAL PROFESSIONAL/PHARMACIST

Please detail below the name of the medical professional/pharmacist that terminated the pregnancy or supplied the relevant product, otherwise than in fulfilment of a prescription issued by another person.

Full name: ……

Permanent address: ……

Regulatory body: ……

Registration number: ……

give notice that I terminated the pregnancy of/supplied a relevant product, otherwise than in fulfilment of a prescription issued by another person to* the woman identified overleaf and to the best of my knowledge and belief the particulars on this form are correct.

…….. ……

Signature Date

*delete as appropriate

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2. CERTIFICATION

Please detail below the particulars of the medical professional/pharmacist who completed Form ARA1.

Medical professional/pharmacist

Full name: ……

Permanent address: ……

Did the medical professional/pharmacist certify that s/he saw/and examined the pregnant woman before giving the certificate: Yes/No

In a case where the 24th week of the gestation period had commenced and the practitioner deemed it appropriate to take specialist medical advice, please state the particulars of the specialist that joined in giving Form ARA1:

Specialist

Full name: ……

Permanent address: ……

Did the specialist certify that s/he saw/and examined

the pregnant woman before giving the certificate: Yes/No

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3. PATIENT'S DETAILS

a) Patient's reference

Patient's hospital/clinic or NHS number: ……..

If the patient's hospital/clinic or NHS number is not available enter her full name below.

.....……

b) Date of birth

.....……..

c) Postcode

Full postcode: ……

If the full postcode is not available enter the full address below.

……

.....……..

d) Country of residence

For non-Isle of Man residents state the country of residence below.

.....……..

e) Ethnicity

Note: Please tick the patient's self-reported ethnicity below.

White - British	Mixed – White and Black Caribbean
White - Irish	Mixed – White and Black African
White – Any other White background	Mixed – White and Asian
	Mixed – Any other
Asian or Asian British – Indian	Black or Black British - Caribbean
Asian or Asian British – Pakistani	Black or Black British – African
Asian or Asian British – Bangladeshi	Black or Black British – Any other
Asian – any other Asian background	
Chinese	Any other ethnic group
Not known/not stated	

f) Marital status

Note: Please tick the patient's self-reported marital status below.

Single no partner

Single with partner

Single not stated

Married/civil partnership

Separated/widowed/divorced

Not known and not stated

g) Parity

Number of pregnancies resulting in:

Live births and stillbirths over 24 weeks …….	Spontaneous miscarriages and ectopic pregnancies…….	Legal terminations ……

(if nil enter 0)

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4. TREATMENT DETAILS

a) Name and address of the place of termination, including the place of treatment with anti-progesterone

……
……
……

Hospital/clinic code: ……

Specify whether this was an NHS or privately funded abortion: ……

b) Feticide

Note: If feticide is used complete this section, otherwise proceed to 4c) or 4d), as appropriate.

Date of feticide: …….....

Method of feticide: …….....

c) Surgical termination

Date of termination: …….....

If the date of admission or discharge is different from the date of termination please complete the following:

Date of admission to place of termination: ……..

Date of discharge from place of termination: ……..

Please tick/specify the method used:

Vacuum aspiration/suction:

Dilatation and evacuation:

Other surgical – specify:

Note: an evacuation of retained products of conception is not a termination and should not be entered. Please now go to section 5.

d) Medical termination

Date of treatment with Anti-progesterone: ……..

Date of treatment with Prostaglandin: ……..

Date termination confirmed: ……..

Name and address of place of treatment with Prostaglandin (if different from the address at section 4a))

.....

…….....

.....

Hospital/clinic code:

If other medical agents were used, specify:

Date of treatment: ……..

Medical agent used: ……..

(*Note:* if an overnight stay was required please also complete date of discharge in section 4c) above)

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5. GESTATION

Specify the number of completed weeks: ……

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6. REASONS FOR TERMINATION

The certified grounds for terminating the pregnancy stated on Form ARA1 were:

(Ring the appropriate letters/numerals)

A. the pregnancy had NOT exceeded the 14th week of the gestation period and abortion services had been requested by or on behalf of the patient.

B. the pregnancy was in the period commencing with the beginning of the 15th week and ending at the end of the 23rd week of the gestation period, abortion services were requested by or on behalf of the patient and one or more of the following applied in her case:

a. the continuation of the pregnancy would have posed a substantial risk of serious injury to the patient's life or health:

state the main medical condition(s):

……

……

……..

b. there was a substantial risk that the foetus was or would be affected by a significant physical or mental impairment which would have had a seriously debilitating effect on the child or would have resulted in the death of the foetus in the womb:

i. state the significant physical or mental impairment:

…….

ii. state the method of diagnosis:

Amniocentesis

Ultrasound

Chorionic villus sampling

Other – specify

c. according to the patient the pregnancy resulted from rape, incest or other unlawful intercourse; or

d. according to the patient there were serious social grounds justifying the termination of the pregnancy.

State the social grounds given:

……...
……...
……...

C. The 24th week of the gestation period had commenced, abortion services had been requested by or on behalf of the patient and, having taken such specialist medical advice as appeared appropriate to the practitioner:

a. the termination was necessary to prevent grave long-term injury to her health;

b. the continuation of the pregnancy would have involved risk to her life, greater than if the pregnancy was terminated;

For a. or b. state the main medical condition(s):

…….
…….
…….

c. there was a substantial risk that because of its physical or mental condition the foetus would have died before or during labour;

i. state the main medical condition(s):

……..
…….
…….....

ii. the method of diagnosis:

Amniocentesis

Ultrasound

Chorionic villus sampling

Other – specify

d. there was a substantial risk that, if the child was born alive—

i. the child would have died shortly after birth because of severe foetal developmental impairment; or

ii. the child would have suffered a serious impairment which would have been likely to limit both the length and quality of the child's life.

iii. state the impairment:

……
……
……..

iv. the method of diagnosis:

Amniocentesis

Ultrasound

Chorionic villus sampling

Other – specify

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8. SELECTIVE TERMINATION

If this was a selective termination, state:

a) Original number of foetuses: ……

b) Number of foetuses reduced to:……

(*Note:* All other relevant sections of this form should also be completed)

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9. CHLAMYDIA SCREENING

Was screening for chlamydia offered: Yes…… No……

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10. COMPLICATIONS (up until the time of discharge)

(*Note:* tick the appropriate box(es))

None Haemorrhage Uterine Perforation Sepsis

Other, please specify

(*Note:* an evacuation of retained products of conception is not a complication)

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11. DEATH OF A WOMAN

In the case of death, specify:

Date of death:……..

Cause of death:…….....

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ENDNOTES

Table of Endnote References

[1] The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.