Abortion (Scotland) Amendment Regulations 2021 – changes to how information about abortions is provided

Business and Regulatory Impact Assessment

December 2021

Scottish Government
Riaghaltas na h-Alba
gov.scot

Contents

1. Title of Proposal

The draft Abortion (Scotland) Amendment Regulations 2021 ("the Regulations").

2. Purpose and intended effect

The Abortion (Scotland) Amendment Regulations 2021 (the 2021 Regulations) amend the Abortion (Scotland) Regulations 1991 ("the 1991 Regulations") to change the arrangements by which notifications of a termination of a pregnancy must be given to the Chief Medical Officer (CMO) by a registered medical practitioner (RMP – in other words a doctor) who has carried out the termination of pregnancy.

The changes aim to modernise the process for providing notifications to the CMO and also streamline the process by which data about abortions is submitted by providers, which is currently via the CMO as part of the notification. The 2021 Regulations will make the following changes to the 1991 Regulations:

- increase the deadline for giving notice of a termination from "within 7 days" of the termination to "before the fifteenth day of the calendar month immediately following the calendar month in which the practitioner terminated the pregnancy";
- remove the restriction that notifications must be sent by post or delivered in a sealed envelope, so allowing notice to be given using electronic communication as an alternative;
- remove the form currently prescribed in the 1991 Regulations (which is commonly known as the 'yellow form') which requires information to be provided including about the woman who has had a termination, the termination itself and the doctor who terminated the pregnancy;
- require a simpler notification to be sent to the CMO containing only the name of the doctor who terminated the pregnancy and the name of the doctor's employer (Health Board or private abortion provider).

Currently, patient data provided as part of a notification is used by Public Health Scotland (PHS) to create abortion statistics. As a consequence of the fact that detailed patient data will no longer be part of the notification to the CMO, arrangements will be put in place by PHS to receive this data directly from providers electronically, for the purpose of producing abortion statistics.

To provide assurance that patient data will continue to be collected by PHS for the creation of statistics, the intention is that Scottish Ministers will issue a Direction to Health Boards requiring that they provide such data to PHS. The one approved private provider has given an undertaking to provide data directly to PHS.

2.1 Background

There are over 13,000 terminations carried out every year in Scotland. The Abortion Act 1967 sets out legal requirements which must be met before an abortion can be carried out lawfully in Scotland. The Act requires the Scottish Ministers to make regulations to require the RMP who terminates a pregnancy to give notice of the termination, and such other information as the Ministers wish to provide for in those regulations, to the CMO.

The 1991 Regulations set out requirements which must be met in relation to the notifications made to the CMO. They require that notifications are made within seven days of the abortion taking place; that notifications must be sent by post or delivered in a sealed envelope, and that they must include certain information, as currently prescribed by the yellow form included in Schedule 2 of the 1991 Regulations.

The Regulations permit the information provided in the notification forms to be shared by the CMO with PHS, which uses the information contained in the forms to produce abortion statistics.

Current practice

Currently, the 'yellow form' is filled in by hand, usually by NHS Board admin staff, and signed by the relevant doctor. Patient data, including that provided as part of the consultation with the patient, is usually retrieved from NHS IT systems in order to complete the form.

The forms are placed in sealed envelopes and are sent by courier or recorded delivery, or hand delivered, to the CMO within seven days of the abortion taking place. The CMO's office then transports the envelopes to PHS. Staff in PHS then enter the data they require from the forms onto its Abortion Act Scotland electronic database in order to allow them to compile abortion statistics. The hard copies of the forms are kept securely locked away for six years before being securely destroyed.

2.2 Rationale for Government intervention

The 2021 Regulations are necessary to enable notifications to the CMO to be sent electronically (for example by email) and to update the requirements around notifications to ensure that special category (formerly known as 'sensitive') personal data is no longer sent to the CMO in order reduce data security risks. The extended time limit for notifications also takes account of the fact that some doctors find it difficult to meet the seven day timescales due to work pressures.

These changes are needed to improve the security of personal data provided for the abortion statistics and reduce any risks of a data breach by asking providers to submit this directly to PHS in future via secure electronic means, rather than submitting the data to CMO on paper forms and CMO's office then transferring the forms on to PHS to enter the relevant information in their database. While steps are already made to mitigate risks of data security breaches, minimising the numbers of individuals needing to handle and having access to the data, as well as using electronic transfer, is expected to reduce risks further. Given that most other health data is already provided directly to PHS electronically, this will ensure data is provided in a more efficient and secure way.

3. Consultation

3.1 Public consultation

A public consultation[1] on the proposed changes ran between 1 March 2021 and 30 April 2021. The consultation was open to anyone to respond to. The consultation was circulated to the Scottish Abortion Care Providers (SACP) group and NHS Boards, to the one approved private abortion provider in Scotland and to other stakeholders with an interest, such as Public Health Scotland, the Information Commissioner's Office and groups representing women.

The consultation received 35 responses, of which 15 were from organisations and 20 were from individuals. Many individual respondents either indicated a clinical background or submitted responses from NHS email addresses. Organisational respondents included NHS organisations, including Public Health Scotland, private abortion care providers (not based in Scotland), faith organisations, pro-life groups, and women's organisations.

The analysis[2] of the consultation responses shows that overall responses were in favour of the proposed changes, with the greatest support for enabling electronic submission of notifications (91%), followed by permitting a period longer than seven days in which to do so provide notifications (79% of those who answered the question, with the greatest proportion supporting a one month period – 45%) and enabling data to be provided directly to PHS (73% of those who answered the question).

Comments in support of the specific proposals mainly focused on the benefits in terms of streamlining processes, providing increased flexibility and increased data privacy. The future data requirements was a key area of focus for those who caveated their support for the proposals, including the need to ensure transparency about data requirements and the opportunities for increased/improved data collection. Responses also focused on the practicalities of moving from one system to another and the need to ensure synchronisation and no data loss as a result.

3.2 Within government

The proposals have been discussed and developed with internal colleagues in the following areas: data protection, CMO's office, Scottish Government Legal Directorate and the team which sponsors Public Health Scotland.

3.3 Business

There is only one private provider of abortion services approved by Scottish Ministers (BMI Ross Hall Hospital) which provides a very small number of

[1] https://www.gov.scot/publications/abortion-notifications-data-consultation-changing-process-giving-notice-abortion-providing-information-abortions/

[2] https://consult.gov.scot/population-health/abortion-notifications-and-data/

terminations per year, typically fewer than five. BMI Ross Hall Hospital was invited to respond to the consultation. It did not respond in writing, but the Scottish Government subsequently arranged a meeting with them (along with PHS) to discuss the proposals.

4. Options

The Scottish Government has considered three main options for abortion notifications as follows:

- **Option 1: Do nothing**
- **Option 2: Allow electronic submission of data, but still via CMO**
- **Option 3: Allow simple electronic (email) notifications to CMO, with patient abortion data submitted directly to PHS**

4.1 Sectors and groups affected

These proposed changes affect abortion providers – in this case this is those services operated by NHS Boards and the one private provider which is approved by Scottish Ministers to provide abortions in Scotland. The changes will also affect PHS. All these groups have been involved in discussions and/or the public consultation on the proposals and have been generally supportive of the proposals.

4.2 Costs and Benefits

Option 1: Do nothing

This option would involve the 1991 Regulations and the arrangements they provide for remaining in place, with notifications and patient data being sent on paper forms to the CMO within 7 days, for onward transmission to PHS.

This option presents no additional costs e.g. for updating electronic systems. However it would mean that the current inefficient approach is retained requiring data to go, in hard copy, via the CMO, which includes additional risks to data security.

It would continue to require providers to fill in notification forms on paper and send or deliver them to the CMO's office for onward transmission to PHS. PHS staff would then continue to type the information into their database for use to produce the abortion statistics. The paper forms would continue to need to be stored securely for six years and then securely destroyed.

Option 2: Allow electronic submission of data, but still via CMO

This option would involve the establishment of an electronic system for providers to submit notifications and patient data to the CMO and for the CMO to submit patient data to PHS.

This option would include costs for Scottish Government for the setting up of the new system and costs for PHS to update its systems to receive data electronically from the Scottish Government (CMO). It would not be expected to include additional

costs for providers as instead of entering the data by hand on the paper form, it would be entered directly onto the electronic system.

This approach would enable providers to provide just one set of data (notification of the termination and patient data), via a web-based form or IT system, to CMO, who would then be able to share the data with PHS, ideally through an automated system to avoid CMO office staff having to manually enter the data.

This would have the benefit of making the process electronic and so minimise risks of errors or missing data in the forms (for example through drop down boxes or mandatory data fields in the form). It would also reduce postal costs for abortion providers and would reduce the impacts of printing around 13,000 papers forms per year (printed by Scottish Government), which are transported to and from providers and from CMO's office to PHS.

However, this approach would still have the disadvantage and potential risks of CMO receiving personal data about patients and passing it on to PHS, albeit electronically. In order to comply with the requirements of the Abortion Act 1967, the IT system required would also be likely to be more complex as the data would need to come to the CMO first (through the Scottish Government firewall) and then be released on to PHS (as the data could not be sent to both parties at the same time).

Option 3: Allow simple email notifications to CMO, with patient abortion data submitted directly to PHS

The third option, which is the proposed option, would involve RMPs sending notification of terminations to the CMO which include no patient data, by email. In practice, RMPs would notify multiple terminations at once, by indicating the number of terminations they have carried out over a specific time period.

Patient data would be sent directly from providers to PHS, using an existing electronic system, which will be updated for this purpose. The specific range of data to be provided to PHS in relation to each termination would be established separately by PHS in discussion with providers (they have already had initial discussions on this). As part of that discussion, PHS is discussing with providers the information they currently collect in order to ensure as far as possible that they seek data from providers which is either already collected or can readily be provided.

The CMO's office would compile the notifications and share numerical data from them (the number of terminations per NHS Board) with PHS so PHS could compare against the data it is receiving from Boards to ensure it is receiving data in relation to all terminations.

This option, which is the proposed option, will include costs for PHS associated with the updating of its IT system to receive detailed abortion data directly from providers electronically, rather than through paper forms sent via the CMO. The estimated cost of this is approximately £36,000 to enable NHS Board staff to have access to allow them to enter data directly into PHS' IT system (although NHS Boards will only have access to the records they have entered into the system and not to any other data in the database). This investment will allow for future proofing so that, for example categories of drop down options can be easily updated in future. It would

also involve reduced data entry work for PHS as its staff would no longer need to input data from the yellow forms, as this would be done by the individual providers.

It is not expected to lead to additional costs for providers, as they will still be providing patient data per abortion, but will enter it directly into the PHS electronic system, rather than by hand onto the yellow form. Using an electronic form with drop down options should make the completion of the data less time consuming than having to enter all the fields in writing by hand and will also reduce the potential for missing data which requires to be queried by PHS and therefore often needs Board staff to check to find the missing data.

This option has the benefit of streamlining the process to avoid the risks associated with the CMO receiving and needing to pass on personal data about patients. By enabling personal and other data about patients having abortions to be provided directly to PHS by providers via secure means this minimises the number of people having access to this sensitive data and therefore should help ensure data security.

Increasing the timescale in which RMPs must provide notifications to the CMO, and enabling notifications of multiple abortions to be provided at once, meaning in effect a notification can be made monthly, will have a benefit for providers.

5. Scottish firms impact test

Scottish Government and PHS officials held a meeting with BMI Ross Hall hospital to discuss the proposed changes, both to the notifications process and the transfer of patient data to PHS. Ross Hall was content that the changes to notifications would be minimal and would be able to be implemented easily as it would involve only sending an email to the CMO instead of a paper notification form. There would be no costs associated with this change. Ross Hall and PHS are exploring the most appropriate option for the secure transfer of patient data directly to PHS as it may not be possible for it to use the secure portal into the PHS system. Similar to the notifications side of the process, Ross Hall was content that the changes would be minimal as it would involve entering similar levels of patient data, but just potentially in a different format. It is not expected that any of the options will attract a cost.

6. Competition assessment

The proposal will have no impact on competition.

7. Consumer assessment

The proposal will have a positive impact on patients accessing abortion services as the arrangements will provide improved handling of their personal data, therefore limiting further those who have access to the data and minimising any risks of data security breaches.

8. Test run of business forms

The proposal will not introduce any new forms. PHS will be responsible for making adaptations to its existing IT system to receive data directly from providers and ensuring that providers are able to use it efficiently.

9. Digital impact test

The proposal amends the current inflexible approach which mandates that notifications must be made only on paper by allowing them to also be made electronically (in practice by email).

10. Legal aid impact test

Access to legal aid will not be impacted by this policy.

11. Enforcement, sanctions and monitoring

It is a legal requirement for an RMP to provide notification of any termination carried out to the CMO and the proposals do not change that. Providers will no longer provide patient data as part of the notification and so, to ensure that there is assurance that patient data will continue to be collected by PHS for the creation of statistics, the intention is that Scottish Ministers will issue a Direction to NHS Boards requiring that they provide such data to PHS. As mentioned above, the one approved private provider in Scotland has given an undertaking to provide data directly to PHS.

12. Implementation and delivery plan

The Regulations will come into force on **1 May 2022**. We have worked closely with PHS and NHS Boards to ensure that the PHS system will be able to be operationalised at that point and that providers will be able to use it. PHS is developing implementation plans for the introduction of its new system to ensure it can receive patient data directly from providers from that point and will also produce guidance and deliver training. Separately, guidance will be produced from the CMO's office to assist with the implementation of the new arrangements for notifications to the CMO.

12.1 Post-implementation review

We will work with PHS and providers to monitor the implementation of the new arrangements, including through the Scottish Abortion Care Providers Network. No formal review period is included.

13. Summary and recommendation

Option 3 is being recommended as this provides the strongest mitigation against potential data risks including sensitive patient data and provides for more efficient and practical arrangements for the supply of data for abortion statistics. As detailed in section 4.2 there are costs associated with this option in the form of the adaption of the existing PHS IT system. These costs are relatively small and are justified by the benefits the new arrangements will provide.

14. Declaration and Publication

"I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and

impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland."

Signed: 

Date: 29 November 2021

Minister's name: Maree Todd MSP
Minister's title: Minister for Public Health, Women's Health and Sport

Scottish Government contact point:

Sam Baker
Health Protection Division
Directorate for Population Health
sam.baker@gov.scot

This publication is available at **www.gov.scot**

Any enquiries regarding this publication should be sent to us at

The Scottish Government
St Andrew's House
Edinburgh
EH1 3DG

ISBN: 978-1-80201-728-1 (web only)

Published by The Scottish Government, December 2021

Produced for The Scottish Government by APS Group Scotland, 21 Tennant Street, Edinburgh EH6 5NA
PPDAS984906 (12/21)