CARE SUBMISSION TO THE SECONDARY LEGISLATION SCRUTINY COMMITTEE ABORTION (AMENDMENT) REGULATIONS 2022

1. On 14 July the Abortion (Amendments) Regulations 2022 were laid before Parliament.[1] The objection period ends on 30 October.

2. The Regulations amend the notification arrangements that operate under section 2 of the Abortion Act 1967 because of changes to section 1 of the Act made under the Health and Care Act 2022. The changes apply only in England and Wales and come into effect on 30 August 2022.[2] The law will allow abortions before 10 weeks gestation (referred to in these Regulations as Early Medical Abortion (EMA) cases[3]) to take place at home using medical abortion pills and allow women to be prescribed the pills via telemedicine.

Issue (a) that it is politically or legally important or gives rise to issues of public policy likely to be of interest to the House

3. Abortion is a sensitive political issue. The majority of those who responded to the Government consultation on the arrangements for early medical abortion introduced during the pandemic did not support making it permanent.[4]

4. CARE wishes to raise several points about the **amendments to the requirements for the HSA4 notification form.**[5] This is the form used to notify the Chief Medical Officer of the abortion and various information about the woman within 14 days of the abortion.[6] The HSA4 form was originally detailed in the Abortion Regulations 1991[7] and previously updated in The Abortion (Amendment) (England) Regulations 2002 and the Abortion (Amendment) (Wales) Regulations 2002.[8]

5. The 2022 amendments set out several new requirements when the woman takes one or two pills at home.[9] The notification requirement includes a requirement to be clear whether one or two medications have been taken at home. CARE strongly welcomes the positive new requirement to confirm whether the patient's consultation took place without any face-to-face contact.[10]

6. As currently specified in the notification requirements for non-surgical means, and continued in these Regulations,[11] it would be very helpful if the provider was able to confirm that the home abortion had taken place. Current guidance says, "*If the termination cannot be confirmed, you should leave the 'Date termination confirmed' box blank. If, after sending the form, it is found that the pregnancy has not ended, a letter must be sent to the CMO and the form will be cancelled.*"[12] As there is no requirement for the patient to confirm that the abortion took place nor the provider to conduct any patient follow-up, it seems

1 https://www.legislation.gov.uk/uksi/2022/811/made
2 See section 178 of the Health and Care Act 2022
3 Regulation 2(2)(b)
4 https://www.gov.uk/government/consultations/home-use-of-both-pills-for-early-medical-abortion/outcome/home-use-of-both-pills-for-early-medical-abortion-ema-up-to-10-weeks-gestation-summary-of-consultation-responses
5 As set out in the Schedule of Abortion (Amendment) (England) Regulations 2002 and Abortion (Amendment) (Wales) Regulations 2002
6 Guidance notes for completing HSA4 paper forms Department of Health and Social Care
7 https://www.legislation.gov.uk/uksi/1991/499/contents/made
8 https://www.legislation.gov.uk/uksi/2002/887/contents/made and https://www.legislation.gov.uk/wsi/2002/2879/contents/made
9 Regulation 2(4)(b) and 2(4)(d). New paras 7A, 8A and 8B of Schedule 2 to the Abortion Regulations 1991
10 Regulation 2(4)(b). New para 7A(a)(ii)
11 Regulation 2(4)(d). New para 8A(d)
12 Guidance notes for completing HSA4 paper forms Section 4: Medical terminations

unlikely this requirement is going to provide any additional data and could count abortions that never occurred if a woman changes her mind.

7. CARE is disappointed that under Regulation 3, the changes on notification come into effect on 31 December 2022 (i.e. 4 months after the changes to the Abortion Act come into effect) which seems unnecessary as most of this data has been collected and reported during the pandemic.[13] Furthermore, it is optional for providers to give notification under these new arrangements if the abortion takes place before 1 April 2023. They can choose to provide data under the old arrangements which could make the 2023 statistical data opaque. The Government press release of 23 August says that new data requirements "*will allow for analysis of trends in abortion provision as well as monitoring pathways for home-use abortions*."[14] However, this stepwise implementation of information that has been collected since March 2020 will likely not allow for trend analysis based on the 2023 data.

8. Very regrettably, there are no changes to the required information to address concerns about the recording of abortion complications which has been acknowledged in several PQs[15] and in the Guide to the Abortion Statistics 2020[16] and 2021 where the latter says, "*This means that for terminations where either both or the second stage was administered at home, complications may be less likely to be recorded on the HSA4. [The Office for Health Improvement and Disparities (OHID)] is currently undertaking a project to review the system of recording abortion complications data to address this going forward*."[17] It is disappointing that this issue has not been addressed since telemedicine was introduced in March 2020 and work on reviewing the recording of abortion complications was due to be completed before the end of 2021.[18]

Issue (f) that there appear to be inadequacies in the consultation process which relates to the instrument

9. There has been no public consultation on the Regulations where the public could have raised the points above.

30 August 2022

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[13] See Abortion statistics during the coronavirus pandemic: January to June 2020; Abortion statistics 2020: additional tables; Abortion statistics 2021: additional tables

[14] https://www.gov.uk/government/news/at-home-early-medical-abortions-made-permanent-in-england-and-wales 23 August 2022

[15] UIN 164679, answered 30 March 2021, "The Department acknowledges there are limitations with the abortion complications data that is collected. We are planning to examine with partner organisations how well these systems are working in relation to recording complications arising from abortions and whether improvement is required." Also UIN 178577, answered 22 April 2021,

[16] https://www.gov.uk/government/statistics/abortion-statistics-for-england-and-wales-2020/guide-to-abortion-statistics-england-and-wales-2020 - see section 2.8

[17] https://www.gov.uk/government/statistics/abortion-statistics-for-england-and-wales-2021/guide-to-abortion-statistics-england-and-wales-2021#data-quality

[18] UIN 20373, answered 29 June 2021. On 20 December 2021, the project was due "to be completed shortly". See UIN 92108

Response from the Department of Heath and Social Care

Q1: Current guidance says, "If the termination cannot be confirmed, you should leave the 'Date termination confirmed' box blank. If, after sending the form, it is found that the pregnancy has not ended, a letter must be sent to the CMO and the form will be cancelled." As there is no requirement for the patient to confirm that the abortion took place nor the provider to conduct any patient follow-up, it seems unlikely this requirement is going to provide any additional data or count abortions that did not occur because a woman changed her mind.

A1: This advice is set out in guidance to doctors on completing abortion notification forms. It does not specifically relate to the Abortion (Amendment) Regulations 2022. Abortion providers will have systems in place locally regarding the completion of abortion notifications and follow up contact with patients.

Q2: If there is no requirement to confirm that the abortion took place how is the medical professional to be sure that the applicant was the one who actually took the pills (and did not pass them on to a friend/relative for use)? We assume this is why the "in good faith" element has been added since the practitioner is reacting to the information provided by the patient and cannot be held responsible if given incorrect dates or information during a remote consultation.

A2: During the consultation, the doctor should explain to the patient the legal requirements regarding the supply and use of abortion pills. It is a criminal offence to procure abortion pills by deception.

Q3: This system enabling remote authorisation and administering of the pills has been in effect since March 2020 and the writer suggests that there will be some discontinuity in the data as a result of the staggered implementation dates

A3: There will be no discontinuity of data during the transition period. The information that has been collected through abortion notifications on where pills were administered since March 2020 will continue to be collected. The transition period relates to the collection of additional information, such as whether the abortion pathway was fully remote. The transition period is required in order to provide time for DHSC and abortion providers to amend and test their IT systems to ensure there is a smooth transition.

Q4: The submission states that despite responding to several PQs on the issue the SI does not address concerns about the recording of abortion complications. The Guide to the Abortion Statistics 2021 says, "This means that for terminations where either both or the second stage was administered at home, complications may be less likely to be recorded on the HSA4. [The Office for Health Improvement and Disparities (OHID)] is currently undertaking a project to review the system of recording abortion complications data to address this going forward" which was due to be completed before the end of 2021.

A4: The Department conducted a review of abortion complications data in 2021 which identified a number of areas where action could be taken to improve the quality of data available. We are aware that data collected via HSA4 abortion notification forms indicates a decrease in the medical abortion complication rate which coincided with the uptake in taking both pills for early medical abortion at home. The work included reviewing information held in existing data systems to identify any additional sources of information that could be used to complement complications data collected via HSA4 abortion notification forms. There is

also ongoing work looking at reviewing and improving the reporting of serious incidents and the flow of data between organisations, with a view to building clinical consensus on the definition of complications and serious incidents in relation to abortions. Officials are now working to take this forward and will provide further updates in due course.