EXPLANATORY MEMORANDUM TO

THE ABORTION (AMENDMENT) REGULATIONS 2022

2022 No. 811

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (DHSC) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument amends the Abortion Regulations 1991 ('the 1991 Regulations') to make provision for certifying an opinion under section 1(3B) of the Abortion Act 1967 and set outs the information required to be notified to the Chief Medical Officer where a pregnancy is terminated under 10 weeks gestation known as Early Medical Abortion (EMA).

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England and Wales.

5. European Convention on Human Rights

5.1 As this instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 This instrument is required following amendments made by the Health and Care Act 2022 to section 1 of the Abortion Act 1967 to insert new sub-sections (3B) to (3D) into that Act. These new sub-sections permit the medicine for Early Medical Abortion to be taken at the home of the pregnant woman and to permit registered medical practitioners (RMPs) to prescribe the medicine for EMA from their home, provided certain conditions are met.

6.2 The changes to the Abortion Act require consequential amendments to the Abortion Regulations 1991 to meet the requirement under section 2(1) of the Abortion Act to make Regulations setting out how the RMP must certify any opinion referred to in section 1 of that Act. This instrument therefore prescribes how the RMP must certify the opinion formed in good faith as to the gestation of the pregnancy in order for EMA at home to be permitted, as required by new section 1(3B).

6.3 In addition, the changes to section 1 of the Abortion Act to permit EMA at home necessitate consequential amendment to the notification requirements that are placed on the RMP who terminated the pregnancy under regulation 4 of the 1991 Regulations to ensure that the notification information that is required to be submitted to the Chief

Medical Officer following a termination accurately reflects the new provisions in relation to EMA at home.

7. Policy background

7.1 The Abortion Act 1967 sets out the legal framework under which termination of pregnancy may be carried out in England and Wales. Prior to the amendment by the Health and Care Act 2022, the Abortion Act provided that, except in an emergency, an abortion was permitted only in an NHS hospital or in a place approved by the Secretary of State.

7.2 EMA is the termination of a pregnancy by medical (non-surgical) means where the pregnancy is under 10 weeks and currently involves the taking of two pills. In 2018, the Secretary of State used section 1(3) of the Abortion Act to approve the home of a pregnant woman in England as a place where EMA was permitted, provided that the first pill was taken in a clinic approved by the Secretary of State or in a hospital and that the pregnancy had not exceeded 10 weeks when the first pill was taken. Welsh Ministers made a similar approval which applied in Wales. Under this approval, women could attend a clinic to take the first EMA pill (mifepristone, which is an antiprogestrone) and had the choice of taking the second EMA pill (misoprostol, which is a prostaglandin) at home or in the clinic (either taking this simultaneously with the first pill or returning to the clinic 24 to 48 hours after taking the first pill).

7.3 In March 2020, DHSC Ministers put in place a temporary approval in England, enabling women to take both pills for EMA in their own homes. This was provided that the pregnancy had not exceeded 10 weeks when the first pill was taken and that the patient had had a consultation about the termination of the pregnancy by telephone, video call or in person and was considered eligible for home EMA. This approval removed the need for most women eligible for EMA to attend a hospital or clinic first. The approval was put in place to reduce the risk of Covid-19 transmission and ensure continued access to abortion services during the pandemic. The approval also allowed RMPs in England to prescribe EMA medication from their homes. The temporary approval was set to expire on 28 March 2022 or when the temporary provisions in the Coronavirus Act expired, whichever was sooner. Welsh Ministers made a similar approval in respect of pregnant women and RMPs' homes in Wales.

7.4 In November 2020, following a commitment made in Parliament on 6 July 2020, DHSC ran a public consultation on whether the temporary approval should be made permanent in England. In February 2022, DHSC published a summary of responses to the consultation and announced that home use of both pills for EMA would end in England on 29 August 2022, after which point the pre-COVID arrangements would be reinstated, and women would have to attend a clinic to take the first EMA pill (mifepristone), while continuing to have the choice of taking the second EMA pill (misoprostol) at home or in the clinic. A further temporary approval was published with the revised 29 August 2022 expiry date to ensure abortion providers had sufficient time to revert to the 2018 arrangements. In February 2022, Welsh Ministers announced that home use of both pills for EMA would be a permanent arrangement in Wales.

7.5 In February 2022 when the Health and Care Bill was being considered by Parliament, an amendment was tabled in the Lords to amend the Abortion Act to make the arrangements permitted under the temporary approval permanent.

7.6 The amendment was further amended and was passed in both Houses of Parliament, on a free vote on 30 March 2022. This amendment became section 178 of the Health and Care Act 2022 and commences on 30 August 2022 to coincide with the temporary approval ending on 29 August 2022.

7.7 Section 178 of the Health and Care Act 2022 amends section 1 of the Abortion Act by inserting new sub-sections (3B) to (3D). These sub-sections permit the home of a pregnant women in England or Wales to be a place where termination of pregnancy is permitted and the home of a RMP in England or Wales to be a place where the medication used for termination of pregnancy may be prescribed, provided that the conditions set out in section 1(3B) are met.

7.8 The circumstances in which home use and home prescription are permitted are set out in section 1(3B) and mirror the conditions that were set out in the temporary approval. Section 1 (3B) also includes a requirement that the RMP must be of the opinion, formed in good faith, that the pregnancy will not exceed 10 weeks at the time when the medicine (in the case of two pills, the first pill) is administered. The good faith requirement mirrors the good faith requirement under section 1(1) in relation to grounds for termination. This provision ensures that a termination will not be unlawful where, as a matter of fact, the pregnancy has exceeded 10 weeks, provided the opinion as to gestation was given in good faith. This good faith wording was not included in the original amendment but was included prior to the vote as a safeguard for practitioners.

7.9 Section 2 of the Abortion Act requires the Secretary of State to make Regulations to set out how any opinion required under section 1 is to be certified. Accordingly, this instrument makes consequential amendments to the 1991 Regulations to set out how the opinion required under section 1(3B) must be certified. The new certification requirement comes into force on 30 August 2022 to coincide with the commencement of section 178 of the Health and Care Act and ensures that the Secretary of State has met his statutory duty under section 2(1)(a) of the Abortion Act.

7.10 The 1991 Regulations also set out the information that must be notified to the Chief Medical Officer (CMO), as required by section 2(1)(b) of the Abortion Act and regulation 4 of the 1991 Regulations. This is to ensure that the CMO in England and the CMO in Wales have data relating to terminations in England and Wales to enable them to monitor compliance with the Abortion Act and to publish annual abortion statistics. The information that is required to be provided to the CMO under regulation 4 of the 1991 Regulations must be provided within 14 days of the termination and may be submitted to the CMO either electronically or on a form issued by DHSC known as the "HSA4 form". The HSA4 form pre-dates the 2018 and 2020 temporary approvals. The additional information which these Regulations require to be notified in relation to early medical abortion (EMA) will enable the Secretary of State to update the HSA4 form to ensure it accurately reflects the treatment options for early medical abortion now it is permanently available. This in turn will provide DHSC with the information to accurately analyse the full impact of the change for patients and providers, monitor patient pathways for example by being able to analyse how many women are treated entirely via remote telemedicine and how many attend a clinic for some or all of the treatment, and to monitor compliance with the Act.

7.11 This instrument makes consequential amendments to Schedule 2 of the 1991 Regulations to require additional information to be notified in relation to the use of

abortion medicines at home, including the place and date of termination. It includes options to cover where both or one of the medicines is taken at home or where treatment was entirely in clinic, as well as whether the patient pathway was completely remote. The Secretary of State uses this information to produce the annual abortion statistics which are published on gov.uk. The HSA4 form and electronic version will be updated to ensure that they reflect the additional information that will be required.

7.12 To ensure that both DHSC and providers have sufficient time to update their respective data systems to allow this additional data to be submitted by providers and processed by DHSC, providers will only be required to submit the new additional information where the prescription for EMA was prescribed after 1 April 2023. From 31 December 2022 until 1 April 2023 providers can choose whether to submit the new HSA4 form, should their systems allow, or the old or existing HSA4 form.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union or trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 This instrument does not consolidate legislation.

10. Consultation outcome

10.1 There has been no public consultation as this instrument makes consequential amendments following the amendment to the Abortion Act 1967 by the Health and Care Act 2022 and because it implements the duty under section 2(1) of the Abortion Act to set out in Regulations how any opinion required under section 1 is to be certified. However, DHSC has consulted with abortion providers to seek their views on the practical implementation of the changes, including the form that the new certification of opinion should take and on the timing of the implementation of the changes. DHSC has also consulted with the Welsh Government.

10.2 As set out in paragraph 7, a public consultation was held between November 2020 and February 2021 to gather views on whether the temporary approval put in place during the Covid-19 pandemic should become permanent. DHSC received 18,834 responses to the consultation. A link to the summary of consultation responses is here: https://www.gov.uk/government/consultations/home-use-of-both-pills-for-early-medical-abortion. A hard copy is also obtainable by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU. The Welsh Government also ran a public consultation on this issue between December 2020 and February 2021, which is available here- https://gov.wales/sites/default/files/consultations/2021-09/termination-of-pregnancy-arrangements-in-wales-consultation-summary-of-response.pdf .

11. Guidance

11.1 DHSC has published a suite of guidance notes to support RMPs with the completion of forms for recording information that is legally required to be provided under the Abortion Act 1967 and the Abortion Regulations 1991. This guidance is available on the gov.uk website.

11.2 Following publication of this instrument, DHSC will publish a new guidance note in summer 2022 to support RMPs with the recording of their opinion, formed in good faith, that the pregnancy will not exceed 10 weeks at the time when the medicine (in the case of two pills, the first pill) is administered. In addition, the existing guidance notes on completing the HSA4 abortion notification form will be revised to reflect the additional information that will be required in relation to the use of abortion medication at home or in clinic.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment relating to the changes made by section 178 of the Health and Care Act is being prepared and will be published in the autumn. DHSC will continue to monitor the Abortion Act 1967 and the implementation of these changes. As part of the impact assessment, DHSC will set out a monitoring and evaluation plan.

13. Regulating small business

13.1 In so far as this legislation applies to activities that are undertaken by small businesses, DHSC has sought to minimise the impact of the requirements on providers by providing flexibility in how to certify the opinion required and carefully considering any requirements for additional information, including the timetable for delivery.

14. Monitoring & review

14.1 This instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Parliamentary Under Secretary of State, Maggie Throup MP has made the following statement:

"There are no plans to review these Regulations as they are made to comply with the Secretary of State's duty under section 2(1)(a) and (b) of the Abortion Act in consequence of the amendments to that Act. In so far as there would be any impact at all, I consider that a review clause would be disproportionate. The approach to monitoring this legislation in terms of provision of abortion services on the ground will be a matter for the Department of Health and Social Care."

15. Contact

15.1 The Sexual and Reproductive Health and Abortion Policy team at the Department of Health and Social Care, email sexualreproductivehealthandabortionpolicyteam@dhsc.gov.uk can be contacted with any queries regarding this instrument.

15.2 Clare Perkins, Deputy Director for Sexual and Reproductive Health and Abortion policy at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.

15.3 Maggie Throup MP, Parliamentary Under Secretary of State for Vaccines and Public Health at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.