

THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMIN COURT

CO/1402/2020

IN THE MATTER OF AN APPLICATION FOR JUDICIAL REVIEW

R
(on the application of
CHRISTIAN CONCERN)

Claimant

-v-

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Defendant

DEFENDANT'S EVIDENCE BUNDLE



102 Petty France, Westminster, London, SW1H 9GL

DX 123243, Westminster 12

INDEX TO DEFENDANT'S EVIDENCE BUNDLE

	Document Description	Date	Page
1.	Witness Statement of Andrea Duncan	12.05.2020	3-15
2.	Witness Statement of Imogen Stephens	12.05.2020	16-30
3.	Letter from RCOG	12.05.2020	31
4.	Email from DHSC – meeting readout	12.03.2020	32-33
5.	Email from RCOG	17.03.2020	34
6.	Email from BPAS	17.03.2020	35
7.	Ministerial Submission – COVID-19: Access to early medical abortion services + annexures: a. Proposed temporary approval – Option 1 b. Proposed temporary approval – Option 2 c. Letter from BPAS d. Attached BPAS Draft Guidelines	18.03.2020	36-63
8.	Email from RCOG – two signature requirement	18.03.2020	64-65
9.	Ministerial Submission – COVID-19: Abortion Act and two signature requirement	18.03.2020	66-68
10.	Letter from RCOG to SSHSC + Provision of Signatures for HSA1 Forms and Proposed Amendment	22.03.2020	69-74
11.	Email from SSHSC's office	24.03.2020	75
12.	Supplementary Note – Access to abortion services – COVID-19	25.03.2020	76-78
13.	Letter from Lucy Allan MP to Nadine Dorries MP	25.03.2020	79
14.	Updated Supplementary Note – Access to abortion services – COVID-19 (Dated 25.03.2020 but sent 27.03.2020)	27.03.2020	80-83
15.	Open Letter regarding telemedicine	28.03.2020	84-87
16.	Email from SSHSC's office	28.03.2020	88
17.	Ministerial Submission – COVID-19 and abortion: approval of women's homes for early medical abortion and doctor's homes for prescribing + annexures: a. Proposed temporary approval – Option 1 b. Proposed temporary approval – Option 2	29.03.2020	89-97
18.	Email from SSHSC's office	29.03.2020	98

THE HIGH COURT OF JUSTICE

CO/1402/2020

QUEEN'S BENCH DIVISION

ADMIN COURT

IN THE MATTER OF AN APPLICATION FOR JUDICIAL REVIEW

R

**(on the application of
CHRISTIAN CONCERN)**

Claimant

-v-

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Defendant

WITNESS STATEMENT OF ANDREA DUNCAN

I, **ANDREA DUNCAN**, of the Department for Health and Social Care, 39 Victoria Street, London, SW1H 0EU will say as follows:

1. I am the Head of policy for Alcohol, Sexual and Reproductive Health (which includes abortion policy) and Physical Activity in the Healthy Behaviours Team in the Department of Health and Social Care. I have been a civil servant for over 30 years and prior to my current role led policy on sexual and reproductive health in DHSC for over 15 years. I have worked in the team which leads on abortion policy within the Department for a number of years and my role includes managing policy on home use for early medical abortion.
2. I make this statement to explain the decision, published on 30 March 2020, to grant approval for two temporary measures in England to ensure continued access to

abortion services, as follows: (1) women and girls are able to take both pills (Mifepristone and Misoprostol) for early medical abortion up to 10 weeks gestation in their own homes, without the need to first attend a hospital or clinic (subject to eligibility following a telephone or e-consultation with a clinician); and (2) registered medical practitioners are able to prescribe both pills for the treatment of early medical abortion up to 10 weeks from their own homes (the “**Decision**”) [JR/38]. In my role, I was closely involved in the events leading to the Decision.

3. Except where indicated otherwise, the matters contained in this witness statement are within my own knowledge and are true. Where I refer to matters which are not within my own knowledge, I believe them to be true and indicate the source of my information.
4. References in this statement:
 - a. to [JR/x] are to page references in the judicial review bundle
 - b. to [DB/x] are to page references in the Defendant’s material which has been provided at the same time as this statement.

Abortion legislation and guidance

5. The 1967 Abortion Act sets out the legal framework under which abortions can be performed in England and Wales. In accordance with section 1(3) of the Abortion Act 1967, all independent sector clinics wishing to perform termination of pregnancy must be approved by the Secretary of State for Health and Social Care. The Secretary of State’s approval is conditional upon the provider’s compliance with the Abortion Act, the Health and Social Care Act 2008, and the Department’s Required Standard Operating Procedures (“RSOPs”):

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874241/Procedures_for_approval_of_independent_sector_places_for_abortion.pdf

6. The RSOPs make explicit the conditions and requirements for independent sector places to be approved by Secretary of State to perform termination of pregnancy. Failure to comply can lead to withdrawal of approval at any time. The RSOPs have been developed to:

- Ensure compliance with all legal requirements,
 - Provide the best quality of care for patients, and
 - Provide sound management, organisational and clinical governance arrangements including issues such as child and adult safeguarding.
7. Providers must also comply with the regulatory framework set out in the Health and Social Care Act 2008 and accompanying regulations and guidance. The Care Quality Commission (“CQC”) is responsible for implementing the regulatory framework set out in the regulations made under the Act. The (Regulated Activities) Regulations 2014 provides that the termination of pregnancy is a regulated activity. All providers of regulated activities must be registered with the CQC and meet fundamental standards of quality and safety as set out in Part 3 to the 2014 regulations. Registered providers must also meet the requirements set out in the Care Quality Commission (Registration) Regulations 2009. CQC registration must be in place before the Secretary of State will consider an application for approval.
8. In 2014 my team developed “*Guidance in Relation to Requirements of the Abortion Act 1967 for all those responsible for commissioning, providing and managing service provision.*”

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/313459/20140509 - Abortion Guidance Document.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/313459/20140509_-_Abortion_Guidance_Document.pdf).

9. The intention of the guidance was to provide support for doctors. The guidance dealt with a number of issues including the role of the certifying doctors and the steps they should take to assess risk to the woman’s physical or mental health, the role of the multi-disciplinary team and consultations via webcam or telephone. In relation to the latter, a key extract is set out below:

“6. Although there is no legal requirement for at least one of the certifying doctors to have seen the pregnant woman before reaching a decision about a termination, the Department’s view is that it is good practice for this to be the case. It is recognised however that, with technological advances, this

may well mean that a doctor does not physically see the woman, e.g. there could be a discussion by phone or over a webcam...”

10. Service provision in England has for some years included remote consultations, with women then subsequently attending a service for treatment. Certification takes place before the woman attends for treatment.
11. The Royal College of Obstetricians and Gynaecologists (“RCOG”) have published a series of guidance documents in response to the Covid-19 pandemic, including guidance for healthcare professionals on Covid-19 infection and abortion care services (the latest version of this was published on 9 April 2020).

<https://www.rcog.org.uk/globalassets/documents/guidelines/2020-04-09-coronavirus-covid-19-infection-and-abortion-care.pdf>

12. The guidance sets out that during the Covid-19 pandemic access to normal healthcare processes will be disrupted, and that to ensure safe and effective abortion care, greater use of remote consultations and medical abortion at home may be necessary. It outlines an evidence-based approach to delivering best practice care using well established models that are already widely used, but may have been limited or restricted in UK practice.
13. The development of this guidance followed a meeting which the Department led on 10th March (see below).
14. The guidance also includes a flow-chart which summaries the care pathway for management of EMA during COVID-19. The guidance includes the circumstances in which women will not be eligible for remote treatment.

Early medical abortion

15. Early medical abortion (“**EMA**”) involves taking two different tablets, Mifepristone and Misoprostol, which are most effective with a time gap between taking the first and second pill of 24-48 hours.

16. For a number of years there were calls for the Secretary of State to use powers in Section 1(3A) of the Abortion Act 1967 to approve English homes as a class of place where EMA could be performed. This would mean that women would only attend clinic once where they would take Mifepristone and be supplied with the Misoprostol to take in their home 24-48 hours later. These calls were based on: international evidence as to home use being effective, safe and acceptable for EMA; many women preferring to have the choice to take pills at home to help balance family and personal needs; and, because of concerns around patient safety, where women returning home for self-management after taking Misoprostol in the clinic may begin to abort whilst travelling home, which could be traumatic. Simultaneous administration of pills, which was commonly chosen by women to avoid a second visit, also has a higher risk of side effects and reduced effectiveness.
17. Scottish Ministers approved “Scottish homes” as a class of place for EMA on 26th October 2017. This was followed by Welsh Ministers on 27th June 2018. DHSC Ministers announced, on 25th August 2018 [**JR/96**], that they would approve homes in England as a place where the second stage of EMA could be performed and that this change would come into force by the end of 2018. There was no consultation prior to those approvals.
18. The announcement highlighted that the Department would work with the RCOG to develop clinical guidance for all professionals to follow for home use.
19. The approval was published on 27th December 2018 – [**JR/98**]. Clinical guidance was published on 3 January 2019. This set out recommendations for best practice, which includes identification and management of vulnerable groups.
20. Following publication of the approval, women and girls have been able to take the second pill for early medical abortion in their own homes. Typically in these cases, the individual will contact the provider and will be offered a consultation, prior to which she will be emailed written information about the procedure. The woman will then have a video or telephone consultation where the clinician – which might be a nurse or midwife, working as part of a multidisciplinary team - will gather through sensitive questioning information about the woman including her health and personal circumstances. The woman will also have the opportunity to ask

questions. Informed consent for the procedure can then take place. Two doctors will then consider whether there are grounds under the Abortion Act 1967 for treatment to proceed. If this is the case, the woman attends the clinic to take the first pill and then returns home to take the second pill 24-48 hours later.

Pre-existing evidence on approving homes as a class of place where EMA could be performed

21. A systematic review of home-based abortion published by the World Health Organisation (WHO) in 2011 concluded that home use of abortion pills was safe provided certain safeguards (such as telephone support from health professionals) are in place. Guidance subsequently published in 2012 from WHO “Safe Abortion: technical and policy guidance for health systems” states that “home use of misoprostol is a safe option for women”. For some years, women have been supplied with exactly the same medicines used in medical abortions to complete miscarriage at home. Home use of EMA has been routine in the USA since 2000 and in Sweden and France since 2004.

22. In 2019, the National Institute for Health and Care Excellence’s evidence review on “Abortion care: [A] Accessibility and sustainability of abortion services” (September 2019) was published. At pp. 39-41 and 44, it found that there was no difference in satisfaction between women who received abortion services by telemedicine compared to face-to-face services. Moreover, the quantitative and qualitative evidence showed that telemedicine services may improve access to abortion services. They commented that there was the potential to reduce inequalities associated with groups who find it difficult to travel to abortion services. By way of example, it would improve access to those who suffered from threats of violence, controlling circumstances and cultural backgrounds that accept honour-based violence. Finally, it found that telemedicine services were likely to be cost-saving rather than lead to increased resources being used.

Impact of Coronavirus

23. On 3rd March 2020, I was copied into a letter from Ann Furedi, Chief Executive of the British Pregnancy Advisory Service (BPAS), addressed to the Secretary of State for Health, the Minister for Care (Helen Whately) and the Chief Medical Officer, Prof. Chris Whitty [DB/45]. This highlighted the work that BPAS were doing to prepare for the Coronavirus pandemic including “risk-assessing the continued provision of our services in circumstances where women who need to terminate a pregnancy may be unable to attend treatment units, and also when units may be short of staff, or need to close”.

24. Ms Furedi went on to say that:

“an obvious measure we have identified would be for the Secretary of State to use his power now to enable both the medications involved in early medical abortion (EMA) to be taken at home. Precedent has been established already with the approval for the home-use of misoprostol, which has resulted in a significant improvement to services. The same action regarding mifepristone would allow us to provide the entire procedure without the need for the woman to visit a facility, using proven telemedicine protocols.....”

25. A telephone meeting was arranged for 10th March, which was attended by BPAS, Marie Stopes UK (MSUK), National Unplanned Pregnancy Advisory Service (NUPAS), the Royal College of Obstetricians and Gynaecologists, Public Health England and Scottish and Welsh Government officials. The readout of the meeting is at [DB/32]. It recorded the view of the external bodies who attended that there ought to be home use for both abortion pills for EMA up to 10 weeks gestation. The view was that this was supported by clinical evidence and the necessary infrastructure was already in place, but that there needed to be appropriate safeguarding of vulnerable patients. It was also agreed that doctors ought to be able to prescribe from home, and there was also support for midwife / nurse prescribing.

26. Following the meeting, stakeholders continued to flag issues with provision of abortion services: see [DB/34 to 35].

27. A submission was sent to Ministers on 18 March 2020 recommending that the power to approve women’s homes as a class of place where both abortion pills

could be taken for early medical abortion, and for the home of a registered medical practitioner (a doctor; "RMP") as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion" [DB/36].

28. This action was agreed by the Minister of State for Care. It was assumed that the Secretary of State was also content, as his office had been copied into the submission, and abortion matters had been delegated to the Minister for Care for decision under ordinary Ministerial arrangements. The approval was published on GOV.UK on 23 March 2020 (not 20 March 2020 as the Claimant's Statement of Facts and Grounds states).
29. On the evening of 23 March, my media colleagues were alerted by the Secretary of State's office that he had become aware of the publication of the approval and had asked for it to be withdrawn immediately. They informed me that he had not seen the submission and did not agree that changes needed to be made. I attach an e-mail of 24 March 2020 timed at 13.13 from the Secretary of State's private office which confirmed this [DB/75].
30. As a result, the approval was withdrawn from the GOV.UK website and a message appeared as follows: *"The information on this page has been removed because it was published in error. This was published in error. There will be no changes to abortion regulations"*.
31. That accurately explained things because we obviously would not have proceeded to publication if we were aware that our Secretary of State was not content. Unfortunately, an error was made and he had not had sight of the submission. That is clearly regrettable. However, I should also say that the Department was dealing with a completely unprecedented set of events at this time. I cannot recall anything similar in the whole of my career. Ministers, their offices and the wider Department were working long hours and having to adapt to working to manage the COVID-19 pandemic. Many urgent decisions were being taken and there were large volumes of issues and email traffic to manage.

The Coronavirus Act 2020

32. Around the same time that we were considering the granting of approval under s1(3A) of the Abortion Act 1967, we were approached by RCOG by e-mail, dated 18th March [DB/64]. They asked for urgent consideration to be given to using the emergency legislation - the Coronavirus Bill - going through Parliament to relax the rule that two doctors must certify an abortion during the current COVID-19 crisis. Instead, they wanted to allow for one doctor, nurse or midwife to certify that the grounds had been met.
33. We understand that Peers also approached Lord Bethell – the Parliamentary Under-Secretary of State – about this matter. On 18th March 2020, a second submission was sent to Ministers [DB/66] asking them to indicate whether they wanted us to urgently pursue avenues to use the Coronavirus Bill to relax the two-doctor certification rule. As things turned out, this was overtaken by events, as described below.
34. RCOG continued to press for an amendment to be included in the Bill to relax the requirements on certification and over the weekend wrote a formal letter to the Secretary of State's office asking for the certification requirements to be relaxed [DB/69].
35. In the early afternoon of 24th March 2020, the Secretary of State made a statement to the House of Commons to update the House on COVID-19. In response to questions, the Secretary of State confirmed that there were no plans to change abortion regulations due to COVID-19. This reflected the Secretary of State's position at that time, as set out above.
36. The amendment to the Bill was tabled in the House of Lords by Baroness Barker and Baroness Bennett late in the evening of 24 March and this sought:
- To allow one doctor (rather than two) to certify that the grounds have been met for an abortion to be performed and additionally allow one nurse or midwife to certify abortions;

- To allow nurses and midwives to perform abortions;
- To classify women's homes as a place where both stages of medical abortion could be performed (England and Wales only); and,
- To allow doctors, nurses or midwives to prescribe medication for abortion from their home (E&W only).

37. This amendment would have made significant changes to the current legislative framework, in particular permitting nurses and midwives to perform abortions, certify that the grounds had been met and prescribe medication for abortion from their homes. Whilst nurses and midwives are likely to be part of a multi-disciplinary team providing abortion services, this is a different role from that of the RMP.

38. The Government's response to the amendment is on record in the speech by Lord Bethell on 25 March 2020. The amendment was withdrawn following debate. Lord Bethell committed to keeping the position under review in light of the concerns raised by the Baroness Barker and Baroness Bennett over access to services. He stated that:

"Her point on monitoring the situation is exactly the one that the noble Baroness, Lady Watkins, made earlier. I commit the department to monitoring it. We will remain engaged with the Royal College of Obstetricians and Gynaecologists and other stakeholders. She is absolutely right that we can return to the subject with two-monthly reporting back, and it can be discussed in Parliament in the debates planned on a six-monthly basis."

Further developments

39. The withdrawal of the approval on 23rd March 2020, so as not to allow both stages of EMA to be performed at home, caused concern among abortion service providers and other groups, such as RCOG.

40. On 25th March 2020, the Secretary of State's Private Office requested a short note on other potential options for women accessing abortion services in light of

concerns raised by stakeholders. A note was sent to the Minister for Care and the Secretary of State's private office on 25th March 2020 [DB/76].

41. The Department and Ministers received a number of representations following the withdrawal.

42. On 25th March 2020, we received an email from Ms Ann Furedi at BPAS, stating that:

- “Across **BPAS**, over a quarter of clinics (23/73) have closed as of 25th March due to staff shortages. We have 85 members of staff either diagnosed with actual or suspected COVID infection - or self-isolating.
- **Nupas anticipates 60-70% of its services will close down within days at current rates of sickness and isolation.**
- **MSI – around 12% (54) of staff have been self-isolating. Women who have booked but been unable to attend appointments has doubled.**
- **NHS – many services have staff self-isolating or services reduced withdrawn because spare capacity is needed.** Hospitals are seeing a contraction in their services because of the need to take anaesthetic machines out of theatre to use as ventilators OR take over clinical spaces for early surgical for mgmt. of COVID+ patients or staffing issues – they need to ramp up EMA but can't because of mid upper gestation restrictions and delivery remotely but can't because of home mife restriction
- **Independent providers** not been able to access some of the locations where we normally provide EMAs (like GP surgeries) – this and number 1 mean there are fewer actual places for people to go.
- Access to surgical abortion is reducing due to
 - Hospitals taking back their theatres to use the ventilators
 - Surgeons self-isolating
 - Anaesthetists and surgeons being called into the NHS to care for COVID patients
- We are getting increasing numbers of messages via social media from women who **cannot leave their homes or will be pushed over the limit for EMA during isolation.** Without the ability to provide EMA at home some will be forced to continue their pregnancies.
- Forced pregnancy is bad enough at the best of times but infinitely worse in the midst of a healthcare crisis. Some will be pushed into gestations where they need surgical – see above.” (original emphasis)

43. On 27th March 2020 we were informed by Ms Ann Furedi at BPAS that:

“ ...

1. As of today 25 out of 71 units are closed. Some due to staff shortages, some because health centres that we operate from are not functioning normally.
2. In total through clinic closures and staff shortages we cancelled 1,120 appointments.”

44. On the same day, correspondence was received through Ms Nadine Dorries MP, Minister of State for Patient Safety, Mental Health and Suicide Prevention, from Lucy Allan MP, detailing BPAS’s concerns about the deteriorating situation [DB/79].

45. Also on 27th March 2020, a letter was sent to the Secretary of State from Mr Richard Bentley at Marie Stopes UK, stating that:

“...By way of information, we currently have 68 out of 400 of our team members away from work self-isolating because of the virus; I understand other independent providers are also experiencing a similar deteriorating position. Given the ongoing number of people visiting our clinics, this is only set to increase. If we, the independent sector, are increasingly unable to provide services and the NHS is diverting resources to treating COVID-19 cases, abortion services will very soon be in a critical state across the country.

Activity at our centres is showing no sign of abating; in fact, our nurses, midwives, doctors and call centre teams are being asked to take on higher caseloads in support of NHS Trusts, which are having to suspend termination of pregnancy services and re-direct resources. As things stand, we have been approached by 15 NHS Trusts & CCGs to ask if we can support them to deliver services. One of these is **West Suffolk Hospital**, which, I understand is within your own constituency.” (original emphasis)

46. An updated note was sent to Ministers on 27 March 2020 [DB/80].

47. On 28th March 2020, we received an open letter signed by 55 public health specialists urging the Secretary of State to enable telemedicine for EMA so that women would not have to leave their houses [DB/84].

48. On the evening of Saturday 28th March 2020, the Secretary of State agreed to grant approval for women to take both abortion pills at home. This is recorded in an e-mail from the Secretary of State’s private office timed at 21.45, which also records the detailed briefing which was being given to the Sunday Times [DB/88].

49. At that time, there remained an issue about whether RMPs could prescribe the medicine from their homes, and we were asked to send up a further submission.

50. In response to a submission sent on 29th March 2020 [DB/89], the Secretary of State confirmed that he agreed to approve the home of an RMP as a class of place where both abortion pills could be prescribed [DB/98].

51. The approval was published on GOV.UK on 30th March 2020 [JR/38].


52. DHSC are monitoring how home use of abortion pills up to 10 weeks is working in practice, and the necessity of this temporary measure, through regular engagement with abortion providers and RCOG. CQC are also continuing to monitor the provision of abortion services following the approval.

Conclusion

53. Temporary approvals of women's homes as a place where both stages of EMA up to 10 weeks gestation and doctor's homes as a place where medication for medical abortion can be prescribed are now in place during the COVID-19 pandemic. Ministers have taken difficult decisions at pace in an unprecedented and changing climate. They have taken account of clinical advice and women's safety and wellbeing has been at the forefront of their decision making.

I believe that the facts stated in this witness statement are true.

SIGNED:

A handwritten signature in black ink, appearing to read 'Andrea Durcan'.

DATED: 12 May 2020

THE HIGH COURT OF JUSTICE

CO/1402/2020

QUEEN'S BENCH DIVISION

ADMIN COURT

IN THE MATTER OF AN APPLICATION FOR JUDICIAL REVIEW

R

**(on the application of
CHRISTIAN CONCERN)**

Claimant

-v-

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Defendant

WITNESS STATEMENT OF IMOGEN STEPHENS

I, **IMOGEN STEPHENS** FRCOG, FFSRH, FPH, of Public Health England, Wellington House, 133-155 Waterloo Road, London, will say as follows:

1. I am a consultant in Public Health Medicine and a Fellow of the Royal College of Obstetricians and Gynaecologists ("**RCOG**"). I have clinical, research, commissioning, corporate and government-level experience. I have particular expertise in revalidation, quality, clinical governance and improvement of health service delivery, in particular for women's reproductive health. From 2013-2019, I was Deputy Medical Director at Public Health England. From 2017 until July 2019, I was Medical Director and Responsible Officer for Marie Stopes UK, a leading provider of NHS-funded abortion.

2. I am currently a Clinical Advisor to the Department for Health and Social Care (the “**DHSC**”) and the Northern Ireland Office. I am also advising on implementation of abortion provision in Northern Ireland.
3. Except where indicated otherwise, the matters contained in this witness statement are within my own knowledge, and are true. Where I refer to matters which are not within my own knowledge, I believe them to be true and indicate the source of my information.
4. References in this statement to [JR/x] are to page references in the judicial review bundle.
5. I make this statement to set out the clinical evidence supporting the decision, made on 30 March 2020, to grant approval for two temporary measures in England to ensure continued access to abortion services, as follows: (1) women and girls being able to take both pills (Mifepristone and Misoprostol) for early medical abortion up to 10 weeks gestation in their own homes, without the need to first attend a hospital or clinic (subject to eligibility following a telephone or e-consultation with a clinician); and (2) registered medical practitioners being able to prescribe both pills for the treatment of early medical abortion up to 10 weeks from their own homes (the “**Decision**”).
6. I also make this statement to address and respond to issues raised by the Claimant and in the Statement of Dr Gregory Gardner.

Abortion arrangements before the COVID-19 pandemic

7. Abortion prior to 10 weeks gestation is termed Early Medical Abortion (“**EMA**”). This now usually occurs with the taking of two medicines – Mifepristone and Misoprostol – either at a 24-48 hours interval (which is associated with fewer adverse events, including reduced risk of ongoing pregnancy) or simultaneously. The regime used depends on the clinical and organisational aspects in place at the provider level and on the woman’s preference. Mifepristone works by blocking the hormone progesterone. Without progesterone, the lining of the uterus breaks down and the pregnancy cannot continue. Misoprostol makes the uterus contract,

causing cramping, bleeding and the loss of the pregnancy in a similar way to a miscarriage.

8. Before these medicines are administered, many women would normally have a remote teleconsultation with a nurse or midwife. The purpose of this would be to obtain information from the pregnant woman as to the reasons for the abortion and to ensure there are no medical issues, or contra-indications to abortion in general or EMA in particular. Issues relating to, for example, safeguarding and mental capacity would be explored. It would also be a chance for the pregnant woman to ask questions about the procedure. In order to fulfil the statutory requirements of the Abortion Act 1967, two registered medical practitioners in England, Wales and Scotland must sign to certify and specify that grounds have been met for an abortion. Guidance from the DHSC (2014) states that a registered medical practitioner can rely on the information obtained by other members of their team when certifying an abortion. This certification could therefore be performed remotely, including through use of an electronic signature.
9. It used to be the case that both Mifepristone and Misoprostol would then be administered in a clinical setting. Taking Misoprostol at home, however, was introduced as part of EMA provision in December 2018 following approval by the Secretary of State. This enables women, at the time of the Mifepristone being administered, also to be handed the Misoprostol pill which can then be taken at home. This avoids the risks of experiencing pain and heavy bleeding whilst travelling back from the clinic. There has been no observed increase in complications as a result of this change. It is likely, in fact, that the risks of ongoing pregnancy have been reduced, since many women opted for the convenience of taking both Mifepristone and Misoprostol simultaneously when required to attend a clinical setting.
10. Regulated access to abortion ensures services are provided to women in accordance with nationally agreed standards of clinical care and quality governance.

11. Standards of care for abortion provision in England are clearly described in recent NICE guidance NG140 'Abortion Care' (2019)¹. Even before the pandemic, these supported self-referral and recommended the use of telephone and video consultations in clinical assessment where appropriate, with appropriate information governance safeguards in place. The basis of these recommendations (i.e. self-referral and use of teleconsultation) was to minimise delay in the abortion process, to ensure women have more options available, to decrease adverse events, and improve women's experience. In addition, there was strong evidence that substantial cost savings can be achieved when women present earlier, as this increases the likelihood that women can have a medical rather than a surgical abortion.

Reasons why COVID-19 pandemic required change in approach

12. Abortion is an urgent, time-sensitive clinical procedure. This means that any upset in access to abortion services is liable to have substantial negative impacts for women.

13. The COVID-19 pandemic had multiple impacts on abortion treatment and that this would be the case was evident from, at the latest, mid-March 2020. First, fewer women were willing or able to travel to abortion services because of the danger to themselves in contracting COVID-19 and the difficulties faced in leaving home by those with young children or living in coercive and abusive relationships. Second, the incidence of staff illness within some providers had reduced the availability of provision of services and lengthened waiting times. Third, abortion services themselves were being withdrawn because spare capacity was needed for patients suffering from COVID-19.

14. Not making any changes to abortion rules, such as that made by the Decision, would have led to the following potential harms:

- a. Women who were intent on having EMAs would have been forced to leave their homes and travel to clinical settings in order to take Mifepristone and obtain Misoprostol. This would have increased the

¹ NICE guidance NG140: Abortion Care; 2019.

possibility of them being infected with Covid-19 as well as tending to increase the spread of that disease. In 2018, 131,838 EMAs were carried out in England. Prior to the temporary change in approval of class of place, each of these women would have attended a clinic or NHS service at least once, and sometimes on 2 or more occasions. The increased use of teleconsultation and telemedicine will therefore have a significant impact on travel and social interaction and thus play a part in reducing transmission of infection during the pandemic;

b. Alternatively, women seeking abortions would not have been able to take Mifepristone and Misoprostol, either because they did not want to leave their homes, or, even if they had been willing to, would not be able to access treatment because clinics had closed. The result of this would have been:

- Women missing the 10-week deadline meaning that they would be having later terminations leading to greater health complications. The clinical risks of EMA are significantly less than abortions at later stages;²
- There would be a build-up of desired abortion treatments swamping capacity when more women felt able to leave their homes; and,
- Women seeking to undertake illegal, unsafe abortions.

15. In my view, these risks far outweigh any risks posed by women taking both Mifepristone and Misoprostol at home following a remote consultation. A detailed review of the evidence in support of self-administration of Mifepristone and Misoprostol by WHO³ in 2015 recommended the option of women managing Mifepristone and Misoprostol medication without direct supervision of a health provider in circumstances where women have a source of accurate information and access to a health provider should they need or want it at any stage of the process.

² Harris L & Grossman D. N Engl J Med 2020;382:1029-40.

³ Health worker roles in providing safe abortion care and post-abortion contraception: Evidence-to-decision framework, WHO, 2015.

More women report the method to be satisfactory when it is self-managed. Women find the option acceptable and feasible and providers also find the option feasible.

16. This was supported more recently by an evidence review conducted by the National Institute for Health and Care Excellence's, titled "Abortion care: [A] Accessibility and sustainability of abortion services" (September 2019, pp39-41 and 44).

Abortion arrangements in light of the COVID-19 pandemic

17. Following the Decision, in England (and also in Wales and Scotland following similar decisions made in those areas), providers can now offer a complete EMA service with the consultation taking place via video or teleconferencing and, if appropriate, a treatment package either sent to the woman's home or made available for her to collect from an abortion service provider.
18. Additional guidance for abortion care during the current COVID-19 pandemic response, including in relation to telemedicine and EMAs, was published by RCOG⁴ on 9 April 2020 to ensure continuation of essential services when acute services are disrupted and/or women or clinical staff may be self-isolating (the "**RCOG COVID-19 Guidance**").
19. For women requesting an EMA, the RCOG COVID-19 Guidance only requires her to attend in person where the clinician judges that the benefit of doing so outweighs the risk of Covid-19 exposure and transmission, for example where there are safeguarding, language or capacity concerns, or when she is unsure of her gestation.
20. As before, in order to fulfil the statutory requirements of the Abortion Act 1967, an abortion must still be signed-off by two registered medical practitioners in England, Wales and Scotland. There is no change to this nor to the fact that a registered medical practitioner will often rely on the information obtained by other members of their team when certifying an abortion.

⁴ RCOG Coronavirus (Covid19) infection and abortion care: information for healthcare professionals, 2020.

21. Counselling is available for all women undergoing EMA at any point in the care pathway, including post-abortion.

Response to issues raised by the Claim

22. I address here the various issues which have been raised by the Claimant in relation to the measures introduced by the Decision, which is being challenged in this claim. Where necessary, I also directly rebut the claims made in the Statement of Dr Gregory Gardner, dated 15 April 2020. I have used the same sub-headings as those used by Dr Gregory Gardner.

(a) Risks of physical complications

23. Dr Gardner sets these risks out at §§10-16 of his Statement. I disagree with his assessment and do not consider that these are good reasons for requiring women to take Mifepristone in a clinical setting, at least during the COVID-19 pandemic.

24. On infections, the RCOG guidance from that Dr Gardner refers to, at §10, has been superseded by NICE guidance 140 (Abortion Care, 2019) which does not recommend routine antibiotic prophylaxis for EMA. This is because the risk of ascending infection is very low in a non-surgical abortion and at early gestations. In line with guidance from the Chief Medical Officer, this approach also helps to prevent further development of antimicrobial resistance.

25. Pelvic Inflammatory Disease (PID) and subsequent infertility is unlikely following EMA, since ascending infection is not a risk.

26. The NICE guidance does not recommend routine screening for Chlamydia and other sexually transmitted diseases sexually transmitted infections (STIs) for women having EMA, but if STI screening is part of NHS commissioning it can be safely and easily performed by telemedicine: a swab kit is posted to the woman, who then sends this to the relevant laboratory, who then notify the provider. If treatment is required this can be sent by post. Sexual health services are increasingly provided in this way (e.g. by SH24, a well-known provider of telehealthcare).

27. On haemorrhage and subsequent surgical evacuation, the evidence does not support Dr Gardner's position.
28. The first Finnish registry-based study cited by Dr Gardner, at §13 of his Statement, looked at complications following medical abortions to 20 weeks gestation in adolescents compared with older adults. It was not designed to demonstrate gestation-related risks of 'haemorrhage' (which was not clearly defined) and the quoted risks are therefore not relevant to the risks of women undergoing medical abortions to 10 weeks gestation only.
29. The second Finnish registry-based study cited compared immediate complications following surgical versus medical abortion to 9 weeks gestation only, but again did not clearly define 'haemorrhage'. Medical abortion regimens in this study included those using Misoprostol alone, which is known to have a lower success rate and consequent increased risk of prolonged bleeding. The techniques used for surgical abortion inevitably produce less bleeding as the procedure is designed to be more immediately complete. Despite this, the incidence of significant haemorrhage (requiring further surgical evacuation) was only 2.9% in the EMA group.
30. The Swedish study, referred to at §14 of his Statement, categorised either heavy bleeding lasting longer than 12 hours or longstanding bleeding (> 21 days) as a bleeding complication, or haemorrhage. Only 1.9% (72 women) out of 3696 undergoing medical abortion <12 weeks were deemed to have had haemorrhage.
31. Finally, the Australian study, referred to at §15, included a subset of 947 women undergoing EMA to 9 weeks gestation, of whom only 6 (0.6%) experienced a clinically significant complication (haemorrhage, sepsis, treatment failure).

(b) Risks of psychological trauma

32. Dr Gardner sets these risks out at §§17-19 of his Statement. I disagree with this assessment.
33. An extensive systematic review of the association between induced abortion and adverse mental health outcomes in 2011 conducted by the National Clinical Collaborating Centre for Mental Health concluded that when studies with weak

design and quality were excluded: “*rates of mental health problems will be largely unaffected whether she has an abortion or goes on to give birth.*”⁵

34. The Sullins study from the Catholic University of America, cited in §18 of his Statement, considered all abortion gestations and cannot be considered authoritative for women undergoing EMA.
35. In any event, as already set out above, telemedicine consultations were common well before the pandemic and so Dr Gardner’s concerns are not material to the Decision.

(c) Communication risks

36. Dr Gardner sets out his concerns at §§20-22 of his Statement. I disagree with his assessment.
37. All abortion providers who have experience in the use of teleconsultation and telemedicine already have well developed and effective systems for assessing and managing risks (medical, psychological, safeguarding). Whenever any risks or concerns are identified or considered possible the woman is required to attend for face-to-face consultation.
38. Following the temporary change in approval of place, and in line with RCOG and NICE guidance, providers have instigated a thorough process of informed verbal consent which ensures that all women have access to detailed web-based and written information, which is then discussed with them in detail by the registered medical professional performing the relevant stage of the teleconsultation process. This is clearly documented in electronic case records and signed electronically by the registered medical professional.
39. If there are any identified language understanding concerns, the woman may be offered a 3rd party interpreter as part of the teleconsultation process or be required to attend for a face-to-face consultation.

⁵ Academy of Medical Royal Colleges and National Clinical Collaborating Centre for Mental Health: Induced abortion and mental health: a systematic review (2011), p125.

40. Finally, there is growing evidence⁶ that, in EMA, it is not necessary to perform a scan to assess the gestation of the pregnancy if the woman is certain of the date of her last menstrual period.

(d) Relaxation of safeguards: clinical

41. Dr Gardner sets out his concerns at §§23-32 of his Statement. I disagree with his assessment.

42. Dr Gardner asserts that the safeguards for use of EMA medication such as access to emergency and follow up facilities have not been considered in granting the temporary approval.

43. Teleconsultation is a longstanding feature of abortion provision for EMA. All women are given information about aftercare, have access to a 24-hour helpline and are given information about the nearest acute gynaecology emergency centre to attend if necessary.

44. Women are informed about the failure rate for EMA as part of the informed consent process, and advised what to look for, including the relevance and importance of prolonged bleeding and/or pain.

45. All women are asked to perform self-follow up within 14-21 days through use of a low sensitivity pregnancy test which will detect residual b-HCG if at clinically significant levels. This has been standard clinical practice for several years in abortion provision and is not associated with adverse clinical outcomes or increased rates of ongoing pregnancy. All women undergoing EMA have access to 24 hr helpline support and advice. 'Remote' follow up following EMA has been found to be both highly acceptable and safe.⁷

46. All women are screened at teleconsultation for a range of pre-existing medical conditions which may mean they are not suited for early medical abortion. This

⁶ Upadhyay U & Grossman D. Telemedicine for medication abortion. *Contraception* (100) 351-353. 2019.

⁷ Bracken H. et al. RU OK? The acceptability and feasibility of remote technologies for follow-up after early medical abortion. *Contraception* 2014 (90) 29-35.

would include conditions such as anaemia or hypocoagulability, history of female genital mutilation and a range of other conditions.

(e) Safeguarding and risk of coercion

47. The Claimant asserts that the new system introduced by the Decision carries with it significant medical and ethical risks, in particular relating to the adequacy of safeguarding assessments. There is a particular concern about vulnerable women being pressured into having an abortion by an abusive partner: SFG, §22. Dr Gardner also deals with this in his Statement, at §33. I disagree with this assessment.

48. Independent Sector Providers, who provide the majority of NHS-commissioned abortion services in England and are approved places for this purpose, have been performing clinical assessment and ‘remote’ prescribing for EMA for many years: since 2006 in the case of one major provider. Providers are therefore highly experienced in clinical and safeguarding risk assessments by teleconsultation and telehealthcare, which must meet the requirements of commissioners and in which their use has not historically been associated with increased adverse effects. In response to the Decision, providers have enhanced still further their safeguarding screening processes during remote consultation, for example by requiring detailed videoconsultation if concerns are identified during screening, or by requiring face-to-face attendance if any concerns are identified. These practices are in line with the RCOG COVID-19 guidance.

49. As already set out, at §18 above, RCOG published the RCOG COVID-19 Guidance in light of the pandemic and following the Decision. This followed the guidance published alongside the approval in 2018 allowing Misoprostol to be taken at home: NICE guidance (NG140) Abortion Care (September 2019).

50. The RCOG COVID-19 Guidance has a whole section, titled “*Consent and Safeguarding with remote consultations*” (Section 4). For example, at p21, it states:

“Safeguarding is an essential part of the assessment for abortion care, and providers should follow their processes and assess each case on an individual basis. However there is no automatic need to have to do this in person if adequate assessment is possible via remote consultation,

although it is recommended that this should be tailored to the individual. 35 The clinician should be confident that the woman is not being coerced and that she is able to discuss any concerns privately.”

51. Under the new arrangements, face-to-face consultation is still required should any clinical or safeguarding concerns be identified, or if it is felt that the woman has language, literacy or mental capacity difficulties that would hinder the assimilation of information in order to provide Montgomery-compliant consent. The temporary changes aim to reduce the need for women to travel at a time when this may not be possible, due to local clinic closures and/or self-isolation.

52. All service providers ensure that women have 24 hr access to online and telephone support, including counselling, should this be necessary, including at any time following an abortion procedure.

(f) Longer term risks

53. Dr Gardner raises these concerns at §§34-35 of his Statement. They do not relate to the Decision. The same points could be made, for example, of the EMA where both medicines are taken in a clinical setting.

54. In any event, I disagree that the evidence stands for the proposition he asserts.

55. The Decision makes no difference to the necessity or appropriateness of raising these issues in consultation.

(g) Self-regulation

56. Dr Gardner raises this concern at §36 of his Statement. He asserts that, in answer to a parliamentary question in February 2020, it was reported that 121 facilities performing abortions (59% of the total) required improvement for safety. This is not a concern that relates specifically to the Decision.

57. In any event, I am aware that only 9 are rated as ‘inadequate’ for safety.

58. Furthermore, the Claimant asserts that taking both Mifepristone and Misoprostol at home is unsafe: SFG, §48(e). I disagree.

59. There is international evidence that 'home abortion' is safe.⁸
60. The safety of 'home abortion' is further assured by the pre-existent experience of abortion providers in England in carefully assessing suitability for 'home abortion' through longstanding professionally developed teleconsultation practices.
61. As to the suggestion that the Decision somehow undermines the regulatory regime, I disagree: SFG, §§58-60. Both NHS and ISP providers remain subject to CQC registration and oversight.
62. Teleconsultation and teleprescribing are not new approaches to abortion provision, having been in use for many years by ISPs.
63. EMA resembles, physiologically, a spontaneous abortion (miscarriage), a common outcome of early pregnancy where the abortion or miscarriage would normally take place within the woman's own home. Induced abortion at home incurs no additional hygiene risks or skill requirements.

(h) Systemic risks

64. Dr Gardner raises this concern at §37 of his Statement. I disagree. There is no increased risk of complications when women take both pills at home for EMA. Moreover, women are already able to complete their abortion at home following the approval in 2018 to take Misoprostol at home and there has been no observed increase in complications. (cite ref 13),
65. In fact, the option for women not to be required to attend a healthcare setting, together with the approval of the home of a registered medical practitioner as a class of place for prescribing the medicines for EMA, reduces the pressure on health services at this difficult time.
66. There has been no relaxation in the requirement for two medical practitioners to certify and specify the grounds which determine a patient's suitability for abortion and there has been no downgrading of assessment as suggested at §37 of Dr

⁸ Aiken A et al. Self reported outcomes and adverse events after medical abortion. through online telemedicine: population based study in the Republic of Ireland and Northern Ireland BMJ 2017;357:j2011.

Gardner's Statement. Therefore, it is unlikely that there would be any increase in the risk of medical error.

(i) Other risks

67. Most of the concerns raised by Dr Gardner at §38 of his Statement have already been dealt with above.

68. The Claimant states that the doctor has no control as to when the patient will take the drugs: SFG, §44. This leads to the alleged risks of taking the medicine after 10 weeks, handing the drugs to other women and the sale of these drugs on the black-market. I disagree that these are new concerns which arise as a result of the Decision.

69. These concerns would apply equally to the taking of Misoprostol at home, a policy which has now been in place since January 2019 and has not led to any identified clinical compliance or other concerns. It is also worth saying that the same argument could be made for many prescribed drugs that are taken at home.

70. The outcome of any clinical assessment between clinician and patient ultimately rests on trust. There is no evidence that a teleconsultation, carefully and professionally performed, negatively impacts upon this important relationship in abortion care. The issue of abortion is highly sensitive and deeply personal: women who attend abortion service providers are highly motivated to complete their abortion.

Conclusion

71. Ultimately, Dr Gardner concludes, in §39 of his Statement, that the new arrangements are "*more likely than not to depart from the essential tenets of duty of care through proper clinical assessment, thereby raising the risk of serious injury and harm being done to women self-administering Mifepristone and Misoprostol at home.*" As will be clear from my evidence above, I fundamentally disagree. In my experience, the measures which have been introduced are necessary to secure the safety of women and practitioners during the pandemic, and to ensure that

there is a continued ability for women to access abortion provision. The adverse consequences of them not being able to do so would be significant, as I have explained. In developing the new arrangements, important steps have been taken to ensure safety, as I have explained above.

I believe that the facts stated in this witness statement are true.

SIGNED:

A handwritten signature in black ink, appearing to read "JFD Stephens". The signature is written in a cursive, slightly slanted style.

DATED: 12 May 2020

Direct telephone: +44 (0)207 772 6345
Email: president@rcog.org.uk



**Royal College of
Obstetricians &
Gynaecologists**

Dr Edward Morris
Royal College of Obstetricians and Gynaecologists
10-18 Union Street
London
SE1 1SZ

Department of Health and Social Care
39 Victoria Street
London
SW1H 0EU

12 May 2020

RE: HOME USE OF MIFEPRISTONE

On behalf of the Royal College of Obstetricians and Gynaecologists, I would like to endorse the statement made by Dr Imogen Stephens FRCOG.

With best wishes,

Dr Edward Morris, President
Royal College of Obstetricians and Gynaecologists

From: [REDACTED]
Sent: 12 March 2020 16:00
To: Duncan, Andrea [REDACTED] @dhsc.gov.uk>; [REDACTED] @bpas.org>; [REDACTED] @mariestopes.org.uk>; [REDACTED] @nupas.co.uk>; [REDACTED] @bpas.org>; [REDACTED] (MANCHESTER UNIVERSITY NHS FOUNDATION TRUST) @nhs.net>; [REDACTED] @exeter.ac.uk>; [REDACTED] @RCOG.ORG.UK>; [REDACTED] @nhs.net>; [REDACTED] @phe.gov.uk>; [REDACTED] @phe.gov.uk>; [REDACTED] @gov.scot>; [REDACTED] @gov.wales>; [REDACTED] @nupas.co.uk>; [REDACTED] @nupas.co.uk>; [REDACTED] @nupas.co.uk>; [REDACTED] @phe.gov.uk>; [REDACTED] @dhsc.gov.uk>; [REDACTED] @dhsc.gov.uk>; [REDACTED] @dhsc.gov.uk>; [REDACTED] @governmentlegal.gov.uk>; [REDACTED] @governmentlegal.gov.uk>
Cc: [REDACTED] @dhsc.gov.uk>; [REDACTED] @dhsc.gov.uk>; [REDACTED] @dhsc.gov.uk>; [REDACTED] @governmentlegal.gov.uk>; [REDACTED] @governmentlegal.gov.uk>
Subject: RE: COVID 19 AND ACCESS TO ABORTION

Hi all,

Thanks for your time earlier this week to discuss continuation of access to abortion services in the context of COVID-19.

I've provided a readout of the five key issues raised at the meeting below, supported by the specific points raised. These issues have now been fed into the wider work within DHSC on planning for COVID-19 and will be subject to wider decisions on management of COVID-19 at a national level. We will of course keep you updated with any progress and do keep us updated if new issues emerge at your side.

Best wishes,

[REDACTED]

1. *Abortion should be designated as an essential service if there is going to be a mandate to stop non-essential services.*
2. *Ensuring access to early medical abortion in cases where women and/or doctors are self-isolating (either with a COVID-19 diagnosis or not)*
 - Support for BPAS proposal for home use for both abortion pills for early medical abortion up to 10 weeks (9 + 6) gestation. This is supported by clinical evidence and the infrastructure is already in place for this to happen. Need to ensure safeguarding of patients who are vulnerable to ensure only appropriate patients are assessed via telemedicine. The detail of BPAS' proposal would need to be tailored to work for other providers.
 - Support for extending home use provisions so that this can occur after 10 weeks gestation.
 - It was raised that if women in self-isolation cannot access services, it is likely that they may attempt to access pills online.
3. *How to ensure access to later abortions in cases where women are self-isolating (either with a COVID-19 diagnosis or not)*

- Consensus from attendees that women seeking later-term abortions would need to be treated in isolation in NHS services. BPAS are working to establish how many NHS services that they refer into have isolation facilities for treatment and will send through these figures once they have them. Need for clear comms about protocol for women in these situations.
- Consensus from attendees that providers do not want to state to women that they should wait two weeks in isolation before accessing services. This would be particularly detrimental for women who are 22 weeks pregnant and would therefore be pushed over the gestational limit.

4. *Where abortion pills can be prescribed by Doctors*

- Support for expanding this to Doctors homes (to cover a scenario where doctors are self-isolating but able to work) and call centres.
- Support for expanding to nurses and midwives.

5. *How to ensure continuity of drug supply*

- Support for exploring with MHRA whether restrictions could be lifted on where packing down of pills can take place, as at the moment this is restricted to one NHS Trust.
- Support for escalation of approval of medabon by MHRA.



Abortion and Sexual Health

From: [REDACTED]@RCOG.ORG.UK>
Sent: 17 March 2020 10:46
To: [REDACTED]@dhsc.gov.uk>
Subject:

Hi [REDACTED]

RCOG is currently putting together some guidance to help with managing abortion care during COVID-19.

Sorry to chase, but following the announcement yesterday, I've had lots of providers telling me that they are inundated with queries around accessing services.

Not sure if you have heard back from the national response team yet?

If we can't deliver mifepristone from home, the sector is likely to go into standstill, and women will be presenting at NHS premises requiring care.

Best wishes

[REDACTED]

[REDACTED]

Political Adviser to the President

Royal College of Obstetricians and Gynaecologists

T: [REDACTED]

M: [REDACTED]

E: [REDACTED]@rcog.org.uk

Website: www.rcog.org.uk

10-18 Union Street, London, SE1 1SZ

Switchboard: +44 20 7772 6200

Registered Charity No: 213280

From: [REDACTED]@bpas.org>
Sent: 17 March 2020 11:55
To: [REDACTED]@dhsc.gov.uk>; Duncan, Andrea
[REDACTED]@dhsc.gov.uk>
Subject: Urgent: EMA decisions

Dear both,

Sorry to press, but please would you let me know when a decision will be taken about home use of miso. We need to move to this immediately for two reasons. Firstly, we have a growing number of staff required to self isolated home - 35 as of today. Secondly, we know that NHS services are under extreme pressure and we anticipate demand increasing. (Not your geographical area I know, but we know that the NHS hospital in Cardiff has requested use of our unit because they have lost the theatre time for their abortion list)

So - the request is for a decision asap - and immediate advice on when that will be.

Thanks.

Hope you and yours are fit and well,

[REDACTED]

From: psmatthancock <[REDACTED]@dhsc.gov.uk>
Sent: 24 March 2020 13:13
To: [REDACTED]@dhsc.gov.uk; psmatthancock
<[REDACTED]@dhsc.gov.uk>; Duncan, Andrea <[REDACTED]@dhsc.gov.uk>; pshelenwhately
<[REDACTED]@dhsc.gov.uk>; [REDACTED]@dhsc.gov.uk>;
PsBethell <[REDACTED]@dhsc.gov.uk>
Cc: Marron, Jonathan <[REDACTED]@dhsc.gov.uk>; Davies, Mark <[REDACTED]@dhsc.gov.uk>;
[REDACTED]@governmentlegal.gov.uk>; [REDACTED]@dhsc.gov.uk>;
[REDACTED]@dhsc.gov.uk>; [REDACTED]@dhsc.gov.uk>; [REDACTED]@dhsc.gov.uk>;
[REDACTED]@dhsc.gov.uk>; [REDACTED]@dhsc.gov.uk>; E [REDACTED]
[REDACTED]@dhsc.gov.uk>; Jones, Elin
[REDACTED]@dhsc.gov.uk>; McMordie, Adam <[REDACTED]@dhsc.gov.uk>; [REDACTED]
[REDACTED]@dhsc.gov.uk>; [REDACTED]@dhsc.gov.uk>; [REDACTED]
[REDACTED]@dhsc.gov.uk>; Reeve, Simon <[REDACTED]@dhsc.gov.uk>; [REDACTED]
[REDACTED]@dhsc.gov.uk>; [REDACTED]@dhsc.gov.uk>; [REDACTED]
[REDACTED]@dhsc.gov.uk>; [REDACTED]@dhsc.gov.uk>; [REDACTED]
[REDACTED]@dhsc.gov.uk>

Subject: RE: URGENT SUBMISSION: COVID19 AND ABORTION ACCESS

Hi [REDACTED],

The Secretary of State has just reviewed the submission and has decided that he does not want any changes to abortion.

He has asked for a letter to be sent to all of the recipients of the first letter along the lines of: Sorry, this letter was sent in error. This change is not happening.

Thanks,

[REDACTED]

Access to abortion services – COVID-19

This note follows the submission of 18/03/2020 which set out possible measures to increase access to early medical abortion services in light of COVID-19.

We remain concerned about access to abortion services in light of COVID-19. Around 4,000 women have an abortion each week in England and Wales and access to abortion services is urgent:

- The procedure's risk increases at later gestations;
- The Abortion Act 1967 sets gestational limits for accessing services, so if women present to services near to the gestational limit they will have only a short time to access services. Women who present later in pregnancy are more likely to be vulnerable, so delays will likely mean that vulnerable women will be forced to continue with unwanted pregnancies.
- Any disruption to normal business (i.e. women not being able to access services for several weeks) will have a major impact on the future system's capacity. Surgical abortions require surgical facilities, so ensuring as many women as possible can access early medical services will reduce the strain on hospital facilities.

Key concerns

1. **All women must attend a clinic or hospital in person at least once.** In light of COVID-19, our advice is that travel to abortion clinics or hospitals is classed as essential travel, however this remains a concern for the following reasons:
 - The majority of women accessing abortions will travel on public transport, increasing their risk of COVID-19 transmission. Many women do not have a local clinic so these journeys will often be very long, and following the recent school closures, with children (over 50% of women accessing abortions have given birth to children previously).
 - The need to travel to a clinic will be a particular issue for **women who are shielding, those who have COVID-19 symptoms or those with children** (as clinics can't accommodate children). Providers have told us that in these circumstances, women will be forced to continue with unwanted pregnancies or obtain abortion pills unlawfully online.
2. Providers have informed DHSC that **large numbers of clinic staff are self-isolating and that clinics are having to close in light of this, given doctors are unable to prescribe abortion medication from home.** We have been informed of at least two NHS hospitals where the only available doctors are self-isolating and if they cannot prescribe from home the service will stop. We have been told that ensuring there is a continued level of service provision in clinics and hospitals will be challenging or simply impossible. Clinic closures also mean that women will need to travel longer distances to access services if their nearest clinic closes, increasing concerns around travel outlined above.

Options considered

We have engaged with abortion providers and stakeholders (including the Royal College of Obstetricians and Gynaecologists) to consider a range of options to ensure women and girls are able to access services in the context of COVID-19. The range of options that have been considered are outlined in the table below, along with a DHSC view on each.

Temporary measure to ensure access	DHSC view
1. DHSC to work with abortion providers to provide whatever support we can to ensure continued service provision. This includes clear messaging that abortion is an essential service that must continue and that we expect providers to work together to maintain service provision as far as possible.	This work is ongoing.
2. Using their powers under the Abortion Act, DHSC Ministers approve that women can take both abortion pills for early medical abortion in their own homes so that no travel is necessary (currently women can take the second pill in their home, but must attend the clinic or hospital to take the first). This is supported by clinical evidence.	Ministers have not approved.
3. Using their powers under the Abortion Act, DHSC Ministers approve that doctors can prescribe both pills for early medical abortion from their own homes , to ensure doctors can prescribe when self-isolating.	Ministers have not approved.
4. Amend the Abortion Act to enable one doctor to certify abortions (under the Abortion Act two doctors must certify), to respond to concerns around reduced doctor capacity.	Ministerial view that this should not be progressed. We expect doctors to work flexibly to ensure certification is timely and doesn't delay treatment. Assessment can take place via telemedicine, webcam or on the phone.
5. Amend the Abortion Act to enable nurses, midwives and nurses to perform and certify abortions , to respond to concerns around reduced doctor capacity.	This was not be progressed given Ministerial steer to not to accept amendments on abortion. We do not think it is right that midwives and nurses are suddenly expected to take on expanded roles without proper training and guidance in place.

Next steps

Due to the restrictions in the Abortion Act, options for changing service provision are limited.

- Ministers have powers under the Abortion Act to approve additional places where abortions may be performed. Approval of additional locations (other than the options

outlined in the table above) would not in practice improve access. For example, approving GP practices would mean that a woman could in theory attend her local GP in person to access services, however GPs are not trained to provide abortions and women would still need to travel. GPs are likely to be very reluctant to take on a new service during the current time.

- We have been asked to consider what support could be provided to women to address concerns about women travelling to services on public transport. In our view options here are limited. For example, if Ministers were minded to fund taxis for high risk women (e.g. those who are shielding) to access services, it would be difficult to ensure that taxi drivers did not have COVID-19 infection. However, if Ministers are minded to pursue this option further then we can provide further advice and work with colleagues to see what is being done to enable vulnerable groups to access other healthcare services.
- As you have decided to require women to attend clinics in person to access services it is critical that we ensure adequate service provision to ensure women are not forced to continue with unwanted pregnancies. If the situation escalates and services are increasingly unavailable, we recommend that we return to you with further advice on whether to approve home use for early medical abortion and home prescribing of abortion pills (i.e. options 2 and 3 above), to prevent unwanted pregnancy or women being forced into taking actions which are illegal.

The Hon. Nadine Dorries MP
Minister for Patient Safety and Women's Health
Department for Health and Social Care
39 Victoria Street
London SW1H 0EU

25 March 2020

Dear Nadine

I have been contacted by the Telford branch of the British Pregnancy Advisory Service (BPAS), who have raised a number of concerns about the ongoing operation of their services.

BPAS has informed me that under the current circumstances, thousands of women will be unable to access abortion care during the next three months, and thousands more will have no option but to travel to healthcare clinics for unnecessary appointments, further straining the healthcare system. I understand that one in four of BPAS's clinics have been closed due to staff shortages and illness. This includes the Telford clinic in my constituency, and many women are now having to travel to Stafford or Cannock to access BPAS services.

In particular, BPAS has explained that under the law, 500 women a day have to travel to abortion clinics to take a pill before self-managing the abortion at home. BPAS has stated that this is not clinically required and contradicts Government guidance on non-essential travel. They have asked if the Government would consider allowing BPAS to provide telemedicine services to ensure women can continue to access their advice and support.

I would appreciate if you would look into this matter and provide any assurances for BPAS and women around the UK who rely on their pregnancy services, so that they can continue to support women's access to abortions and pregnancy throughout this time.

Thank you in advance.

Yours ever,

Lucy Allan MP
Member of Parliament for Telford

Access to abortion services – COVID-19

This note follows the submission of 18/03/2020 which set out possible measures to increase access to early medical abortion services in light of COVID-19.

We remain concerned about access to abortion services in light of COVID-19. Around 4,000 women have an abortion each week in England and Wales and access to abortion services is urgent:

- The procedure's risk increases at later gestations;
- The Abortion Act 1967 sets gestational limits for accessing services, so if women present to services near to the gestational limit they will have only a short time to access services. Women who present later in pregnancy are more likely to be vulnerable, so delays will likely mean that vulnerable women will be forced to continue with unwanted pregnancies.
- Any disruption to normal business (i.e. women not being able to access services for several weeks) will have a major impact on the future system's capacity. Surgical abortions require surgical facilities, so ensuring as many women as possible can access early medical services will reduce the strain on hospital facilities.

Key concerns

1. **All women must attend a clinic or hospital in person at least once.** In light of COVID-19, our advice is that travel to abortion clinics or hospitals is classed as essential travel, however this remains a concern for the following reasons:
 - The majority of women accessing abortions will travel on public transport, increasing their risk of COVID-19 transmission. Many women do not have a local clinic so these journeys will often be very long, and following the recent school closures, with children (over 50% of women accessing abortions have given birth to children previously). Clinic closures as set out in paragraph two will make these journeys even harder.
 - The need to travel to a clinic will be a particular issue for **women who are shielding, those who have COVID-19 symptoms or those with children** (as clinics can't accommodate children). Providers have told us that in these circumstances, women will be forced to continue with unwanted pregnancies or obtain abortion pills unlawfully online.
2. Providers have informed DHSC that **large numbers of clinic staff are self-isolating and that clinics are having to close in light of this, given doctors are unable to prescribe abortion medication from home.** For example, Marie Stopes UK have written to SoS to say that 68 of their 400 staff are now self-isolating or showing symptoms. They have also been asked to take on work from 15 areas covered by the NHS given their staff have been re-deployed. BPAS have informed us that 20% of their staff are currently absent. We have been informed of at least two NHS hospitals where the only available doctors are self-isolating and if they cannot prescribe from home the service will stop. We have been told that ensuring there is a continued level of service provision in clinics and hospitals will be challenging or simply impossible.

Clinic closures also mean that women will need to travel longer distances to access services if their nearest clinic closes, increasing concerns around travel outlined above.

Options considered

We have engaged with abortion providers and stakeholders (including the Royal College of Obstetricians and Gynaecologists) to consider a range of options to ensure women and girls are able to access services in the context of COVID-19. The range of options that have been considered are outlined in the table below, along with a DHSC view on each.

Temporary measure to ensure access	DHSC view
1. DHSC to work with abortion providers to provide whatever support we can to ensure continued service provision. This includes clear messaging that abortion is an essential service that must continue and that we expect providers to work together to maintain service provision as far as possible.	This work is ongoing.
2. Using their powers under the Abortion Act, DHSC Ministers approve that women can take both abortion pills for early medical abortion in their own homes so that no travel is necessary (currently women can take the second pill in their home, but must attend the clinic or hospital to take the first). This is supported by clinical evidence.	<p>Pros:</p> <ul style="list-style-type: none"> Ministers have the powers to approve homes as places where both pills can be taken. Providers are ready to go if the approval is given. Would enable access to women who are self-isolating and or who have symptoms. <p>Cons:</p> <ul style="list-style-type: none"> Secretary of State does not currently support this approach. Is controversial and we will be faced accusation of “DIY” abortions. Concerns about safeguarding women if they are not physically seen in a clinic.
3. Using their powers under the Abortion Act, DHSC Ministers approve that doctors can prescribe both pills for early medical abortion from their own homes , to ensure doctors can prescribe when self-isolating.	<p>Pros:</p> <ul style="list-style-type: none"> Ministers have the powers to approve doctors' homes as places where treatment for early medical abortion can be prescribed. Providers are ready to go if the approval is given. Would enable doctors who are self-isolating or who only have mild symptoms to continue to work from home. <p>Cons:</p> <ul style="list-style-type: none"> Secretary of State does not currently support this approach.

<p>4. 4. Ministers approve a wider range of settings, including GP surgeries, to maintain access to services</p>	<p>Pros:</p> <ul style="list-style-type: none"> Ministers have the power approve GP surgeries or any other premises where abortions can legally be performed. GP surgeries are more local for women than abortion services. <p>Cons:</p> <ul style="list-style-type: none"> Prescribing would need to be undertaken physically within the surgery and women would still need to leave their home to collect the medication, including those with symptoms and those who are self-isolating. The first pill would need to be taken at the surgery. GPs may be reluctant to undertake this work at rapid pace given they currently are not involved in abortion care. We do not know how many GPs would conscientiously object to providing abortion care. Funding issues would need to be addressed. Abortion services have 24-hour helplines in place so that women can seek advice on managing pain and bleeding. It is not clear how this would be provided in a GP run service.
<p>5. Pharmacy provision including home deliveries</p>	<p>Pros:</p> <ul style="list-style-type: none"> May ensure quick access and most women live near a pharmacy. Ministers have the power to approve pharmacies as a place where abortions can legally be performed. <p>Cons:</p> <ul style="list-style-type: none"> Legally only a doctor can perform an abortion which includes prescribing the medication. Primary legislation is required to amend this. Ministers did not support an attempt to amend the emergency bill to allow nurses and midwives to perform abortions and the amendment was withdrawn. Home deliveries would involve both pills being taken at home and would require women's homes to be approved as above.

Other Issues/ Options

Due to the restrictions in the Abortion Act, options for changing service provision are limited.

- We have been asked to consider what support could be provided to women to address concerns about women travelling to services on public transport. In our view options here are limited. For example, if Ministers were minded to fund taxis for high risk women (e.g. those who are shielding) to access services, it would be difficult to ensure that taxi drivers did not have COVID-19 infection. However, if Ministers are minded to pursue this option further then we can provide further advice and work with colleagues to see what is being done to enable vulnerable groups to access other healthcare services.
- As you have decided to require women to attend clinics in person to access services it is critical that we ensure adequate service provision to ensure women are not forced to continue with unwanted pregnancies. If the situation escalates and services are increasingly unavailable, we recommend that we return to you with further advice on whether to approve home use for early medical abortion and home prescribing of abortion pills (i.e. options 2 and 3 above), to prevent unwanted pregnancy or women being forced into taking actions which are illegal.

28 March 2020

Open letter to: Rt Hon Matt Hancock MP, Secretary of State for Health

Dear Secretary of State,

Request for immediate introduction of telemedical abortion services to reduce coronavirus transmission

First let us express our best wishes for a speedy recovery from your illness and apologise for having to bring another issue to your attention at this challenging time.

We are writing to you as public health specialists to implore you to advise the Prime Minister, and the wider government, on the capacity of telemedical abortion services to help curb the COVID-19 pandemic and protect wider public health.

- Despite instruction to avoid any unnecessary travel by the Prime Minister, in the next 13 weeks as the pandemic is predicted to reach its peak, at least 44,000 women will have to leave their homes needlessly to access early medical abortion care, with an increasing number of clinic closures forcing them to travel long distances across the country exposing themselves and others to COVID-19.
- This equates to over 3,000 journeys per week, with each woman making multiple contacts during her journey and during her time in both independent clinics and high-risk NHS settings. Telemedical early abortion services would eliminate all such contact and therefore protect the health of the wider population, our health system, and our healthcare workers.
- The government is repeatedly refusing to follow advice from scientific and professional bodies to enable telemedicine for early medical abortion so women can be safely cared for in their own homes whilst fulfilling their moral obligation to protect the health of others.
- Comprehensive regulations on permitting telemedicine for early medical abortion were introduced by the Department of Health on Monday, on the advice of healthcare bodies including the Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Midwives (RCM), and then inexplicably retracted the same evening.
- Telemedicine for abortion has been recommended by NICE.

We believe that the impact of failing to implement this service on both individuals and the wider population will be grave, and services are currently at the brink of collapse.

- Women with severe health issues who have been told to self-isolate for 12 weeks say they are being forced to choose between risking their health by leaving their house and being compelled to continue an unwanted pregnancy that also threatens their health.
- Vulnerable women are already turning outside the regulated healthcare system for help from online providers, breaking the law and foregoing the inbuilt safeguarding and support provided by regulated services.

- A quarter (23%) of abortion clinics run by bpas, which cares for 100,000 women per year, were closed on the 24th of March due to staff sickness and isolation, with further closures expected across NHS funded services today.
- Surgical abortion lists are being cancelled across the UK as operating theatres are being used as ICUs. Women who cannot access a safe early medical abortion will have no back up later in their unwanted pregnancy.
- Abortion services are at risk of collapse if the Prime Minister does not act swiftly.

We urge you to act immediately to protect the health of individuals, the wider population, and our healthcare workers.

Signed:

Professor Maggie Rae, President of the Faculty of Public Health

Professor Helen Ward, Professor of Public Health, Imperial College London

Professor Trish Greenhalgh, Professor of Primary Care Health Sciences, Nuffield Department of Primary Care Health Sciences, Medical Sciences Division, University of Oxford

Dr Edward Morris, President, Royal College of Obstetricians and Gynaecologists. Consultant in Obstetrics and Gynaecology, Norfolk and Norwich University Hospital, Norwich

Dame Lesley Regan, Professor Obstetrics & Gynaecology, Imperial College; Chair RCOG Abortion Task Force and Past President RCOG

Professor Martin McKee, Professor of European Public Health, London School of Hygiene and Tropical Medicine

Professor Jim McManus, Vice-President, Association of Directors of Public Health

Professor Majid Ezzati, Chair in Global Environmental Health, Imperial College London

Professor David McCoy, Professor of Global Public Health, Queen Mary University of London

Professor Paul Roderick, Professor of Public Health, University of Southampton

Professor Nicola Shelton, Professor of Population Health, University College London

Professor Allyson Pollock, Professor of Public Health, Newcastle University

Professor Mark S Gilthorpe, Professor of Statistical Epidemiology, University of Leeds

Professor Elio Riboli, Chair in Cancer Epidemiology and Prevention, Imperial College London

Professor Lefkos Middleton, Chair in Clinical Neurology, Imperial College London

Dr Rochelle Burgess, Lecturer in Global Health, University College London

Dr Miriam Orcutt, Senior Research Fellow, University College London

Dr Cleone Rooney, retired Consultant in Public Health and Health Protection

Professor Steph Taylor, Professor in Public Health and Primary Care, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Professor Adrian Martineau, Professor of Respiratory Infection and Immunity, , Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Professor Ernestina Coast, Professor of Health and International Development, London School of Economics & Political Science

Professor Guiqing Lily Yao, Professor of Health Economics, University of Leicester.

Dr Jocalyn Clark, Executive Editor, The Lancet; Assistant Professor of Medicine, University of Toronto

Dr Geordan Shannon, Lecturer in Global Health, University College London

Dr Rishita Nandagiri, LSE Fellow in Health and International Development, London School of Economics and Political Science

Professor Cicely Marston, Professor of Public Health, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Rebecca French, Associate Professor of Sexual & Reproductive Health Research, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Professor Oona Campbell, Professor of Epidemiology and Reproductive Health, Faculty of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine

Dr Alexis Palfreyman, Research Fellow in Global Health, University College London

Professor Deborah Ashby, Director of the School of Public Health, Imperial College London

Dr Rachel Scott, Research Fellow in Demography, London School of Hygiene and Tropical Medicine

Dr Francesca Cavallaro, Research Fellow in Maternal and Child Health Epidemiology, University College London

Dr. Neha Singh, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Heini Vaisanen, Lecturer in Social Statistics and Demography, Department of Social Statistics and Demography, University of Southampton

Professor Veronique Filippi, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine

Professor Caroline Free, Professor of Primary Care and Epidemiology. General Practitioner.

Dr Rudiger Pittrof, NHS Consultant in Community Sexual Health and HIV, GSTT,

Dr Sam Miles, Research Fellow, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Professor Mark Petticrew, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Professor Nicholas Mays, Professor of Health Policy, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Alicia Renedo, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Helen Burchett, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Jennie Gamlin, Senior Research Fellow, UCL Institute for Global Health

Professor Susannah Mayhew, Faculty of Public Health and Policy, London School of Hygiene & Tropical Medicine

Martine Collumbien, Associate Professor of Sexual Health Research, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Dina Balabanova, Associate Professor, Health Systems/Policy, London School of Hygiene & Tropical Medicine

Dr Ruth Lewis, Research Fellow, University of Glasgow

Dr Nambusi Kyegombe, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Carrie Purcell, Research Fellow, MRC/CSO Social and Public Health Sciences Unit, University of Glasgow

Dr Fiona Bloomer, School of Applied Social and Policy Sciences, Ulster University

Dr Jenevieve Mannell, Lecturer, Institute for Global Health, University College London

Dr Ruth Ponsford, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Susannah Woodd, Research Fellow, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, General Practitioner

Harriet Ruysen, Research Fellow: London School of Hygiene & Tropical Medicine & Midwife: Dumfries and Galloway Royal Infirmary

Professor Sam Rowlands, Visiting Professor, Dept of Medical Sciences and Public Health, Bournemouth University

From: psmatthancock

Sent: 28 March 2020 21:45

To: pshelenwhately [REDACTED] <[REDACTED]@dhsc.gov.uk>; [REDACTED] <[REDACTED]@dhsc.gov.uk>; Duncan, Andrea [REDACTED] <[REDACTED]@dhsc.gov.uk>; psmatthancock [REDACTED] <[REDACTED]@dhsc.gov.uk>

Cc: Covid19 Comms [REDACTED] <[REDACTED]@dhsc.gov.uk>; Miller, Stuart [REDACTED] <[REDACTED]@dhsc.gov.uk>; Davies, Mark [REDACTED] <[REDACTED]@dhsc.gov.uk>

Subject: RE: Urgent - lines on abortion

Hi All,

Just had an update from Jamie. He has briefed the Sunday times along the following lines:

- We will be allowing the home use of abortion pills, with the following stipulations:
 - Any abortion will require a telephone or e-consultation with a doctor
 - This change will be made on a temporary basis only and is time limited for two years, or until the crisis is over, on the same timetable as the emergency legislation. It is not permanent.
 - This applies for medical abortions up to 10 weeks as it is currently.

Jamie said No.10 were happy with this, and the ST are reflecting this in their copy. It is likely we will have fall out tomorrow depending on how this lands with the ST, so would be grateful if officials could be on hand tomorrow morning.

I appreciate this doesn't answer your question on doctors prescribing these pills from home. I think SofS will need to review the policy options on doctors prescribing from home sent up in the original sub last week again. **So would you be able to prepare a short sub for tomorrow morning on the doctors prescribing from home policy options given the new steer please?** Really sorry about the timings of this!

Just to let you know, [REDACTED] will be covering the Covid work in SofS office tomorrow morning.

Thanks,

[REDACTED]



[REDACTED]
Covid response - SofS Private Office

(Rota system with [REDACTED])

E: [REDACTED]@dhsc.gov.uk

T: [REDACTED] M: [REDACTED]

CLEARANCE CHECKLIST

Inclusion of this checklist is mandatory. Please complete the whole list and private office will remove before putting submission in the box. A submission without it will be sent back.

Note: Contact names provided must have seen and approved the submission.

Finance:

Does this involve any spending or affect existing budgets?

- ☐ If yes, named official:
Click here to enter text.
☐ No

Legal:

[Redacted]

Communications:

Could this generate media coverage, or a response from the health sector?

- ☒ If yes, named official:
[Redacted]
☐ No

Analysis and data fact-checking:

Does this include complex data, statistics or analysis?

- ☐ If yes, named official:
Click here to enter text.
☐ No

Devolved Administrations:

Will this affect Scotland, Wales or Northern Ireland?

- ☐ If yes, named official:
Click here to enter text.
☐ No

Fraud:

Have you considered fraud risks?

- ☐ If yes, named official:
Click here to enter text.
☐ No

Commercial:

Does this include commercial or contractual implications?

- ☐ If yes, named official:
Click here to enter text.
☐ No

Strategy Unit:

Does this relate to cross-cutting or longer-term implications for wider DH strategy?

- ☐ If yes, named official:
Click here to enter text.
☐ No

Implementation Unit:

Does this relate to one of the Secretary of State priorities?

- ☐ If yes, named official:
Click here to enter text.
☐ No

Legislation:

Does this include options that may require secondary legislation?

- ☐ If yes, do you have a prioritisation reference number? (contact Parly or SOPL if unsure):
Click here to enter text.
☐ No

Duties, Tests and Appraisals:

The following tests apply and have been considered.

- ☐ Secretary of State Statutory Duties, including on health inequalities
☐ Public Sector Equality Duty
☐ Family test
☐ Other(s) (please specify)
Click here to enter text.

OFFICIAL-SENSITIVE

To: SofS

From:

Clearance: Mark Davies

Date: 29 March 2020

Copy:

[Private Office Submissions
Copy List](#)

COVID-19 AND ABORTION: APPROVAL OF WOMEN'S HOMES FOR EARLY MEDICAL ABORTION AND DOCTOR'S HOMES FOR PRESCRIBING

Issue	Following your agreement to a temporary approval of home use of both abortion pills for early medical abortion up to 10 weeks gestation, this submission seeks a steer on whether doctors should be able to prescribe both pills for treatment of early medical abortion from their homes and the terms of the approval that will be sent to providers.
Timing	<div>Urgent (two working days)</div> <p>An urgent steer is required as a new temporary approval needs to be sent to providers and stakeholders as soon as possible.</p>
Recommendation	To limit transmission of COVID-19 and ensure access to early medical abortion services, we recommend that you use your powers under the Abortion Act 1967 to temporarily approve the home of a doctor as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion up to 10 weeks and agree the updated temporary approval at annex A.

Discussion

1. You have agreed to use your powers under the Abortion Act 1967 to temporarily approve women's homes as a class of place where both abortion pills can be taken for early medical abortion up to 10 weeks. This is a temporary approval and is time limited (see paragraph 4).
2. This submission seeks a decision on whether you are content to also approve, on a temporary time limited basis, the home of a registered medical practitioner (a doctor) as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion up to 10 weeks. This will also be a temporary approval (see paragraph 4). This approach was previously supported by No10 and MS(C). Providers and stakeholders are likely to seek urgent clarification on this point. It was included in the temporary approval circulated on Monday 23 March that has now been withdrawn.
3. If you are content to approve, the temporary approval at Annex A will be sent to abortion providers from a senior DHSC official and also to stakeholders and published on gov.uk. This will include approval of both: women's homes as a class of place where both abortion pills can be taken for early medical abortion up to 10 weeks gestation; and the home of a doctor as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion up to 10 weeks. Providers must also ensure that a telephone or e-consultation with a

doctor takes place as part of the certification process. As with existing practice, this may be a consultation with a nurse or midwife acting under the instruction of a doctor (currently only doctors are allowed to perform abortions, but midwives and nurses sometimes undertake the consultation acting under the instruction of a doctor). Two doctors must always review the information from the consultation and agree that there are grounds under the Abortion Act 1967 before the abortion can proceed.

4. The temporary approval at Annex A sets out that the approval of women's homes for taking both abortion pills and doctors home's for prescribing medication up to 10 weeks gestation **is not permanent**. The temporary approval at Annex A sets out that **the approval expires on the day on which the temporary provisions of the Coronavirus Act 2020 expire, or the end of the period of 2 years beginning with the day on which it is made, whichever is earlier**.

Enabling doctors to prescribe medication for early medical abortions at home

5. The Abortion Act 1967 permits abortions to be performed in NHS hospitals or a place approved by the SofS. The courts have ruled that this includes the whole course of treatment (including prescribing). The Act also sets out that abortions can only be carried out by doctors. This means that a doctor has to be located within an approved clinic or hospital in order to prescribe abortion medication.
6. We have been told that large numbers of doctors are now self-isolating. **We therefore recommend that you agree to include in the updated temporary approval the home of a registered medical practitioner (a doctor) as a class of place where both abortion pills (Mifepristone and Misoprostol) can be prescribed for the treatment of early medical abortion. We will be clear that the temporary approval expires on the day on which the temporary provisions of the Coronavirus Act 2020 expire, or the end of the period of 2 years beginning with the day on which it is made, whichever is earlier.**
7. This will enable doctors who are self-isolating but well enough to work to prescribe medication from their home. Their home would be approved as a class of place only for prescribing the medication. Approval of this measure alongside would enable medication to be prescribed by the doctor in their home in any of the following circumstances:
 - a. A woman has attended a consultation in a clinic or hospital; or
 - b. A woman has had a consultation with a clinic or hospital via video link, telephone or other electronic means; or
 - c. A woman has had a consultation with a doctor (who is self-isolating in their home) via video link, telephone or other electronic means.
8. This approach has strong consensus support from abortion providers, the Royal College of Obstetricians and Gynaecologists and PHE. As above, the use of telemedicine is supported by NICE abortion guidance.
9. Whilst this measure is less controversial than home use for both abortion pills, it may still be viewed as controversial by pro-life organisations and MPs. However, our advice is that this measure is necessary in the COVID-19 context and is in line with clinical evidence. This measure will be supported by pro-choice organisations and it is likely that these organisations will put pressure on DHSC to extend this measure after COVID-19. As with home use for both abortion pills,

we will be clear that the temporary approval at Annex A is not permanent, and expires on the day on which the temporary provisions of the Coronavirus Act 2020 expire, or the end of the period of 2 years beginning with the day on which it is made, whichever is earlier.

Legal [REDACTED]

10. [REDACTED]
11. [REDACTED]
12. [REDACTED]

Public Sector Equality Duty

13. In making any decisions or exercising any other functions, ministers must comply with the public sector equality duty ("PSED") in section 149 of the Equality Act 2010. When exercising functions relating to the NHS, the SofS must also comply with general duties under the NHS Act 2006 and with the Families Test.
14. This policy will have a positive impact on the need to eliminate discrimination between sexes. It is important to note that women and girls still have the option of attending a clinic to take the first, or both, abortion pills, which will foster good relations between different groups of women and girls. This policy forms a part of our efforts to ensure no groups are disadvantaged in the current COVID-19 crisis. A more detailed PSED analysis is being developed.

Communications – [REDACTED]

15. The abortion guidance, and its subsequent change this week, has received significant media interest from the majority of nationals over the past few days, with several journalists asking for our response on the guidance changes. We

OFFICIAL-SENSITIVE

anticipate that this further amendment will also receive interest from both stakeholders and media.

16. If this is agreed to, Media Relations will prepare a robust reactive line emphasising this importance of this new guideline, but also that patient safety is still a priority and this is a temporary measure. We will also prepare a Q&A for use in case approached by media on the specifics. Everything will be cleared appropriately through SpAds and No.10.
17. External Affairs will pre-brief relevant stakeholders ahead of the new guidance being published, so that they're aware of the changes being made and can inform their members accordingly.

Conclusion

18. To limit transmission of COVID-19 and ensure access to early medical abortion services, we recommend that you:
 - a. Use your powers under the Abortion Act 1967 to temporarily approve the home of a doctor as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion.
 - b. Agree the draft temporary approval for early medical abortion which includes women's homes for taking both treatments and doctors home's for prescribing medication up to 10 weeks gestation at Annex A.



The Abortion Act 1967 - Approval of a Class of Places

This approval supersedes the approval of 27 December 2018. This approval has effect until the earlier of the end of the period of 2 years beginning with the day on which it is made or the day on which the temporary provisions of the Coronavirus Act 2020 expire.

The Secretary of State makes the following approval in exercise of the powers conferred by section 1(3) and (3A) ¹of the Abortion Act 1967²:

Interpretation

1. In this approval –

“home” means, in the case of a pregnant woman, the place in England where a pregnant woman has her permanent address or usually resides or, in the case of a registered medical practitioner, the place in England where a registered medical practitioner has their permanent address or usually resides;

“approved place” means a hospital in England, as authorised under section 1(3) of the Abortion Act 1967, or a place in England approved under that section.

Approval of class of place

2. The home of a registered medical practitioner is approved as a class of place for treatment for the termination of pregnancy for the purposes only of prescribing the medicines known as Mifepristone and Misoprostol to be used in treatment carried out in the manner specified in paragraph 4.

3. The home of a pregnant woman who is undergoing treatment for the purposes of termination of her pregnancy is approved as a class of place where the treatment for termination of pregnancy may be carried out where that treatment is carried out in the manner specified in paragraph 4.

4. The treatment must be carried out in the following manner-

a) the pregnant woman has-

i) attended an approved place;

¹ Section 1(3A) was inserted by section 37(3) of the Human Fertilisation and Embryology Act 1990 (c. 37).

² 1967 c. 87.

ii) had a consultation with an approved place via video link, telephone conference or other electronic means, or

iii) had a consultation with a registered medical practitioner via video link, telephone conference or other electronic means; and

b) the pregnant woman is prescribed Mifepristone and Misoprostol to be taken for the purposes of the termination of her pregnancy and the gestation of the pregnancy has not exceeded nine weeks and six days at the time the Mifepristone is taken.

Mark Davies

Director, Population Health

20 March 2020



The Abortion Act 1967 - Approval of a Class of Places

This approval supersedes the approval of 27 December 2018. This approval expires on the day on which the temporary provisions of the Coronavirus Act 2020 expire, or the end of the period of 2 years beginning with the day on which it is made, whichever is earlier.

The Secretary of State makes the following approval in exercise of the powers conferred by section 1(3) and (3A) ¹of the Abortion Act 1967²:

Interpretation

1. In this approval –

“home” means, in the case of a pregnant woman, the place in England where a pregnant woman has her permanent address or usually resides or, in the case of a registered medical practitioner, the place in England where a registered medical practitioner has their permanent address or usually resides;

“approved place” means a hospital in England, as authorised under section 1(3) of the Abortion Act 1967, or a place in England approved under that section.

Approval of class of place

2. The home of a registered medical practitioner is approved as a class of place for treatment for the termination of pregnancy for the purposes only of prescribing the medicines known as Mifepristone and Misoprostol to be used in treatment carried out in the manner specified in paragraph 4.

3. The home of a pregnant woman who is undergoing treatment for the purposes of termination of her pregnancy is approved as a class of place where the treatment for termination of pregnancy may be carried out where that treatment is carried out in the manner specified in paragraph 4.

4. The treatment must be carried out in the following manner-

a) the pregnant woman has-

i) attended an approved place;

¹ Section 1(3A) was inserted by section 37(3) of the Human Fertilisation and Embryology Act 1990 (c. 37).

² 1967 c. 87.

ii) had a consultation with an approved place via video link, telephone conference or other electronic means, or

iii) had a consultation with a registered medical practitioner via video link, telephone conference or other electronic means; and

b) the pregnant woman is prescribed Mifepristone and Misoprostol to be taken for the purposes of the termination of her pregnancy and the gestation of the pregnancy has not exceeded nine weeks and six days at the time the Mifepristone is taken.

Mark Davies

Director, Population Health

20 March 2020

