

ASSEMBLY JOINT RESOLUTION

No. 176

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED JULY 2, 2020

Sponsored by:

Assemblywoman VALERIE VAINIERI HUTTLE

District 37 (Bergen)

Co-Sponsored by:

Assemblywoman Speight

SYNOPSIS

Urging FDA to remove restrictions on mifepristone.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 7/30/2020)

1 **A JOINT RESOLUTION** urging the United States Food and Drug
2 Administration to remove restrictions on mifepristone.

3
4 **WHEREAS**, Mifepristone is an evidence-based treatment prescribed
5 for the management of early pregnancy loss; and

6 **WHEREAS**, The United States Food and Drug Administration (FDA)
7 has placed regulations on mifepristone, implementing a Risk
8 Evaluation and Mitigation Strategy (REMS) which requires that
9 mifepristone can only be dispensed in clinics, medical offices,
10 and hospitals under the supervision of a certified healthcare
11 provider; and

12 **WHEREAS**, REMS restrictions were placed on mifepristone when the
13 drug was first approved, but the last two decades have demonstrated
14 that the drug's side effects are reasonably minimal and can be well-
15 managed; and

16 **WHEREAS**, These restrictions on mifepristone make it difficult to
17 access care, especially for low-income patients that might have
18 to arrange transportation and childcare to receive treatment; and

19 **WHEREAS**, Because mifepristone can only be dispensed in clinics,
20 medical offices, and hospitals, patients may experience
21 difficulties obtaining the drug because of inconsistent supply
22 across healthcare facilities, as opposed to the established supply-
23 chain and convenience of commercial pharmacies; and

24 **WHEREAS**, The FDA restrictions may also lead some patients to
25 obtain mifepristone over the internet, which poses significant
26 product safety and quality risks; and

27 **WHEREAS**, Mifepristone has been proven to be safe and effective
28 when prescribed through telemedicine and can be safely taken in
29 a patient's home; and

30 **WHEREAS**, In 2016, the FDA lessened restrictions on mifepristone, by
31 increasing the terms of use from seven to 10 weeks and removing
32 the requirement of patients remaining in the healthcare facility for
33 the full duration of the drug administration; but, patients are still
34 required to register with clinics and keep extensive records of their
35 treatment; and

36 **WHEREAS**, It is imperative that the FDA completely removes the
37 restrictions on mifepristone in order to promote the well-being of
38 patients in this State; now, therefore,

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40 **BE IT RESOLVED** *by the Senate and General Assembly of the*
41 *State of New Jersey:*

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43 1. The Governor and the Legislature of the State of New Jersey
44 urge the United States Food and Drug Administration to lift Risk
45 Evaluation and Mitigation Strategy restrictions on mifepristone.

46
47 2. Copies of this resolution, as filed with the Secretary of State,
48 shall be transmitted by the Clerk of the General Assembly or the

1 Secretary of the Senate to the President of the United States, the
2 United States Secretary of Health and Human Services, and the
3 United States Commissioner of Food and Drugs.

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5 3. This joint resolution shall take effect immediately.
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8 STATEMENT
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10 This joint resolution urges the United States Food and Drug
11 Administration (FDA) to lift Risk Evaluation and Mitigation
12 Strategy restrictions on mifepristone. Mifepristone is an evidence-
13 based treatment prescribed for the management of early pregnancy
14 loss. The FDA has placed regulations on mifepristone,
15 implementing a Risk Evaluation and Mitigation Strategy (REMS)
16 which requires that mifepristone can only be dispensed in clinics,
17 medical offices, and hospitals under the supervision of a certified
18 healthcare provider.

19 These restrictions on mifepristone make it difficult to access
20 care, especially for low-income patients that might have to arrange
21 transportation and childcare to receive treatment. Because
22 mifepristone can only be dispensed in clinics, medical offices, and
23 hospitals, patients may experience difficulties obtaining the drug
24 because of inconsistent supply across healthcare facilities, as
25 opposed to the established supply-chain and convenience of
26 commercial pharmacies. The FDA restrictions may also lead some
27 patients to obtain mifepristone over the internet, which poses
28 significant product safety and quality risks.

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30 increasing the terms of use from seven to 10 weeks and removing the
31 requirement of patients remaining in the healthcare facility for the full
32 duration of the drug administration; but, patients are still required to
33 register with clinics and keep extensive records of their treatment. It is
34 imperative that the FDA completely removes the restrictions on
35 mifepristone in order to promote the well-being of patients in this
36 State.