

HOUSE BILL 1101

J1, J2

9lr2245

By: **Delegates Cox, Boteler, Impallaria, Otto, and Reilly**

Introduced and read first time: February 8, 2019

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Health – Mifepristone – Administration**

3 FOR the purpose of requiring the Maryland Department of Health to adopt certain
4 regulations regarding the administration of mifepristone; requiring that
5 mifepristone be provided by or under the supervision of a physician who meets
6 certain qualifications and conditions; requiring each provider of mifepristone to
7 make certain certifications and make certain information available in a certain
8 manner; establishing a certain penalty; requiring the Department to make a certain
9 report to the General Assembly on or before a certain date each year; and generally
10 relating to the administration of mifepristone.

11 BY adding to
12 Article – Health – General
13 Section 21–228
14 Annotated Code of Maryland
15 (2015 Replacement Volume and 2018 Supplement)

16 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
17 That the Laws of Maryland read as follows:

18 **Article – Health – General**

19 **21–228.**

20 **(A) THE DEPARTMENT SHALL ADOPT REGULATIONS REGARDING THE**
21 **ADMINISTRATION OF MIFEPRISTONE THAT COMPLY WITH 21 C.F.R. § 214.520.**

22 **(B) MIFEPRISTONE SHALL BE PROVIDED BY OR UNDER THE SUPERVISION**
23 **OF A PHYSICIAN WHO:**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 **(1) IS ABLE TO ASSESS THE DURATION OF PREGNANCY ACCURATELY;**

2 **(2) IS ABLE TO DIAGNOSE ECTOPIC PREGNANCIES;**

3 **(3) IS ABLE TO PROVIDE SURGICAL INTERVENTION IN CASES OF**
4 **INCOMPLETE ABORTION OR SEVERE BLEEDING OR HAS MADE PLANS TO PROVIDE**
5 **THE SURGICAL INTERVENTION THROUGH ANOTHER QUALIFIED PHYSICIAN, AND IS**
6 **ABLE TO ASSURE PATIENT ACCESS TO MEDICAL FACILITIES EQUIPPED TO PROVIDE**
7 **BLOOD TRANSFUSIONS AND RESUSCITATION, IF NECESSARY;**

8 **(4) HAS READ AND UNDERSTANDS THE PRESCRIBING INFORMATION**
9 **REGARDING MIFEPRISTONE;**

10 **(5) SHALL EXPLAIN THE PROCEDURE FOR ADMINISTERING**
11 **MIFEPRISTONE TO EACH PATIENT;**

12 **(6) SHALL PROVIDE EACH PATIENT WITH A COPY OF THE MEDICATION**
13 **GUIDE AND PATIENT AGREEMENT REGARDING MIFEPRISTONE AND GIVE THE**
14 **PATIENT AN OPPORTUNITY TO READ AND DISCUSS THE MEDICATION GUIDE AND THE**
15 **PATIENT AGREEMENT;**

16 **(7) SHALL SIGN THE PATIENT AGREEMENT AND OBTAIN THE**
17 **PATIENT'S SIGNATURE ON THE AGREEMENT;**

18 **(8) SHALL NOTIFY THE SPONSOR OR THE SPONSOR'S DESIGNEE IN**
19 **WRITING AS PROVIDED IN THE PACKAGE INSERT FOR MIFEPRISTONE IN THE EVENT**
20 **OF AN ONGOING PREGNANCY THAT IS NOT TERMINATED AFTER THE CONCLUSION OF**
21 **THE TREATMENT PROCEDURE;**

22 **(9) SHALL REPORT ANY HOSPITALIZATION, TRANSFUSION, OR OTHER**
23 **SERIOUS EVENTS TO THE SPONSOR OR THE SPONSOR'S DESIGNEE; AND**

24 **(10) SHALL RECORD THE MIFEPRISTONE PACKAGE SERIAL NUMBER IN**
25 **EACH PATIENT'S MEDICAL RECORD.**

26 **(c) EACH PROVIDER OF MIFEPRISTONE SHALL:**

27 **(1) CERTIFY UNDER PERSONAL KNOWLEDGE AND PENALTY OF**
28 **PERJURY THAT THE REQUIREMENTS OF SUBSECTION (b) OF THIS SECTION HAVE**
29 **BEEN MET; AND**

30 **(2) MAKE THE FOLLOWING INFORMATION AVAILABLE ON THE**
31 **PROVIDER'S WEBSITE:**

1 **(I) ANY CERTIFICATION MADE UNDER PARAGRAPH (1) OF THIS**
2 **SUBSECTION;**

3 **(II) THE NUMBER OF ADMINISTRATIONS OF MIFEPRISTONE**
4 **MADE BY THE PROVIDER; AND**

5 **(III) THE NUMBER OF ADVERSE REACTIONS,**
6 **HOSPITALIZATIONS, AND COMPLICATIONS EXPERIENCED BY INDIVIDUALS AFTER**
7 **THE ADMINISTRATION OF MIFEPRISTONE.**

8 **(D) A PERSON WHO VIOLATES ANY PROVISION OF THIS SECTION OR ANY**
9 **REGULATION ADOPTED UNDER THIS SECTION IS GUILTY OF A MISDEMEANOR AND**
10 **ON CONVICTION IS SUBJECT TO A FINE NOT EXCEEDING \$1,000.**

11 **(E) ON OR BEFORE DECEMBER 1, 2019, AND EACH DECEMBER 1**
12 **THEREAFTER, THE DEPARTMENT SHALL REPORT TO THE GENERAL ASSEMBLY, IN**
13 **ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, ON THE**
14 **IMPLEMENTATION OF THIS SECTION, INCLUDING:**

15 **(1) THE NUMBER OF ADMINISTRATIONS OF MIFEPRISTONE BY EACH**
16 **PROVIDER; AND**

17 **(2) THE NUMBER OF ADVERSE REACTIONS, HOSPITALIZATIONS, AND**
18 **COMPLICATIONS EXPERIENCED BY INDIVIDUALS AFTER THE ADMINISTRATION OF**
19 **MIFEPRISTONE.**

20 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
21 October 1, 2019.