HB 1101

Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

House Bill 1101 (Delegate Cox, *et al.*)
Health and Government Operations

Health - Mifepristone - Administration

This bill requires that mifepristone be provided by or under the supervision of a physician who meets specified criteria. Each provider of mifepristone must take specified actions. The Maryland Department of Health (MDH) must adopt regulations regarding the administration of mifepristone. A violation of the bill's provisions or related regulations is a misdemeanor and a violator is subject to a fine of up to $1,000. Beginning December 1, 2019, and annually thereafter, MDH must report specified information on mifepristone to the General Assembly.

Fiscal Summary

State Effect: Potential minimal increase in general fund revenues due to the bill's monetary penalty provisions from cases heard in the District Court. General fund expenditures increase by $58,800 in FY 2020 for contractual staff. Future years reflect elimination of the contractual position in FY 2021.

(in dollars)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Revenues	$0	$0	$0	$0	$0
GF Expenditure	58,800	16,900	0	0	0
Net Effect	($58,800)	($16,900)	$0	$0	$0

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: None.

Small Business Effect: Potential minimal.

Analysis

Bill Summary: A physician who provides mifepristone must:

- be able to assess the duration of pregnancy accurately;
- be able to diagnose ectopic pregnancies;
- be able to provide surgical intervention in cases of incomplete abortion or severe bleeding or have plans to provide the surgical intervention through another qualified physician, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation;
- read and understand the prescribing information for mifepristone;
- explain the procedure for administering mifepristone to each patient;
- provide a copy of, give the patient the opportunity to read, and discuss with each patient the medication guide and the patient agreement regarding mifepristone;
- sign and obtain the patient's signature on the patient agreement;
- notify the sponsor or sponsor's designee (generally the manufacturer, as provided in the package insert for mifepristone) in the event of a pregnancy that is not terminated after the conclusion of the treatment procedure;
- report any hospitalization, transfusion, or other serious events to the sponsor or the sponsor's designee; and
- record the mifepristone package serial number in each patient's medical record.

Each provider of mifepristone must certify, under personal knowledge and penalty of perjury, that the above requirements have been met. Additionally, the provider must make the following information available on the provider's website: (1) any certification that the above requirements have been met; (2) the number of administrations of mifepristone that the provider has made; and (3) the number of adverse reactions, hospitalizations, and complications experienced by individuals following the administration of mifepristone by the provider.

The regulations adopted by MDH must comply with the U.S. Code of Federal Regulations.

In its annual report, MDH must include the number of administrations of mifepristone by each provider and the number of adverse reactions, hospitalizations, and complications experienced by individuals following the administration of mifepristone.

Current Law/Background: Mifepristone (also known as Mifeprex) is used in combination with the medication misoprostol to end an early pregnancy by both interrupting the hormones that the body needs to maintain a pregnancy and inducing the uterine cramping necessary to cause a medical abortion.

The U.S. Food and Drug Administration (FDA) first approved Mifeprex in 2000. Pursuant to its authority under 21 C.F.R. § 314.520, FDA imposed restrictions on the distribution of the drug as a condition of the drug's approval. Following a 2016 supplemental application regarding Mifeprex, FDA determined that Mifeprex is safe and effective when used to terminate a pregnancy through 70 days gestation (70 days since the first day of a woman's last menstrual period), but that restrictions on its distribution were still necessary.

FDA also approved a risk evaluation and mitigation strategy (REMS) for Mifeprex. The goal of the REMS is to mitigate the risk of serious complications associated with Mifeprex. Under the REMS:

- Mifeprex must be ordered, prescribed, and dispensed by or under the supervision of a health care provider who prescribes it and who meets certain qualifications;
- health care providers who wish to prescribe Mifeprex must complete a prescriber agreement form prior to ordering and dispensing Mifeprex;
- Mifeprex may only be dispensed in clinics, medical offices, and hospitals by or under the supervision of a certified health care provider; and
- the health care provider must obtain a signed patient agreement form before dispensing Mifeprex.

Additionally, health care providers who prescribe Mifeprex are required under FDA regulations to provide the patient with a copy of the Mifeprex Medication Guide. Mifeprex's sponsor (the drug's manufacturer) is required to submit REMS assessment data to FDA that include the cumulative number of health care providers enrolled in the Mifeprex REMS program; the number of providers ordering Mifeprex during the assessment reporting period; and the number of women exposed to Mifeprex, both during the specified reporting period and cumulatively. Furthermore, the sponsor must provide copies of reports for certain adverse events, including hospitalizations due to complications, blood transfusions, serious infections, and deaths, as well as the numbers of these adverse events both during the specified reporting period and cumulatively.

According to the Guttmacher Institute, 34 states, including Maryland, require clinicians who perform medication abortion procedures to be licensed physicians; 3 states (North Dakota, Ohio, and Texas) require mifepristone to be provided in accordance with FDA protocol; and 17 states (Alabama, Arizona, Arkansas, Indiana, Louisiana, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, West Virginia, and Wisconsin) require that the clinician providing a medication abortion be physically present during the procedure, thereby prohibiting the use of telemedicine to prescribe medication for abortion remotely.

State Expenditures: MDH advises that it must hire one part-time (50%) permanent epidemiologist to meet the bill's reporting requirements and one part-time (50%) contractual physician clinical specialist to develop regulations under the bill. The Department of Legislative Services concurs with the need for a half-time contractual employee to develop regulations, but advises that the required annual report is very limited in scope and can likely be prepared using existing resources.

Accordingly, general fund expenditures increase by at least $58,761 in fiscal 2020, which accounts for the bill's October 1, 2019 effective date. This estimate reflects the cost of hiring one part-time (50%) contractual physician clinical specialist to develop regulations. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Contractual Position	0.5
Salary and Fringe Benefits	$51,761
Operating Expenses	7,000
Total FY 2020 State Expenditures	**$58,761**

Future year expenditures reflect a full salary with annual increases and employee turnover, ongoing operating expenses, and elimination of the contractual position on September 30, 2020.

This estimate does not include any health insurance costs that could be incurred for specified contractual employees under the State's implementation of the federal Patient Protection and Affordable Care Act.

Additional Comments: This analysis assumes that the bill's reference to 21 C.F.R. § 214.520 is intended to reference 21 C.F.R. § 314.520. This analysis also assumes that the regulations adopted by MDH will require physicians to report the number of mifepristone administrations and any associated adverse reactions to MDH in order for MDH to submit its annual report.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Maryland Department of Health; U.S. Code of Federal Regulations; U.S. Government Accountability Office; U.S. Food and Drug Administration; Guttmacher Institute; Department of Legislative Services

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