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H.B. 324
(l_136_1373-5)
136th General Assembly

Fiscal Note & Local Impact Statement

Click here for H.B. 324's Bill Analysis

Version: In Senate Health

Primary Sponsors: Reps. A. Mathews and Craig

Local Impact Statement Procedure Required: No

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Highlights

- Public health plans may realize an increase in insurance claims related to the bill's requirement that prescribers of a drug that requires a risk evaluation and mitigation strategy conduct an in-person examination of the patient and schedule the patient for a follow-up appointment.
- Occupational licensing boards, such as the Nursing Board and State Medical Board, may realize an increase in costs related to any complaints regarding potential violations of the bill's provisions.

Detailed Analysis

The bill requires prescribers, before issuing a prescription for a drug for which the U.S. Food and Drug Administration (FDA) requires a risk evaluation and mitigation strategy (REMS),[1] to first conduct an in-person examination of the patient, inform the patient that the drug is subject to a REMS, and schedule the patient for a follow-up appointment. A REMS is a drug safety program for certain medications to help ensure that a medication's benefits outweigh its risks. Most REMS include communication requirements, and some require additional clinical activities that must be taken before prescribing or dispensing a specified drug (e.g., lab work). As a result, public health plans may realize an increase in insurance claims related to the bill's requirement that prescribers conduct an in-person examination of a patient and schedule the patient for a follow-up appointment if prescribing a drug that requires a REMS. The number of additional claims is undetermined but will depend on the number of prescriptions of such drugs. However, depending on the drug, it is possible that a REMS may already require an in-person examination

[1] Risk Evaluation and Mitigation Strategies.

or scheduling of follow-up appointments prior to issuing a prescription for the drug. For example, the current REMS for Camzyos, a drug used to treat a heart condition, requires several activities prior to a patient receiving a first dose. These activities for the patient include receiving certain information from the health care provider, getting an echocardiogram, and enrollment in the REMS by completing the patient enrollment form. After the first dose, additional periodic echocardiograms are required to monitor the patient's heart. There are currently 68 active individual or shared system REMS listed on the FDA's REMS Public Dashboard.[2]

Additionally, while the bill does not establish specific penalties for violating the bill's prohibitions, occupational licensing boards, including the Nursing Board and the State Medical Board, may realize an increase in costs to investigate any complaints regarding potential violations.

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[2] FDA Risk Evaluation and Mitigation Strategy (REMS) Public Dashboard.