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Senate Bill 812 (Substitute S-3)

(Senate-passed version)

Sponsor: Senator Curtis S. VanderWall

Committee: Health Policy and Human Services

Date Completed: 6-23-22

CONTENT

The bill would add Part 216A (Specialized Laboratories) to the Public Health Code to require a person that established or operated a specialized laboratory to register it with the Department of Health and Human Services (DHHS) and pay a \$250 registration fee, and to prescribe penalties for a violation of Part 216A.

Specifically, under the bill, beginning 180 days after its effective date, a person that established or operated a specialized laboratory would have to register the specialized laboratory with the DHHS on a form and in a manner required by the Department.

"Specialized laboratory" would mean an interventional kidney access laboratory, interventional pain management laboratory, or interventional vascular laboratory. "Interventional kidney access laboratory" would mean a facility, other than a hospital or freestanding surgical outpatient facility, in which interventional diagnostic and therapeutic procedures for kidney disease and cardiovascular disease are performed on patients on an ambulatory basis. "Interventional pain management laboratory" would mean a facility, other than a hospital or freestanding surgical outpatient facility, in which interventional diagnostic and therapeutic procedures for pain management and cardiovascular disease are performed on patients on an ambulatory basis. "Interventional vascular laboratory" would mean a facility other than a hospital or freestanding surgical outpatient facility in which interventional diagnostic and therapeutic procedures for vascular disease, kidney disease, arterial disease, and vein disease are performed on patients on an ambulatory basis. "Interventional kidney access laboratory" and "interventional vascular laboratory" would not include a facility that provided dialysis treatment, maintenance, or training to patients or patient caregivers on an ambulatory or home-care basis.

After receiving an application and payment of a \$250 registration fee, the DHHS would have to register a specialized laboratory. A registration would be valid for one year and could be renewed on application and payment of the \$250 fee.

Both of the following would apply to a person that violated Part 216A:

- -- The person would be guilty of a misdemeanor punishable by a maximum fine of \$5,000.
- -- The person would be subject to a \$100 administrative fine for each day that the violation continued.

For an administrative fine, the DHHS would have to provide notice and an opportunity for a hearing in the same manner as provided in Section 20166. (That section requires notice of intent to deny, limit, suspend, or revoke a license or certification to be given by certified mail

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or personal service, to set forth the particular reasons for the proposed action, and to fix a date on which the applicant or licensee must be given an opportunity for a hearing.)

MCL 333.20199 et al. Legislative Analyst: Stephen P. Jackson

FISCAL IMPACT

The bill would have an indeterminate fiscal impact on State and local government.

Under the bill, the DHHS would have to develop a registration form for a specialized laboratory and require a \$250 registration fee. The cost of developing a form and processing a registration likely would be covered by the registration fee and existing appropriations; however, the administrative costs associated with the bill cannot be estimated at this time, as it is unknown how many laboratories would be registered on an annual basis.

A person who failed to register a specialized laboratory would be guilty of a misdemeanor and would be subject to a \$5,000 fine. New misdemeanor convictions could increase resource demands on law enforcement and court systems. However, it is unknown how many people would be prosecuted under the bill's provisions. Any additional revenue from imposed fines would go to local libraries. In addition, a person who violated the bill would be subject to an administrative fine of \$100 per diem for the violation period.

Fiscal Analyst: Ellyn Ackerman

Joe Carrasco, Jr.