Miscellaneous Acts – Fiscal Notes

HF 2377 – Opioid Regulation Act (LSB6028HV.2)
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Fiscal Note Version – Final Action

Description – All Divisions

House File 2377 makes a variety of changes to the practice of pharmacy. Of the seven divisions in the Act, three will have a fiscal impact; two may have a fiscal impact, but the extent of the fiscal impact is indeterminable; and two are expected to have little or no fiscal impact.

- Fiscal impact: Divisions I, III, and IV
- Possible but indeterminable fiscal impact: Divisions II and VII
- No or little fiscal impact: Divisions V and VI

Background – All Divisions

Iowa Code section 147.80 requires licensing boards to establish fees to sustain the cost of operations and services, and to annually adjust the fee schedule to cover projected expenses.

Assumptions – All Divisions

- The Board of Pharmacy (Board) will comply with Iowa Code section 147.80.
- All costs associated with the Act will likely be eligible for expenditure from the Drug Information Program Fund; otherwise, the Board will use its operating budget to cover costs.

DIVISION I: Regulation of the Prescription Monitoring Program

Description

Updates the Prescription Monitoring Program (PMP) in the following ways:

- Adds opioid antagonists to the list of drugs reportable to the Program and requires first responders, excluding emergency medical care providers, to report administration of opioid antagonists. Establishes a transfer of information from the Department of Public Health to the Board on administration of opioid antagonists by emergency medical care providers.
- Requires all prescribing practitioners to register for the Program.
- Requires pharmacies or prescribing practitioners that dispense a controlled substance to report to the Program the dispensing of the controlled substance within one business day.
- Removes the four-year retention limit of Program information.
- Authorizes the Board to establish a surcharge of up to 25.0% on the Controlled Substances Act (CSA) registration fee under Iowa Code section 124.302. Revenues are required to be deposited in the Drug Information Program Fund.

Background

The PMP provides authorized prescribers and pharmacists with information regarding their patients' use of controlled substances. That information is used as a tool in determining appropriate prescribing to and treatment of patients without fear of contributing to a patient's abuse of or dependence on addictive drugs or diversion of those drugs to illicit use. Iowa-licensed pharmacies, including both in-state and nonresident pharmacies, are required to report to the Iowa PMP all Schedule II, III, and IV controlled substances dispensed by the pharmacy to ambulatory patients.

Assumptions

- The Board will need to develop a separate module of reporting in the PMP for first responders to submit information about opioid antagonist administration.
- There are approximately 16,800 Controlled Substances Act registrants in Iowa.
- Controlled Substances Act registration is currently done biennially. However, Division V of the Act strikes this requirement. Therefore, the Board would establish the frequency of registration. Under the new requirement, registration could take place annually, coincide with a practitioner's license registration, or coincide with federal Drug Enforcement Administration registration (most registrations last three years). This estimate assumes a frequency coinciding with practitioner licensing.
- A 25.0% surcharge on registration would equal $22.50.

Fiscal Impact

The surcharge for registration will result in increased revenue for the Drug Information Program Fund by an estimated $189,000 annually. Adding a module for first responders to report opioid antagonist dispensing will require one-time expenditures estimated at $75,000.

DIVISION II: Electronic Prescriptions

Description

Requires all prescriptions to be electronically transmitted to a pharmacy effective January 1, 2020, and includes provisions for exemptions and administrative penalties.

Assumptions

Hospitals and prescribers will become compliant with the electronic prescribing requirement by the deadline or seek an exemption to receive more time before becoming compliant.

Fiscal Impact

Any administrative penalties associated with electronic prescribing will be deposited into the Drug Information Program Fund and are estimated to be minimal.

DIVISION III: Prescriber Activity Reports

Description

Beginning February 1, 2019, requires the Board to annually issue a prescribing practitioner activity report of PMP activity to each practitioner registered with the Program. The Division also requires the Board to include information on general patient risk factors and educational updates in the PMP.

Assumptions

- The Division will require an initial setup cost for the report issuance and for annual licensing of the NarxCare controlled substances data platform for disseminating educational updates and information on general patient risk factors.
- To provide the information and educational material required, the Board will purchase the AWARxE Prescription Drug Safety Program data platform.

Fiscal Impact

NarxCare will require an estimated annual licensing fee of $186,000. The AWARxE platform setup is estimated to cost $10,000 initially with no annual maintenance costs.

DIVISION IV: Substance Abuse Prevention

Description

Requires the Board to establish criteria for the identification of patients who are potentially misusing or abusing prescription opioids, and authorizes the Board to proactively notify the pharmacist and prescribing practitioner involved in the patient's care of the Board's concern. The Division also requires licensing boards that have prescribing practitioners to establish penalties for those who prescribe in dosage amounts exceeding what would be prescribed by a reasonably prudent prescribing practitioner. The boards of Medicine, Dentistry, Physician Assistants, Podiatry, and Nursing are required to adopt rules requiring licensees to receive continuing education credits regarding the U.S. Centers for Disease Control and Prevention guidelines for prescribing opioids. The Act also rescinds current Board of Medicine administrative rules on training for chronic pain management for permanent or special license renewal.

Assumptions

The Board will need to hire 0.5 full-time equivalent (FTE) position Pharmacist and will need to purchase new general office equipment to implement and administer the Iowa PMP.

Fiscal Impact

The increased expenditure for salaries and benefits is estimated at $64,000 annually beginning in FY 2019. The cost of office equipment is estimated at $3,000 in FY 2019 and less than $1,000 thereafter.

DIVISION V: Registration

Description

Modifies Iowa Code chapter 124 (Controlled Substances Act) in the following ways:

- Removes "biennial" from the CSA registration requirements, which will permit registration frequency to be established by the Board. See assumptions in Division I for more details on available options.
- Expands the disciplinary action available for the Board to take against CSA registrants beyond suspension, revocation, or restriction.

Assumptions

- Similarly to Division I, the CSA registration will be aligned with the professional licensure renewal cycle.
- Less severe disciplinary action available to the Board would include sanctions such as civil penalties, probationary conditions, etc.

Fiscal Impact

No or little fiscal impact.

DIVISION VI: Controlled Substances — Precursor Substances

Description

The Act classifies 12 substances as Schedule I controlled substances under Iowa Code section 124.204(9). Penalties for possession of these substances will range from a serious misdemeanor (first offense of unlawful possession) to a Class B or Class C felony (for manufacturing and delivery).

The Act adds one substance as a Schedule II controlled substance under Iowa Code section 124.206. Penalties for possession of this substance will range from a serious misdemeanor (for first offense of unlawful possession) to a Class C felony (for manufacturing and delivery).

The Act also adds one substance as a precursor substance for purposes of reporting requirements in Iowa Code section 124B.2. The penalty for possession of this substance will be a Class C felony (for manufacturing and delivery).

Assumption

This change conforms Iowa Code to current federal law.

Fiscal Impact

No or little fiscal impact.

Correctional Impact

This Division is estimated to result in minimal correctional impact. Refer to the Legislative Services Agency (LSA) memo addressed to the General Assembly, *Cost Estimates Used for Correctional Impact Statements*, dated January 8, 2018, for information related to the correctional system.

Minority Impact

The minority impact of this Division is unknown. Refer to the LSA memo addressed to the General Assembly, *Minority Impact Statement*, dated January 29, 2018, for information related to minorities in the criminal justice system.

DIVISION VII: Good Samaritan Immunity

Description

Creates a Good Samaritan protection ensuring that a person seeking treatment for a drug-related overdose, or a person seeking medical treatment for a person experiencing a drug-related overdose, cannot be arrested or prosecuted for certain controlled substances-related violations on the basis of information collected or derived from the person's actions in seeking medical assistance.

Assumptions

The Department of Human Rights, Criminal and Juvenile Justice Planning Division is unable to estimate how many charges or convictions were the result of overdoses.

Fiscal Impact

Possible but indeterminable fiscal impact.

Correctional Impact

This Division is estimated to result in minimal correctional impact. Refer to the LSA memo addressed to the General Assembly, *Cost Estimates Used for Correctional Impact Statements*, dated January 8, 2018, for information related to the correctional system.

Minority Impact

The minority impact of this Division is unknown. Refer to the LSA memo addressed to the General Assembly, *Minority Impact Statement*, dated January 29, 2018, for information related to minorities in the criminal justice system.

ALL DIVISIONS

Fiscal Impact – All Divisions

No impact to the General Fund is expected. Since the Board operates using fees for professional licensure and regulation, the Board will need to evaluate the overall fee schedule and budget to ensure that revenues align with expenses, and will need to adjust both of those categories as necessary. Total estimated revenues and expenditures are outlined in the following table.

Estimated Impact of HF 2377

	FY 2019	FY 2020	FY 2021
Division I			
PMP Reporting for First Responders	$ -75,000	$ 0	$ 0
PMP Surcharge	189,000	189,000	189,000
Subtotal Division I	$ 114,000	$ 189,000	$ 189,000
Division III			
Prescriber Activity Report (AWARxE)	$ -10,000	$ 0	$ 0
NarxCare	-186,000	-186,000	-186,000
Subtotal Division III	$ -196,000	$ -186,000	$ -186,000
Division IV			
Proactive Notification (0.5 FTE position)	$ -67,000	$ -64,000	$ -64,000
Grand Total	**$ -149,000**	**$ -61,000**	**$ -61,000**

Correctional Impact – All Divisions

The Act is estimated to result in minimal correctional impact. Refer to the LSA memo addressed to the General Assembly, *Cost Estimates Used for Correctional Impact Statements*, dated January 8, 2018, for information related to the correctional system.

Minority Impact – All Divisions

The minority impact of the Act is unknown. Refer to the LSA memo addressed to the General Assembly, *Minority Impact Statement*, dated January 29, 2018, for information related to minorities in the criminal justice system.

Enactment Date

The Act was passed by the General Assembly on May 2, 2018, and was signed by the Governor on May 14, 2018.

Effective Date

Division VI of the Act amending the Controlled Substance Act took effect May 14, 2018. The remainder of the Act is effective July 1, 2018.

Sources

Board of Pharmacy
Department of Human Rights, Criminal and Juvenile Justice Planning Division
Department of Public Health