Fiscal Note

Fiscal Services Division

HF 626 – Prescription Drug Formularies, Preserving Patient Stability (LSB1359HV)
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Fiscal Note Version – New

Description

House File 626 relates to continuity of care and nonmedical switching by health carriers (carriers), health benefit plans (plans), and utilization review organizations (utilization reviews) and does the following:

- Defines terms.
- Prohibits limiting or excluding the coverage of a prescription drug (prescription) for a medically stable (stable) covered person on such drug, if all of the following apply:
  - The prescription was previously approved by the carrier for the covered person.
  - The covered person's prescribing health care professional (prescriber) has prescribed the drug for the covered person's medical condition within the previous six months.
  - The covered person continues to be an enrollee of the plan.
- Coverage as described in the previous bullet point and subpoints is required to continue through the last day of the covered person's plan eligibility.
- Clarifies that limitations and exclusions of coverage referred to in the Bill include the following:
  - Limiting or reducing the maximum coverage for a covered prescription.
  - Increasing cost sharing for a covered prescription.
  - Moving a prescription to a more restrictive tier if the carrier uses a formulary with tiers.
  - Removing a prescription from a formulary, with exceptions permitted for clinical safety concerns by the federal Food and Drug Administration (FDA) and for manufacturer discontinuance of the prescription.
- Clarifies that the Bill does not prohibit a substitution, formulary change, or preference by a carrier for a prescription that has the same generic name and demonstrated bioavailability, or that is an interchangeable biological product.
- Defines "coverage exemption determination" as a determination made by a carrier, plan, or utilization review whether to cover a prescription that is otherwise excluded from coverage.
- Requires carriers, plans, and utilization reviews to provide to covered persons and prescribers the ability to request a coverage exemption determination.
- Establishes response conditions and requirements for the coverage exemption determination and any ensuing coverage.
- Requires a reason for denial and a procedure to appeal the denial to be provided to the requestor if a request for a coverage exemption is denied.
- Clarifies that the Bill is not to prohibit a health care professional from prescribing another prescription drug covered by the carrier that the health care professional deems medically necessary.
- Permits the Commissioner of Insurance to enforce compliance with the Bill.
- Establishes applicability of the Bill beginning January 1, 2024.

Background

"Nonmedical switching" refers to the practice of switching a stable patient's medication for reasons unrelated to the patient's health. The practice may also be referred to as "formulary-driven switching," "therapeutic switching," or simply "switching."

"Bioavailability" refers to the proportion of a drug that enters the circulation when introduced into the body and is, therefore, able to have an active effect. Without bioavailability, the drug will not take effect.

"Interchangeable biological product" refers to a biosimilar product that meets additional FDA requirements. These additional requirements are outlined by the Biologics Price Competition and Innovation Act at the federal level. The requirements include showing that an interchangeable product is expected to produce the same clinical results as the reference product for any given patient. Additionally, for products administered to patients more than once, the risk in terms of safety and reduced efficacy of multiple switches between an interchangeable product and a reference product must be evaluated by the FDA.

"Biosimilar" means a biological product that is highly similar to, and has no clinically meaningful differences from, an existing FDA-approved reference product. "No clinically meaningful difference" applies to product safety, purity, and potency (safety and effectiveness). Biosimilar drugs must pass tests by the FDA to receive this label.

House File 626 is estimated to impact approximately 25.8% of the population (819,000). This includes individual coverage, fully insured small and large employer groups, self-insured public employees, and the State of Iowa Plan.

Of the individuals not covered by the mandate, approximately 46.5% are covered by government-sponsored health insurance, 22.9% are covered by employer coverage which is governed by the federal Employee Retirement Income Security Act of 1974 (ERISA), and the remaining 4.8% are uninsured. Additional details are presented in **Table 1**.

Table 1 — Population Covered by Insurance Plans Regulated by Iowa Law

Type of Coverage	Iowa Population	Percent of Population
Total Population 2021	3,178,322	100.0%
Included in Mandate		
Individual Coverage	98,836	3.1%
Fully Insured Small Employer Group	146,645	4.6%
Fully Insured Large Employer Group	303,551	9.6%
Self-Insured Public Employees*	215,000	6.8%
State of Iowa Plan	55,000	1.7%
Total	**819,032**	**25.8%**
Not Included in Mandate		
Employer (self-insured + other types not listed)*	728,995	22.9%
Uninsured	152,800	4.8%
Other Public (Military, Tricare, Veterans Affairs)	25,600	0.8%
Medicare	646,874	20.4%
Medicaid - Children's Health Insurance Plan	805,021	25.3%
Total	**2,359,290**	**74.2%**

*Figures represent total population 2020. Source: Iowa Insurance Division

Assumptions

- The number of health insurance members covered by the Board of Regents and the State of Iowa Plan will remain at current levels.
- The number of external reviews by the IID will remain at current levels.
- Formulary management provisions of the Bill will impact a carrier's ability to manage care, causing prescription costs to increase from 0.08% to 0.66%, based on the Milliman Frozen Formularies Report.

Fiscal Impact

House File 626 is estimated to increase the annual cost to the State of Iowa Insurance Plan and the Board of Regents Insurance Plans between $181,000 and $1.5 million, as shown in **Table 2,** beginning in FY 2024.

Table 2 — Annual Fiscal Impact Summary

	Pharmacy Spend	Low Estimate of Increased Pharmacy Costs	High Estimate of Increased Pharmacy Costs
State University of Iowa	$ 102,300,000	$ 82,000	$ 675,000
Iowa State University	20,300,000	16,000	134,000
University of Northern Iowa	7,900,000	6,000	52,000
University Total	$ 130,500,000	$ 104,000	$ 861,000
State of Iowa	95,200,000	76,000	628,000
Total	**$ 225,700,000**	**$ 181,000**	**$ 1,490,000**

Amounts may not total due to rounding

Sources

Board of Regents
Department of Administrative Services
Iowa Insurance Division
Milliman Frozen Formularies Report
United States Food and Drug Administration (FDA)
Wellmark
Legislative Services Agency

/s/ Jennifer Acton

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The fiscal note for this Bill was prepared pursuant to Joint Rule 17 and the Iowa Code. Data used in developing this fiscal note is available from the Fiscal Services Division of the Legislative Services Agency upon request.