# Fiscal Note

*Fiscal Services Division*

HF 626 – Prescription Drug Formularies, Preserving Patient Stability (LSB1359HV.2)
Staff Contact: Xavier Leonard (515.725.0509) xavier.leonard@legis.iowa.gov
Fiscal Note Version – Final Action

## 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 or through the last day of the plan year, whichever is earlier.
- 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.
- 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, 2025.

## 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 25.2% of the population (807,000). 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 47.9% are covered by government-sponsored health insurance, 23.0% are covered by employer coverage that is governed by the federal Employee Retirement Income Security Act of 1974 (ERISA), and the remaining 3.9% are uninsured. Additional details are presented in **Figure 1**.

**Figure 1 — Population Covered by Insurance Plans Regulated by Iowa Law**

| Type of Coverage | Iowa Population | Percent of Population |
|---|---|---|
| Total Population 2022 | 3,200,517 | 100.0% |
| | | |
| **Included in Mandate** | | |
| Individual Coverage | 102,399 | 3.2% |
| Fully Insured Small Employer Group | 140,349 | 4.4% |
| Fully Insured Large Employer Group | 294,013 | 9.2% |
| Self-Insured Public Employees | 215,000 | 6.7% |
| State of Iowa Plan | 55,000 | 1.7% |
| **Total** | **806,761** | **25.2%** |
| | | |
| **Not Included in Mandate** | | |
| Employer (self-insured + other types not listed) | 736,868 | 23.0% |
| Uninsured | 126,000 | 3.9% |
| Other Public (Military, Tricare, Veterans Affairs) | 21,600 | 0.7% |
| Medicare | 658,382 | 20.6% |
| Medicaid + Children's Health Insurance Plan | 850,906 | 26.6% |
| **Total** | **2,393,756** | **74.8%** |

Source: Iowa Insurance Division, Department of Insurance and Financial Services, and Wellmark

## Assumptions

- The number of health insurance members covered by the Board of Regents and the State of Iowa Plan 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 0.1% to 0.7%, based on the Milliman Frozen Formularies Report.
- According to the Department of Administrative Services (DAS), there will be no increase in administrative cost for the DAS to administer the State of Iowa Plan.
- According to Wellmark, there will not be an increase in administrative costs charged to the State of Iowa Plan as a result of this Bill.

## 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 $203,000 and $1.7 million, as shown in **Figure 2**, beginning in FY 2025.

**Figure 2 — Annual Fiscal Impact Summary**

| | Pharmacy Costs | Low Estimate of Increased Pharmacy Costs | High Estimate of Increased Pharmacy Costs |
|---|---|---|---|
| State University of Iowa | $ 106,100,000 | $ 85,000 | $ 701,000 |
| Iowa State University | 29,200,000 | 23,000 | 193,000 |
| University of Northern Iowa | 6,400,000 | 5,000 | 42,000 |
| University Total | $ 141,700,000 | $ 113,000 | $ 936,000 |
| State of Iowa | 111,700,000 | 89,000 | 737,000 |
| **Total** | **$ 253,400,000** | **$ 203,000** | **$ 1,673,000** |

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.