FLORIDA HOUSE OF REPRESENTATIVES BILL ANALYSIS

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BILL #: HB 899

TITLE: Insurer Disclosures on Prescription Drug

Coverage

SPONSOR(S): Gonzalez Pittman

COMPANION BILL: None LINKED BILLS: None

RELATED BILLS: <u>SB 1342</u> (Rodriguez)

Committee References

<u>Health Care Facilities & Systems</u>

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Insurance & Banking

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Health & Human Services

SUMMARY

Effect of the Bill:

The bill regulates changes to prescription drug formularies by commercial health insurers and health maintenance organizations (HMOs) by requiring certain notices to consumers and physicians, and requiring continued coverage under certain circumstances. Insurers and HMOs must maintain records of formulary changes, and detailed data on the effect of those changes, and submit that to the Office of Insurance Regulation (OIR); OIR must submit an annual report on that data to the Governor and the principals of the legislature.

The bill also requires commercial health insurers to allow expenditures for prescription drugs made by the patient or a third party on the patient's behalf to count toward the patient's cost-sharing requirements, under certain circumstances. Insurers must submit an annual report to OIR detailing third-party payments received, and documenting compliance with the bill's cost-sharing requirements.

Fiscal or Economic Impact:

The bill may have a negative fiscal or economic impact on commercial health plans, which may be passed on to the consumer or employers in the form of higher premiums or cost-sharing requirements.

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EFFECT OF THE BILL:

Prescription Drug Formulary Regulation

A formulary is a list of generic and brand name prescription drugs covered by a health insurer's or health maintenance organization's health plan. A formulary is divided into three or four categories, called tiers, which divide prescription drugs based on price, genetic brands, preferred brands, non-preferred brands, and specialty prescription drugs. Tier 1 is comprised of generic drugs with the lowest out-of-pocket costs, while tier 4 is comprised of preferred brands, specialty prescription drugs, and the highest out-of-pocket costs.¹

Notice of Formulary Changes

HB 899 requires health insurers and health maintenance organizations (HMOs) to provide notice of formulary changes to its consumers 60 days prior to the formulary changes' effect, other than changes that add drugs to a formulary. The notice applies only to health insurance policies, health benefit plans, and health maintenance

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¹ How Do Drug Plans Work?, available at https://www.medicare.gov/health-drug-plans/part-d/what-plans-cover/how-drug-plans-work (last visited Mar. 31, 2025).

contracts entered into or renewed on or after January 1, 2026. Health insurers and HMOs must notify all current and prospective consumers by publishing its formulary changes on its website.

Health insurers and HMOs also must provide notice electronically and by first-class mail to current consumers using a prescription drug affected by a formulary change, and to their treating physician. The notice must include information about the impacted prescription drugs and a statement about the process to continue prescription drug or treating physician coverage for the remainder of the policy, plan, or contract year. (Sections 1,8)

Continued Coverage

Health insurers and HMOs must continue to cover the consumer's prescription drugs, despite a change in the formulary, if the consumer's treating physician submits a notice electronically or by first-class mail to the health insurer or health maintenance organization 30 days prior to the formulary change takes effect. (Sections 1, 8) The physician's notice must:

- Describe how the prescription drug is for the purpose of preventing, diagnosing, or treating an illness, injury, disease, or symptom in a manner that is:
 - o In accordance with generally accepted standards of medical practice;
 - o Clinically appropriate in terms of type, frequency, extent, site, and duration; and
 - o Not primarily for the convenience of the patient, physician, or health care provider; and
- Include a one-page form, created by the Financial Services Commission by January 1, 2026, certifying the consumer's medical necessity for the prescription drug.

If these requirements are met, the health insurer or HMO cannot modify the prescription drug's coverage by:

- Increasing consumers' out-of-pocket costs;
- Moving the prescription drug to a more restrictive tier;
- Denying coverage for prescription drugs that the health insurer or health maintenance organization has previously approved for a consumer; or
- Limiting coverage in any other manner, such as requiring new prior authorization or step-therapy protocols.

The bill expressly exempts certain coverages from its notice and continued coverage requirements:

- Grandfathered health plans defined under 42 U.S.C. s. 18011;
- Benefits listed in s. 627.6513(1)-(14), F.S.;
- Medicaid managed care plans defined under part IV of ch. 409, F.S.;

The bill provides that its provisions have no effect on the conditions listed in <u>s. 465.025, F.S.</u>, or <u>s. 465.0252, F.S.</u>, under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product, or a prescribed biological product for another biological product. (Sections <u>1</u>, <u>8</u>)

Annual Report on Formulary Changes

The bill requires insurers and HMOs to maintain records of formulary changes during the year, and each submit an annual report describing its formulary changes during the previous year to the Office of Insurance Regulation (OIR) by March 1 of each year. The annual report must include:

- A list of all prescription drugs removed from the formulary;
- The dates that each prescription drug was removed from the formulary;
- The reasons why each prescription drug was removed from the formulary;
- A list of all prescription drugs that were moved to a different tier and resulted in an increase of consumer's out-of-pocket costs;
- The number of consumers impacted by formulary changes;

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- The number of consumers notified of the formulary changes; and
- Consumer's increased costs due to formulary changes.

OIR must compile the annual reports prepared by the health insurers and HMOs into one reporting summarizing the submitted data. OIR must submit the report to the Governor, the President of the Senate, and the Speaker of the House of Representatives, and publish the report on its website. (Sections 1, 8).

Cost-Sharing Requirements

The bill requires insurers and PBMs working on behalf of health insurers who are offering prescription drug coverage under a health insurance policy issued delivered or renewed on or after January 1, 2026, to apply any payment for a prescription drug paid for by a consumer or a third party on their behalf paid toward the consumer's cost-sharing requirements, including required out-of-pocket expenses, dollar limits, deductibles, copayments, and coinsurance. (Sections 2, 5)

This requirement only applies if the payment was for a prescription drug that:

- Does not have a generic equivalent; or
- Has a generic equivalent that the consumer has obtained authorization for through:
 - o The insurer's or PBM's prior authorization;
 - o The insurer's or PBM's exception or appeal processes; or
 - Step-therapy protocol.

Payments by the consumer or a third-party on their behalf may include a discount through financial assistance, a manufacturer copay card, a product voucher, or any other reduction in out-of-pocket expenses.

Health insurers offering policies issued, delivered, or renewed on or after January 1, 2026 with prescription drug coverage must publish within the policy itself and online that any amount that the consumer or a third party on their party pays must be applied to the consumer's total contribution to any cost-sharing requirement. (Section $\underline{3}$).

The bill makes these cost-sharing requirements applicable to requires small group employer carriers², as well, "for any change to a prescription drug formulary". (Section <u>7</u>). The meaning of this is unclear, as the cost-sharing provisions are not triggered by a change to the formulary.

Annual Report on Cost-Sharing

Health insurers must maintain a record of all third-party payments made or remitted for prescription drugs that are not applied to a consumer's out-of-pocket obligations. Health insurers who are offering a policy with prescription drug coverage must create an annual report summarizing the record of third-party payments and submit the annual report to OIR by March 1 of each year.

The annual report must include:

- A list of all payments for prescription drugs not applied to a consumer's out-of-pocket obligations made or remitted by a third party to the health insurer;
- The date each payment was made;
- The prescription drugs each payment was made for;
- The reason each payment was not applied to the consumer's out-of-pocket obligations;
- The total amount of payments received by the health insurer that were not applied to the consumer's out-of-pocket maximum;
- The total number of consumers who did not have their payments applied to their out-of-pocket maximum:

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² A small employer carrier is a carrier that offers health benefit plans for the employees of one or more small employers, which are employers with fewer than 20 employees. Ss. <u>627.6699(3)</u>, F.S., <u>627.6692(4)</u>, F.S.

- Whether the payments not applied to the consumer's out-of-pocket maximum were returned to the third party who submitted the payment; and
- The total number of payments that were not returned to the third part who submitted the payment. (Section 2).

A contract between a health insurer and a PBM must require PBMs to apply any payment by a consumer or a third party on their behalf toward the consumer's total contribution to any cost-sharing requirement for policies issued, delivered, or renewed on or after January 1, 2026. The contract must also require that the PBM informs consumers that these payments will be applied to the consumer's total contribution to any cost-sharing requirement. (Section

The bill makes a legislative finding that the bill fulfills an important state interest³ (Section 13), and makes numerous conforming changes. (Sections 10, 11).

The bill provides an effective date of July 1, 2025. (Section 14).

FISCAL OR ECONOMIC IMPACT:

PRIVATE SECTOR:

The bill's requirements to credit certain patient expenditures for prescription drugs to the patient's cost-sharing requirements, and to continue coverage of drugs for which a formulary changes is made, will have a negative fiscal or economic impact on health insurers and HMOs, which may be passed on to individual consumers and employers in the form of higher premiums or higher cost-sharing requirements.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Regulation of Health Plans

The (OIR) licenses and regulates the activities of insurers, health maintenance organizations (HMOs), and other risk bearing health coverage entities in Florida.⁴ The Agency for Health Care Administration (AHCA) regulates the quality of care by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from AHCA.⁵

All persons who transact insurance in this state must comply with the Code.⁶ OIR has the authority to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,⁷ and may investigate any matter relating to insurance.8

Pharmacy benefit managers (PBMs) are entities which contract to administer prescription drug benefits on behalf of an HMO, a health insurer, a self-insured employer health plan, a discount card program, or a government-funded health plan.9 Under current law, PBM functions include:

- Pharmacy claims processing;
- Administration or management of a pharmacy discount card program;
- Managing pharmacy networks or pharmacy reimbursement;

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³ A finding of an important state interest is required to trigger an exception to the constitutional prohibition on laws requiring counties or municipalities to spend funds or take an action requiring the expenditure of funds. Such a finding is not sufficient; one of several additional criteria must apply. See, Art. VII Sec. 18, Fla. Const.

⁴ S. 20.121(3)(a), F.S.

⁵ S. <u>641.21(1)(1), F.S.</u>

⁶ S. <u>624.11, F.S.</u>

⁷ S. <u>624.307(4), F.S.</u>

⁸ S. 624.307(3), F.S.

⁹ Ss. 626.88, <u>626.8825, F.S.</u>

- Paying or managing claims for pharmacist services provided to covered persons;
- Developing or managing a clinical formulary, including utilization management or quality assurance programs;
- Pharmacy rebate administration;
- Managing patient compliance, therapeutic intervention, or generic substitution programs; and
- Administration or management of a mail-order pharmacy program.

In addition to regulatory requirements for prescription drug benefits which apply directly to health plans, PBMs are subject to specific regulatory requirements under <u>s. 626.8825, F.S.</u>, and must obtain a certificate of authority from OIR as an insurance administrator under part VI of ch. 626, F.S.¹⁰

Health Plan Formulary Regulation

Current law regulates the mid-year changes to a plan formulary by requiring the insurer, HMO or pharmacy PBM to provide continuity of care for patients. Specifically, the health plan must continue to cover the drug for 60 days at the same cost to the patient; the 60-day period begins when the health plan notifies the patient. Current law provides exemptions from this requirement if the drug:

- Has been approved and made available over the counter by the United States Food and Drug Administration and has entered the commercial market as such;
- Has been removed or withdrawn from the commercial market by the manufacturer; or
- Is subject to an involuntary recall by state or federal authorities and is no longer available on the commercial market.

Current law requires each insurer and HMO to submit a statement to OIR, under penalty of perjury, attesting to its compliance with this requirement.¹²

BILL HISTORY				
COMMITTEE REFERENCE	ACTION	DATE	STAFF DIRECTOR/ POLICY CHIEF	ANALYSIS PREPARED BY
Health Care Facilities & Systems	17 Y, 0 N	4/2/2025	Calamas	Calamas
<u>Subcommittee</u>				
Insurance & Banking				
<u>Subcommittee</u>				
Health & Human Services				
Committee				

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¹⁰ Ss. 626.288, <u>626.8805</u>, F.S.

¹¹ S. 626.8825(2)(h)1., F.S.

¹² Id