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FISCAL AND POLICY NOTE
First Reader

Senate Bill 871 (Senator Jennings)

Finance and Education, Health, and
Environmental Affairs

Mail Order and Specialty Drugs - Physician Dispensing

This bill authorizes a physician with a valid dispensing permit to personally dispense to a patient by mail order a starter dosage of a prescription drug or device or an initial or refill prescription of a specialty drug. A pharmacy benefits manager (PBM) must allow a beneficiary to obtain a specialty drug from a dispensing physician. Cost sharing or any other condition imposed on an insured or a certificate holder who uses the services of a dispensing physician who mails or delivers a specialty drug to the beneficiary cannot be different from that imposed when the beneficiary uses the services of a mail order pharmacy. This prohibition applies to a policy or contract issued by an insurer or nonprofit health service plan as well as to a PBM. A PBM may not reimburse a dispensing physician who mails or delivers a specialty drug in an amount less than the amount that the PBM reimburses itself or an affiliate for providing the same product or service. **The bill takes effect January 1, 2021, and applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after that date.**

Fiscal Summary

State Effect: Minimal increase in special fund revenues for the Maryland Insurance Administration in FY 2021 from the \$125 rate and form filing fee. Contractual assistance is required to review forms in FY 2021 only. To the extent the number of specialty prescriptions filled increases for enrollees, Medicaid expenditures increase by an indeterminate amount beginning in FY 2021. Federal fund revenues increase accordingly.

Local Effect: To the extent the bill increases the number of specialty drugs dispensed, prescription drug expenditures for local jurisdictions that purchase fully insured plans may increase. Revenues are not affected.

Small Business Effect: Meaningful.

Analysis

Current Law: Under the Maryland Pharmacy Act, a person must be licensed by the State Board of Pharmacy in order to practice pharmacy in the State, which includes the dispensing of prescription drugs. “Dispensing” means the procedure that results in the receipt of a prescription or nonprescription drug or device by a patient or the patient’s agent and that entails (1) the interpretation of an authorized prescriber’s prescription for a drug or device; (2) the selection and labeling of the drug or device prescribed pursuant to that prescription; and (3) measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

This requirement does not prohibit specified individuals from personally preparing and dispensing prescriptions under specified circumstances, including a licensed physician who (1) has applied to the State Board of Physicians (MBP); (2) demonstrated to the satisfaction of MBP that the dispensing of prescription drugs or devices by the physician is in the public interest; (3) has received a written permit from MBP to dispense prescription drugs or devices, with the exception of starter dosages or samples without charge; and (4) posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed. The physician also must:

- comply with dispensing and labeling requirements;
- record the dispensing of the prescription drug or device on the patient’s chart;
- allow the Office of Controlled Substances Administration to enter and inspect the physician’s office at all reasonable hours;
- provide the patient with a written prescription and maintain prescription files;
- not direct patients to a single pharmacist or pharmacy;
- not receive remuneration for referring patients to a pharmacist or pharmacy;
- comply with the child resistant packaging requirements;
- comply with drug recalls;
- maintain biennial inventories and comply with any other federal and State recordkeeping requirements relating to controlled dangerous substances;
- purchase prescription drugs from a pharmacy or wholesale distributor who holds a permit issued by the State Board of Pharmacy;
- report annually to MBP whether the physician has personally prepared and dispensed prescription drugs within the previous year; and
- complete 10 hours of continuing medical education over a five-year period relating to the preparing and dispensing of prescription drugs.

Generally, a carrier may require a covered specialty drug to be obtained through a designated pharmacy or other authorized source or a pharmacy participating in the carrier's network, if the carrier determines that pharmacy meets the carrier's performance standards and accepts the carrier's network reimbursement.

Specialty drug means a prescription drug that (1) is prescribed for an individual with a complex, chronic, or rare medical condition; (2) costs \$600 or more for up to a 30-day supply; (3) is not typically stocked at retail pharmacies; and (4) requires a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug or requires enhanced patient education, management, or support, beyond those required for traditional dispensing before or after administration of the drug.

Under Medicaid managed care organization (MCO) regulations (COMAR 10. 67.06.04), "specialty drug" is defined the same as under the Insurance Article. Any option for accessing pharmacy services by mail order may be implemented by an MCO only at the request of the enrollee except for when the drug is a specialty drug. If an enrollee subsequently requests to use a retail pharmacy for specialty drugs, the MCO may not limit the enrollee to the use of a mail order pharmacy. All nine MCOs use PBMs for their pharmacy services.

Under § 15-805 of the Insurance Article, a policy or contract issued by an insurer or nonprofit health service plan that provides reimbursement for a pharmaceutical product prescribed by an authorized prescriber may not (1) establish the amount of reimbursement to the insured or the insured's beneficiary, including copayments and deductibles, based on the identity, practicing specialty, or occupation of the authorized prescriber or (2) impose a copayment, deductible, or other condition on an insured or certificate holder who uses the services of a community pharmacy that is not imposed when the insured or certificate holder uses the services of a mail order pharmacy, if the benefits are provided under the same program, policy, or contract.

Background: According to MBP, there are 674 physicians with dispensing permits in Maryland.

Small Business Effect: Physicians with a valid dispensing permit may dispense specialty drugs to patients and receive specified reimbursement from PBMs.

Additional Information

Prior Introductions: None.

Designated Cross File: HB 943 (Delegate K. Young, *et al.*) - Health and Government Operations..

Information Source(s): Maryland Health Benefit Exchange; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

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