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135th General Assembly
Regular Session
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Sub. H. B. No. 505

A BILL

To amend sections 3902.50, 3959.01, and 3959.111 and to enact sections 3902.75, 3902.76, 3959.121, 3959.151, and 3959.21 of the Revised Code regarding insurer accreditation requirements for pharmacies, to impose drug cost reporting and payment requirements on pharmacy benefit managers, and to name this act the Community Pharmacy Protection Act.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3902.50, 3959.01, and 3959.111 be amended and sections 3902.75, 3902.76, 3959.121, 3959.151, and 3959.21 of the Revised Code be enacted to read as follows:

Sec. 3902.50. As used in sections 3902.50 to ~~3902.72~~ 3902.76 of the Revised Code:

(A) "Ambulance" has the same meaning as in section 4765.01 of the Revised Code.

(B) "Clinical laboratory services" has the same meaning as in section 4731.65 of the Revised Code.

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(C) "Cost sharing" means the cost to a covered person under a health benefit plan according to any copayment, coinsurance, deductible, or other out-of-pocket expense requirement.

(D) "Covered" or "coverage" means the provision of benefits related to health care services to a covered person in accordance with a health benefit plan.

(E) "Covered person," "health benefit plan," "health care services," and "health plan issuer" have the same meanings as in section 3922.01 of the Revised Code.

(F) "Drug" has the same meaning as in section 4729.01 of the Revised Code.

(G) "Emergency facility" has the same meaning as in section 3701.74 of the Revised Code.

(H) "Emergency services" means all of the following as described in 42 U.S.C. 1395dd:

(1) Medical screening examinations undertaken to determine whether an emergency medical condition exists;

(2) Treatment necessary to stabilize an emergency medical condition;

(3) Appropriate transfers undertaken prior to an emergency medical condition being stabilized.

(I) "Health care practitioner" has the same meaning as in section 3701.74 of the Revised Code.

(J) "Pharmacy benefit manager" has the same meaning as in section 3959.01 of the Revised Code.

(K) "Prior authorization requirement" means any practice

implemented by a health plan issuer in which coverage of a health care service, device, or drug is dependent upon a covered person or a provider obtaining approval from the health plan issuer prior to the service, device, or drug being performed, received, or prescribed, as applicable. "Prior authorization requirement" includes prospective or utilization review procedures conducted prior to providing a health care service, device, or drug.

(L) "Unanticipated out-of-network care" means health care services, including clinical laboratory services, that are covered under a health benefit plan and that are provided by an out-of-network provider when either of the following conditions applies:

(1) The covered person did not have the ability to request such services from an in-network provider.

(2) The services provided were emergency services.

Sec. 3902.75. (A) As used in sections 3902.75 and 3902.76 of the Revised Code:

(1) Notwithstanding section 3902.50 of the Revised Code, "health plan issuer" has the same meaning as in section 3922.01 of the Revised Code but also includes an auditing entity, as defined in section 3901.81 of the Revised Code.

(2) "Pharmacy" has the same meaning as in section 4729.01 of the Revised Code and also includes a dispensing physician.

(B) A health plan issuer that offers, issues, or administers a health benefit plan that covers pharmacy services, including prescription drug coverage, shall not require a pharmacy, as a condition of participation in the health plan issuer's network, to meet accreditation standards or

certification requirements that are inconsistent with or in addition to those of the state board of pharmacy.

(C) In addition to any other remedies provided by law, any covered person or pharmacy affected by a violation of this section may file a formal complaint with the superintendent of insurance.

Sec. 3902.76. (A) The superintendent of insurance shall evaluate any complaint filed under section 3902.75 of the Revised Code.

(B)(1) If the superintendent determines, based on a complaint by a covered person or pharmacy or other information available to the superintendent, that a health plan issuer or one or more of its intermediaries has violated section 3902.75 of the Revised Code, the superintendent shall do both of the following:

(a) Issue a notice of violation to the health plan issuer or intermediary that clearly explains the violation;

(b) Impose an administrative penalty on the health plan issuer or intermediary of one thousand dollars for each violation.

(2) Each day that a violation of section 3902.75 of the Revised Code continues after the health plan issuer or intermediary receives notice of violation under division (B)(1)(a) of this section is considered a separate violation for the purposes of the administrative penalty under division (B)(1)(b) of this section.

(C) Before imposing an administrative penalty under this section, the superintendent shall afford the health plan issuer or intermediary an opportunity for an adjudication hearing under

Chapter 119. of the Revised Code. At the hearing, the health plan issuer or intermediary may challenge the superintendent's determination that a violation occurred, the superintendent's imposition of an administrative penalty, or both. The health plan issuer or intermediary may appeal the superintendent's determination and imposition of an administrative penalty in accordance with section 119.12 of the Revised Code.

(D) An administrative penalty collected under this section shall be deposited into the state treasury to the credit of the department of insurance operating fund created by section 3901.021 of the Revised Code.

Sec. 3959.01. As used in this chapter:

(A) "Administration fees" means any amount charged a covered person for services rendered. "Administration fees" includes commissions earned or paid by any person relative to services performed by an administrator.

(B) "Administrator" means any person who adjusts or settles claims on, residents of this state in connection with life, dental, health, prescription drugs, or disability insurance or self-insurance programs. "Administrator" includes a pharmacy benefit manager. "Administrator" does not include any of the following:

(1) An insurance agent or solicitor licensed in this state whose activities are limited exclusively to the sale of insurance and who does not provide any administrative services;

(2) Any person who administers or operates the workers' compensation program of a self-insuring employer under Chapter 4123. of the Revised Code;

(3) Any person who administers pension plans for the

benefit of the person's own members or employees or administers pension plans for the benefit of the members or employees of any other person;

(4) Any person that administers an insured plan or a self-insured plan that provides life, dental, health, or disability benefits exclusively for the person's own members or employees;

(5) Any health insuring corporation holding a certificate of authority under Chapter 1751. of the Revised Code or an insurance company that is authorized to write life or sickness and accident insurance in this state.

(C) "Actual acquisition cost" means the amount that a drug wholesaler charges a pharmacy for a drug product as listed on the pharmacy's billing invoice.

(D) "Aggregate excess insurance" means that type of coverage whereby the insurer agrees to reimburse the insured employer or trust for all benefits or claims paid during an agreement period on behalf of all covered persons under the plan or trust which exceed a stated deductible amount and subject to a stated maximum.

~~(D)~~ (E) "Contracted pharmacy" or "pharmacy" means a pharmacy located in this state participating in either the network of a pharmacy benefit manager or in a health care or pharmacy benefit plan through a direct contract or through a contract with a pharmacy services administration organization, group purchasing organization, or another contracting agent.

~~(E)~~ (F) "Contributions" means any amount collected from a covered person to fund the self-insured portion of any plan in accordance with the plan's provisions, summary plan descriptions, and contracts of insurance.

~~(F)~~ (G) "Drug product reimbursement" means the amount paid by a pharmacy benefit manager to a contracted pharmacy for the cost of the drug dispensed to a patient and does not include a dispensing or professional fee.

~~(G)~~ (H) "Drug wholesaler" means a wholesale drug distributor accredited by a nationally recognized nonprofit organization that represents the interests of state boards of pharmacy and to which the state board of pharmacy is a member.

(I) "Fiduciary" has the meaning set forth in section 1002(21)(A) of the "Employee Retirement Income Security Act of 1974," 88 Stat. 829, 29 U.S.C. 1001, as amended.

~~(H)~~ (J) "Fiscal year" means the twelve-month accounting period commencing on the date the plan is established and ending twelve months following that date, and each corresponding twelve-month accounting period thereafter as provided for in the summary plan description.

~~(I)~~ (K) "Insurer" means an entity authorized to do the business of insurance in this state or, for the purposes of this section, a health insuring corporation authorized to issue health care plans in this state.

~~(J)~~ (L) "Managed care organization" means an entity that provides medical management and cost containment services and includes a medicaid managed care organization, as defined in section 5167.01 of the Revised Code.

~~(K)~~ (M) "Maximum allowable cost" means a maximum drug product reimbursement for an individual drug or for a group of therapeutically and pharmaceutically equivalent multiple source drugs that are listed in the United States food and drug administration's approved drug products with therapeutic

equivalence evaluations, commonly referred to as the orange book.

~~(L)~~ (N) "Maximum allowable cost list" means a list of the drugs for which a pharmacy benefit manager imposes a maximum allowable cost, either directly or by setting forth a method for how the maximum allowable cost is calculated.

~~(M)~~ (O) "Multiple employer welfare arrangement" has the same meaning as in section 1739.01 of the Revised Code.

~~(N)~~ (P) "National drug code number" or "national drug code" means the number registered for a drug pursuant to the listing system established by the United States food and drug administration under the "Drug Listing Act of 1972," 21 U.S.C. 360.

(Q) "Ohio pharmacy" means a pharmacy, including an independent pharmacy, that is incorporated or organized in this state under Title XVII of the Revised Code.

(R) "Pharmacy benefit manager" means an entity that contracts with pharmacies on behalf of an employer, a multiple employer welfare arrangement, public employee benefit plan, state agency, insurer, managed care organization, or other third-party payer to provide pharmacy health benefit services or administration. "Pharmacy benefit manager" includes the state pharmacy benefit manager selected under section 5167.24 of the Revised Code.

~~(O)~~ (S) "Plan" means any arrangement in written form for the payment of life, dental, health, or disability benefits to covered persons defined by the summary plan description and includes a drug benefit plan administered by a pharmacy benefit manager.

~~(P)~~ (T) "Plan sponsor" means the person who establishes the plan.

~~(Q)~~ (U) "Retaliate" means any of the following actions taken by a pharmacy benefit manager:

(1) Terminating or refusing to renew a contract with a pharmacy;

(2) Subjecting a pharmacy to increased audits;

(3) Failing to promptly pay a pharmacy any money the pharmacy benefit manager owes to the pharmacy.

(V) "Self-insurance program" means a program whereby an employer provides a plan of benefits for its employees without involving an intermediate insurance carrier to assume risk or pay claims. "Self-insurance program" includes but is not limited to employer programs that pay claims up to a prearranged limit beyond which they purchase insurance coverage to protect against unpredictable or catastrophic losses.

~~(R)~~ (W) "Specific excess insurance" means that type of coverage whereby the insurer agrees to reimburse the insured employer or trust for all benefits or claims paid during an agreement period on behalf of a covered person in excess of a stated deductible amount and subject to a stated maximum.

~~(S)~~ (X) "Summary plan description" means the written document adopted by the plan sponsor which outlines the plan of benefits, conditions, limitations, exclusions, and other pertinent details relative to the benefits provided to covered persons thereunder.

~~(T)~~ (Y) "Third-party payer" has the same meaning as in section 3901.38 of the Revised Code.

Sec. 3959.111. (A)(1)(a) In each contract between a pharmacy benefit manager and a pharmacy, the pharmacy shall be given the right to obtain from the pharmacy benefit manager, within ten days after any request, a current list of the sources used to determine maximum allowable cost pricing. In each contract between a pharmacy benefit manager and a pharmacy, the pharmacy benefit manager shall be obligated to update and implement the pricing information at least every seven days and provide a means by which contracted pharmacies may promptly review maximum allowable cost pricing updates in an electronic format that is readily available, accessible, and secure and that can be easily searched.

Subject to division (A)(1) of this section, a pharmacy benefit manager shall utilize the most up-to-date pricing data when calculating drug product reimbursements for all contracting pharmacies within one business day of any price update or modification.

(b) A pharmacy benefit manager shall maintain a written procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner. The written procedure, and any updates, shall promptly be made available to a pharmacy upon request.

(2) In each contract between a pharmacy benefit manager and a pharmacy, a pharmacy benefit manager shall be obligated to ensure that all of the following conditions are met prior to placing a prescription drug on a maximum allowable cost list:

(a) The drug is listed as "A" or "B" rated in the most recent version of the United States food and drug administration's approved drug products with therapeutic equivalence evaluations, or has an "NR" or "NA" rating or

similar rating by nationally recognized reference.

(b) The drug is generally available for purchase by pharmacies in this state from a national or regional wholesaler and is not obsolete.

(3) Each contract between a pharmacy benefit manager and a pharmacy shall include an electronic process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes all of the following:

(a) A twenty-one-day limit on the right to appeal following the initial claim;

(b) A requirement that the appeal be investigated and resolved within twenty-one days after the appeal;

(c) A telephone number at which the pharmacy may contact the pharmacy benefit manager to speak to a person responsible for processing appeals;

(d) A requirement that a pharmacy benefit manager provide a reason for any appeal denial, including the national drug code and the identity of the national or regional wholesalers from whom the drug was generally available for purchase at or below the benchmark price determined by the pharmacy benefit manager;

(e) A requirement that if the appeal is upheld or granted, then the pharmacy benefit manager shall adjust the drug product reimbursement to the pharmacy's upheld appeal price;

(f) A requirement that a pharmacy benefit manager make an adjustment not later than one day after the date of determination of the appeal. The adjustment shall be retroactive to the date the appeal was made and shall apply to all situated pharmacies as determined by the pharmacy benefit manager. This

requirement does not prohibit a pharmacy benefit manager from retroactively adjusting a claim for the appealing pharmacy or for any other similarly situated pharmacies.

(B)(1)(a) A pharmacy benefit manager shall disclose to the plan sponsor whether or not the pharmacy benefit manager uses the same maximum allowable cost list when billing a plan sponsor as it does when reimbursing a pharmacy.

(b) If a pharmacy benefit manager uses multiple maximum allowable cost lists, the pharmacy benefit manager shall disclose in the aggregate to a plan sponsor any differences between the amount paid to a pharmacy and the amount charged to a plan sponsor.

(2) The disclosures required under division (B)(1) of this section shall be made within ten days of a pharmacy benefit manager and a plan sponsor signing a contract or on a quarterly basis.

(3)(a) Division (B) of this section does not apply to plans governed by the "Employee Retirement Income Security Act of 1974," 29 U.S.C. 1001, et seq. or medicare part D.

(b) As used in this division, "medicare part D" means the voluntary prescription drug benefit program established under Part D of Title XVIII of the "Social Security Act," 42 U.S.C. 1395w-101, et seq.

(C) A pharmacy benefit manager shall not reimburse an Ohio pharmacy an amount less than the amount that the pharmacy benefit manager reimburses a pharmacy affiliated with the pharmacy benefit manager for providing the same drug product.

(D) An Ohio pharmacy may decline to provide a drug product to an individual or pharmacy benefit manager if, as a result of

a maximum allowable cost list, the Ohio pharmacy would be paid less than the actual acquisition cost of providing the drug product.

(E) Notwithstanding division (B)(5) of section 3959.01 of the Revised Code, a health insuring corporation or a sickness and accident insurer shall comply with the requirements of this section and is subject to the penalties under section 3959.12 of the Revised Code if the corporation or insurer is a pharmacy benefit manager, as defined in section 3959.01 of the Revised Code.

~~(D)~~ (F) No pharmacy benefit manager shall retaliate against an Ohio pharmacy for reporting an alleged violation of, or for exercising a right or remedy under, this section.

(G) In addition to any other remedies provided by law, an Ohio pharmacy may file a formal complaint to the superintendent of insurance alleging that a pharmacy benefit manager has violated this section.

(H) The superintendent of insurance shall adopt rules as necessary to implement the requirements of this section.

Sec. 3959.121. (A) The superintendent of insurance shall evaluate any complaint filed by an Ohio pharmacy pursuant to section 3959.111, 3959.151, or 3959.21 of the Revised Code.

(B)(1) If the superintendent determines, based on a complaint filed by an Ohio pharmacy or other information available to the superintendent, that a pharmacy benefit manager has violated section 3959.111, 3959.151, or 3959.21 of the Revised Code, the superintendent shall do both of the following:

(a) Issue a notice of violation to the pharmacy benefit manager that clearly explains the violation;

(b) Impose an administrative penalty on the pharmacy benefit manager of one thousand dollars for each violation.

(2) Each day that a violation continues after the pharmacy benefit manager receives notice of the violation under division (B)(1)(a) of this section is considered a separate violation for the purposes of the administrative penalty under division (B)(1)(b) of this section.

(C) Before imposing an administrative penalty under this section, the superintendent shall afford the pharmacy benefit manager an opportunity for an adjudication hearing under Chapter 119. of the Revised Code. At the hearing, the pharmacy benefit manager may challenge the superintendent's determination that a violation occurred, the superintendent's imposition of an administrative penalty, or both. The pharmacy benefit manager may appeal the superintendent's determination and the imposition of the administrative penalty in accordance with section 119.12 of the Revised Code.

(D) An administrative penalty collected under this section shall be deposited into the state treasury to the credit of the department of insurance operating fund created by section 3901.021 of the Revised Code.

Sec. 3959.151. (A) As used in this section, "machine-readable format" means a digital representation of information in a file that can be imported or read into a computer system for further processing. "Machine-readable format" includes.XML and.CSV formats.

(B)(1) On or before the fifteenth day of each month, each pharmacy benefit manager shall provide to the superintendent of insurance and to its contracted insurers and plan sponsors,

including contracted public employee benefit plans and contracted employers offering a self-insurance program, an electronic report of all drug claims processed the previous month in a machine-readable format that is also readable in plain language without the use of software.

(2) The electronic report provided to an insurer, a plan sponsor, or the medicaid program shall include an itemized list of the maximum allowable cost of each drug product from all drug product claims processed by the pharmacy benefit manager in the previous month for that insurer, that plan sponsor, or the medicaid program. The electronic report provided to the superintendent of insurance shall include an itemized list of the actual acquisition cost of each drug product from all drug product claims processed by the pharmacy benefit manager in the previous month for all insurers and plan sponsors.

(3) The itemized list shall notate the following for each drug product:

(a) If the drug was procured pursuant to the pharmacy benefit manager, insurer, plan sponsor, or department of medicaid's drug formulary or list of covered drugs;

(b) If the drug was procured outside of the drug formulary or list of covered drugs;

(c) If the drug is a brand-name drug;

(d) If the drug is a generic drug;

(e) If the drug is a specialty drug, including biological products.

(C)(1) No agreement between a pharmacy benefit manager and an insurer or plan sponsor, including a service agreement under

section 3959.15 of the Revised Code, that is entered into, amended, or renewed on or after the effective date of this section shall prohibit disclosure of any of the information included in the itemized list required by division (B) of this section.

(2) Notwithstanding division (B) of this section, a pharmacy benefit manager is not required to disclose information deemed proprietary or confidential by a service agreement between the pharmacy benefit manager and an insurer or plan sponsor that is entered into in accordance with section 3959.15 of the Revised Code before the effective date of this section, and in effect on the date the information would otherwise be submitted as part of the itemized list required by division (B) of this section.

(D) No pharmacy benefit manager shall retaliate against an Ohio pharmacy for reporting an alleged violation of, or for exercising a right or remedy under, this section.

(E) If an Ohio pharmacy believes that a pharmacy benefit manager has violated this section, in addition to any other remedies provided by law, a pharmacy may file a formal complaint to the superintendent of insurance.

(F) The superintendent of insurance shall adopt rules in accordance with Chapter 119. of the Revised Code for the purposes of implementing and administering this section.

Sec. 3959.21. (A) Except as otherwise provided in divisions (E) and (F) of this section, a pharmacy benefit manager shall pay both of the following to an Ohio pharmacy for a claim for a drug product dispensed on or after the ninety-first day following the effective date of this section:

(1) A drug product reimbursement not less than the Ohio pharmacy's actual acquisition cost of the drug dispensed;

(2) A dispensing fee not less than the minimum dispensing fee in effect for the date the drug is dispensed, as determined by the superintendent of insurance under division (B) of this section.

(B)(1) Not later than ninety days after the effective date of this section, the superintendent of insurance shall calculate a minimum dispensing fee to be paid for each drug product dispensed based on data collected by the department of medicaid through the survey conducted pursuant to section 5164.752 of the Revised Code. The superintendent shall publish the amount of the minimum dispensing fee and the dates to which it applies on a publicly accessible web site maintained by the department of insurance.

(2) The superintendent of insurance shall calculate and publish the minimum dispensing fee described under division (B)(1) of this section each time the department of medicaid publishes the survey conducted pursuant to section 5164.752 of the Revised Code.

(C) No pharmacy benefit manager shall retaliate against an Ohio pharmacy for reporting an alleged violation of, or for exercising a right or remedy under, this section.

(D) In addition to any other remedies provided by law, an Ohio pharmacy may bring a formal complaint to the superintendent of insurance that a pharmacy benefit manager has violated this section.

(E) Division (A) of this section does not apply to the extent that it conflicts with a contract or agreement entered

into before the effective date of this section except that, if such a contract or agreement is amended or renewed after the effective date of this section, the contract or agreement shall conform to the requirements of that division. Division (A) of this section does not prohibit a pharmacy benefit manager from paying drug product reimbursements or dispensing fees in excess of the amounts required by that division.

(F) This section does not apply to the state pharmacy benefit manager established pursuant to section 5167.12 of the Revised Code.

Section 2. That existing sections 3902.50, 3959.01, and 3959.111 of the Revised Code are hereby repealed.

Section 3. Sections 3902.75 and 3902.76 of the Revised Code, as enacted in this act, apply to health benefit plans, as defined in section 3922.01 of the Revised Code, delivered, issued for delivery, modified, or renewed on or after the effective date of those sections.

Section 4. Sections 3902.75 and 3902.76 of the Revised Code, as enacted in this act, apply to contracts between health plan issuers, as defined in section 3922.01 of the Revised Code, and pharmacies entered into, modified, or renewed on or after the effective date of those sections.

Section 5. The amendment by this act of section 3959.111 of the Revised Code applies to contracts between pharmacy benefit managers and Ohio pharmacies, as those terms are defined in section 3959.01 of the Revised Code, as amended by this act, that are entered into, amended, or renewed on or after the effective date of this section.

Section 6. This act shall be known as the Community

Pharmacy Protection Act. 507