# HB3630

LRB10214893BMS22454b

## 102ND GENERAL ASSEMBLY

## State of Illinois

## 2021 and 2022

### HB3630

Introduced 2/22/2021, by Rep. Greg Harris

## SYNOPSIS AS INTRODUCED:

See Index

Amends the Illinois Insurance Code. Provides that if a generic equivalent for a brand name drug is approved by the federal Food and Drug Administration, plans that provide coverage for prescription drugs through the use of a drug formulary that are amended, delivered, issued, or renewed in the State on or after January 1, 2022 shall comply with specified requirements. Provides that the Department of Insurance may adopt rules to implement provisions concerning notice of change of drug formulary. In provisions concerning a contract between a health insurer and a pharmacy benefit manager, provides that a pharmacy benefit manager must update and publish maximum allowable cost pricing information according to specified requirements, must provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs, and must comply with specified requirements if an appeal is denied. Sets forth provisions concerning pharmacy benefit manager contracts; specified requirements that a pharmacy benefit manager shall comply with; and specified requirements that an auditing entity shall comply with when conducting a pharmacy audit. Provides that a violation of specified provisions is an unfair method of competition and unfair and deceptive act or practice in the business of insurance. Sets forth provisions concerning applicability of the Pharmacy Benefit Managers Article of the Illinois Insurance Code, and provisions concerning fiduciary responsibility of a pharmacy benefit manager. Defines terms. Makes other changes. Amends the Illinois Public Aid Code. Sets forth provisions concerning reimbursement of professional dispensing fees and acquisition costs for pharmacy providers.

LRB102 14893 BMS 22454 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning regulation.

**Be it enacted by the People of the State of Illinois, represented in the General Assembly:**

Section 5. The Illinois Insurance Code is amended by changing Sections 155.37, 424, and 513b1 and by adding Sections 513b1.1 and 513b1.3 as follows:

(215 ILCS 5/155.37)

Sec. 155.37. Drug formulary; notice.

(a) As used in this Section:

"Brand name drug" means a prescription drug marketed under a proprietary name or registered trademark name, including a biological product.

"Formulary" means a list of prescription drugs that is developed by clinical and pharmacy experts and represents the carrier's medically appropriate and cost-effective prescription drugs approved for use.

"Generic drug" means a prescription drug, whether identified by its chemical, proprietary, or nonproprietary name, that is not a brand name drug and is therapeutically equivalent to a brand name drug in dosage, safety, strength, method of consumption, quality, performance, and intended use. "Generic drug" includes a biosimilar product.

(b) Insurance companies that transact the kinds of

insurance authorized under Class 1(b) or Class 2(a) of Section 4 of this Code and provide coverage for prescription drugs through the use of a drug formulary must notify insureds of any change in the formulary. A company may comply with this Section by posting changes in the formulary on its website.

(c) If a generic equivalent for a brand name drug is approved by the federal Food and Drug Administration, insurance companies with plans that provide coverage for prescription drugs through the use of a drug formulary that are amended, delivered, issued, or renewed in this State on or after January 1, 2022 shall:

(1) immediately substitute the brand name drug with the generic equivalent; or

(2) move the brand name drug to a formulary tier that reduces an enrollee's cost.

(d) The Department may adopt rules to implement this Section.

(Source: P.A. 92-440, eff. 8-17-01; 92-651, eff. 7-11-02.)

(215 ILCS 5/424) (from Ch. 73, par. 1031)

Sec. 424. Unfair methods of competition and unfair or deceptive acts or practices defined. The following are hereby defined as unfair methods of competition and unfair and deceptive acts or practices in the business of insurance:

(1) The commission by any person of any one or more of the acts defined or prohibited by Sections 134, 143.24c,

147, 148, 149, 151, 155.22, 155.22a, 155.42, 236, 237, 364, ~~and~~ 469, and 513b1 of this Code.

(2) Entering into any agreement to commit, or by any concerted action committing, any act of boycott, coercion or intimidation resulting in or tending to result in unreasonable restraint of, or monopoly in, the business of insurance.

(3) Making or permitting, in the case of insurance of the types enumerated in Classes 1, 2, and 3 of Section 4, any unfair discrimination between individuals or risks of the same class or of essentially the same hazard and expense element because of the race, color, religion, or national origin of such insurance risks or applicants. The application of this Article to the types of insurance enumerated in Class 1 of Section 4 shall in no way limit, reduce, or impair the protections and remedies already provided for by Sections 236 and 364 of this Code or any other provision of this Code.

(4) Engaging in any of the acts or practices defined in or prohibited by Sections 154.5 through 154.8 of this Code.

(5) Making or charging any rate for insurance against losses arising from the use or ownership of a motor vehicle which requires a higher premium of any person by reason of his physical disability, race, color, religion, or national origin.

(6) Failing to meet any requirement of the Unclaimed Life Insurance Benefits Act with such frequency as to constitute a general business practice.

(Source: P.A. 99-143, eff. 7-27-15; 99-893, eff. 1-1-17.)

(215 ILCS 5/513b1)

Sec. 513b1. Pharmacy benefit manager contracts.

(a) As used in this Section:

"Audit" means any physical on-site, remote electronic, or concurrent review of a pharmacist service submitted to the pharmacy benefit manager or pharmacy benefit manager affiliate by a pharmacist or pharmacy for payment.

"Auditing entity" means a person or company that performs a pharmacy audit.

"Biological product" has the meaning ascribed to that term in Section 19.5 of the Pharmacy Practice Act.

"Business day" means any day of the week excluding Saturday, Sunday, and any legal holiday, as specified in Section 17 of the Promissory Note and Bank Holiday Act.

"Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:

(1) receiving payments for pharmacist services; or

(2) making payments to a pharmacist or pharmacy for pharmacist services.

"Covered entity" has the meaning given to that term under the federal Health Insurance Portability and Accountability Act of 1996, as specified in 45 CFR 160.103.

"Covered person" means a member, policyholder, subscriber, enrollee, beneficiary, dependent, or other individual participating in a health benefit plan.

"Extrapolation" means the practice of inferring a frequency of dollar amount of overpayments, underpayments, nonvalid claims, or other errors on any portion of claims submitted, based on the frequency of dollar amount of overpayments, underpayments, nonvalid claims, or other errors actually measured in a sample of claims.

"Health benefit plan" means a policy, contract, certificate, or agreement entered into, offered, or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of physical, mental, or behavioral health care services.

"Health carrier" means an entity subject to the insurance laws and rules of this State or subject to the jurisdiction of the Director that contracts or offers to contract or enters into an agreement to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health insurance company, a health maintenance organization, a hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or

health care services.

"Maximum allowable cost" means any listing of pharmaceutical products or method for calculating reimbursement amounts used by a pharmacy benefit manager, directly or indirectly, setting the maximum allowable cost on which reimbursement payment to a pharmacy or pharmacist may be based for dispensing a prescription pharmaceutical product and includes, without limitation: ~~the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.~~

(1) average acquisition cost, including national average drug acquisition cost;

(2) average manufacturer price;

(3) average wholesale price;

(4) brand effective rate or generic effective rate;

(5) discount indexing;

(6) federal upper limits;

(7) wholesale acquisition cost; or

(8) any other term that a pharmacy benefit manager or a third-party payer may use to establish reimbursement rates to a pharmacist or pharmacy for pharmaceutical products.

"Maximum allowable cost list" means a list of drugs for which a maximum allowable cost has been established by a pharmacy benefit manager.

"Other prescription drug or device services" means

services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including, but not limited to:

(1) negotiating rebates, discounts, or other financial incentives and arrangements with drug companies;

(2) disbursing or distributing rebates;

(3) managing or participating in incentive programs or arrangements for pharmacist services;

(4) negotiating or entering into contractual arrangements with pharmacists or pharmacies;

(5) developing and maintaining formularies;

(6) designing prescription benefit programs; or

(7) advertising or promoting services.

"Pharmacy benefit manager" means a person, business, or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides claims processing services or other prescription drug or device services, or both, for health benefit plans. "Pharmacy benefit manager" does not include:

(1) a health care facility licensed in this State;

(2) a health care professional licensed in this State;

(3) a consultant who only provides advice as to the selection or performance of a pharmacy benefit manager; or

(4) a health carrier to the extent that it performs any claims processing and other prescription drug or

device services exclusively for its enrollees.

"Pharmacy benefit manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefit manager.

"Pharmaceutical wholesaler" means a person or entity that sells and distributes, directly or indirectly, prescription pharmaceutical products, including, without limitation, brand name, generic, and over-the-counter pharmaceuticals, and that offers regular or private delivery to a pharmacy.

"Pharmaceutical product" means a generic drug, brand name drug, biologic, or other prescription drug, vaccine, or device.

"Pharmacist" has the meaning given to that term in the Pharmacy Practice Act.

"Pharmacist services" means products, goods, and services or any combination of products, goods, and services, provided as a part of the practice of pharmacy. "Pharmacist services" includes "pharmacist care" as defined in the Pharmacy Practice Act.

"Pharmacy" has the meaning given to that term in the Pharmacy Practice Act.

"Pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice.

"Pharmacy audit" means an audit conducted of any records of a pharmacy for prescriptions dispensed or non-proprietary drugs or pharmacist services provided by a pharmacy or pharmacist to a covered person.

"Pharmacy record" means any record stored electronically or as a hard copy by a pharmacy that relates to the provision of a prescription or pharmacy services or other component of pharmacist care that is included in the practice of pharmacy.

"Prescription" has the meaning given to the term in the Pharmacy Practice Act.

"Retail price" means the price an individual without prescription drug coverage would pay at a retail pharmacy, not including a pharmacist dispensing fee.

"Third-party payer" means any entity involved in the financing of a pharmacy benefit plan or program other than the patient, health care provider, or sponsor of a plan subject to regulation under Medicare Part D, 42 U.S.C. 1395w-101, et al.

(b) A contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

(1) Update and publish maximum allowable cost pricing information at least every 7 calendar days and at least 7 calendar days from an increase of 10% or more in the pharmacy acquisition cost from 60% or more of the pharmaceutical wholesalers doing business in the State or a change in the methodology on which the maximum allowable

cost list is based or in the value of a variable involved in the methodology.

(2) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

(3) Provide access to its maximum allowable cost list to each pharmacy or pharmacy services administrative organization subject to the maximum allowable cost list. Access may include a real-time pharmacy website portal to be able to view the maximum allowable cost list. As used in this Section, "pharmacy services administrative organization" means an entity operating within the State that contracts with independent pharmacies to conduct business on their behalf with third-party payers. A pharmacy services administrative organization may provide administrative services to pharmacies and negotiate and enter into contracts with third-party payers or pharmacy benefit managers on behalf of pharmacies.

(4) Provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs and reimbursements made under a maximum allowable cost for a specific pharmaceutical product or pharmaceutical products as: ~~Provide a process by which a contracted pharmacy can appeal the provider's~~

~~reimbursement for a drug subject to maximum allowable cost pricing.~~

(i) not meeting the requirements of this Section; or

(ii) being below the pharmacy acquisition cost.

The appeals process must, at a minimum, include the following:

(A) A requirement that a contracted pharmacy has 14 calendar days after the applicable fill date to appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the network provider paid to the supplier of the drug.

(B) A requirement that a pharmacy benefit manager must respond to a challenge within 14 calendar days of the contracted pharmacy making the claim for which the appeal has been submitted.

(C) A telephone number and e-mail address or website to network providers, at which the provider can contact the pharmacy benefit manager to process and submit an appeal.

(D) A requirement that, if an appeal is denied, the pharmacy benefit manager must provide the reason for the denial and the name and the national drug code number from national or regional wholesalers operating in Illinois that have the pharmaceutical product currently in stock at a price below the maximum

allowable cost list. If the national drug code number provided by the pharmacy benefit manager is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription pharmaceutical products for resale, then the pharmacy benefit manager shall adjust the maximum allowable cost list above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the pharmaceutical product at a cost that is equal to or less than the previously challenged maximum allowable cost.

(E) A requirement that, if an appeal is sustained, the pharmacy benefit manager must make an adjustment in the drug price effective the date the challenge is resolved and make the adjustment applicable to all similarly situated network pharmacy providers, as determined by the managed care organization or pharmacy benefit manager.

(5) Allow a plan sponsor contracting with a pharmacy benefit manager an annual right to audit compliance with the terms of the contract by the pharmacy benefit manager, including, but not limited to, full disclosure of any and all rebate amounts secured, whether product specific or generalized rebates, that were provided to the pharmacy

benefit manager by a pharmaceutical manufacturer.

(6) Allow a plan sponsor contracting with a pharmacy benefit manager to request that the pharmacy benefit manager disclose the actual amounts paid by the pharmacy benefit manager to the pharmacy.

(7) Provide notice to the party contracting with the pharmacy benefit manager of any consideration that the pharmacy benefit manager receives from the manufacturer for dispense as written prescriptions once a generic or biologically similar product becomes available.

(c) In order to place a particular prescription drug on a maximum allowable cost list, the pharmacy benefit manager must, at a minimum, ensure that:

(1) if the drug is a generically equivalent drug, it is listed as therapeutically equivalent and pharmaceutically equivalent "A" or "B" rated in the United States Food and Drug Administration's most recent version of the "Orange Book" or have an NR or NA rating by Medi-Span, Gold Standard, or a similar rating by a nationally recognized reference;

(2) the drug is available for purchase by each pharmacy in the State from national or regional wholesalers operating in Illinois; and

(3) the drug is not obsolete.

(d) A pharmacy benefit manager is prohibited from limiting a pharmacist's ability to disclose whether the cost-sharing

obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, if one is available in accordance with Section 42 of the Pharmacy Practice Act.

(e) A health insurer or pharmacy benefit manager shall not require an insured to make a payment for a prescription drug at the point of sale in an amount that exceeds the lesser of:

(1) the applicable cost-sharing amount; or

(2) the retail price of the drug in the absence of prescription drug coverage.

(f) In any participation contracts between a pharmacy benefit manager and pharmacists or pharmacies providing prescription drug coverage for health benefit plans, no pharmacy or pharmacist may be prohibited, restricted, or penalized in any way from disclosing to any covered person any health care information that the pharmacy or pharmacist deems appropriate regarding:

(1) the nature of treatment, risks, or alternatives thereto;

(2) the availability of alternative therapies, consultations, or tests;

(3) the decision of utilization reviewers or similar persons to authorize or deny services;

(4) the process that is used to authorize or deny health care services or benefits; or

(5) information on financial incentives and structures

used by the insurer.

(g) A pharmacy benefit manager may not prohibit a pharmacy or pharmacist from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.

(h) A pharmacy benefit manager contract with a participating pharmacist or pharmacy may not prohibit, restrict, or limit disclosure of information to the Director, law enforcement, or State or federal governmental officials if:

(1) the recipient of the information represents that it has the authority, to the extent provided by State or federal law, to maintain proprietary information as confidential; and

(2) before disclosure of information designated as confidential the pharmacist or pharmacy:

(A) marks as confidential any document in which the information appears; or

(B) requests confidential treatment for any oral communication of the information.

(i) A pharmacy benefit manager may not terminate the contract of or penalize a pharmacist or pharmacy due to a pharmacist or pharmacy:

(1) disclosing information about pharmacy benefit manager practices, except for information determined to be

a trade secret as determined by State law or the Director; or

(2) sharing any portion of the pharmacy benefit manager contract with the Director pursuant to a complaint or a query regarding whether the contract is in compliance with this Article.

(j) A pharmacy benefit manager shall not prohibit a pharmacist or pharmacy from or indirectly punish a pharmacist or pharmacy for making any written or oral statement to any State, county, or municipal official or before any State, county, or municipal committee, body, or proceeding.

(k) A pharmacy benefit manager may not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of the covered person's cost-sharing amount under the terms of the health benefit plan or the amount the covered person would pay for the drug if the covered person were paying the cash price. Any amount paid by a covered person under this subsection shall be attributable toward any deductible or, to the extent consistent with Section 2707 of the Public Health Service Act, the annual out-of-pocket maximums under the covered person's health benefit plan.

(l) A pharmacy benefit manager shall not reimburse a pharmacy or pharmacist in this State an amount less than the amount that the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate for providing the same pharmaceutical product. The amount shall be calculated on a

per unit basis based on the same generic product identifier or generic code number. The amount shall not be less than the current national average drug acquisition cost listing for the same pharmaceutical product.

(m) A pharmacy or pharmacist may decline to provide a pharmaceutical product to a patient or pharmacy benefit manager if, as a result of a maximum allowable cost list, a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing the pharmaceutical product.

(n) A pharmacy benefit manager shall pay a pharmacy a professional dispensing fee at a rate not less than the fee-for-service rate paid under the State's Medical Assistance Program established under Article V of the Illinois Public Aid Code for each prescription pharmaceutical product that is dispensed (on a per unit basis based on the same generic product identifier or generic code number) to the patient by the pharmacy. This dispensing fee shall be in addition to the amount that the pharmacy benefit manager reimburses a pharmacy, consistent with the provisions of this Article, for the cost of the pharmaceutical product that the pharmacy dispenses to the patient.

(o) A pharmacy benefit manager shall not assess, charge, or collect any form of remuneration that passes from a pharmacy or pharmacist to the pharmacy benefit manager, including, but not limited to, claim-processing fees,

performance-based fees, network-participation fees, or accreditation fees.

(p) A pharmacy benefit manager shall not directly or indirectly deny or reduce a claim after the claim has been adjudicated, unless one of the following applies:

(1) the original claim was submitted fraudulently; or

(2) the original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmaceutical product.

(q) A pharmacy benefit manager shall not condition payment, reimbursement, or network participation on any type of accreditation, certification, or credentialing standard beyond those required by the State Board of Pharmacy or applicable State or federal law.

(r) A pharmacy benefit manager shall not prohibit or otherwise restrict a pharmacist or pharmacy from offering prescription delivery services to any covered person.

(s) A pharmacy benefit manager shall not require any additional requirement for a prescription claim that is more restrictive than the standards established under the Illinois Food, Drug and Cosmetic Act; the Pharmacy Practice Act; or the Illinois Controlled Substances Act.

(t) A pharmacy benefit manager shall allow participants and beneficiaries of the pharmacy benefit plans and programs that the pharmacy benefit manager serves to utilize any pharmacy within the State that is licensed to dispense the

prescription pharmaceutical product that the participant or beneficiary seeks to fill, if the pharmacy is willing to accept the same terms and conditions that the pharmacy benefit manager has established for at least one of the networks of pharmacies that the pharmacy benefit manager has established to serve patients within the State.

(u) A pharmacy benefit manager shall not:

(1) prohibit or limit any person who is a participant or beneficiary of the policy or plan from selecting a pharmacy or pharmacist of his or her choice who has agreed to participate in the plan according to the terms offered by the insurer;

(2) deny a pharmacy or pharmacist the right to participate as a contract provider under the policy or plan if the pharmacy or pharmacist agrees to provide pharmacy services, including, but not limited to, prescription drugs, that meet the terms and requirements set forth by the insurer under the policy or plan and agrees to the terms of reimbursement set forth by the insurer;

(3) impose upon a beneficiary of pharmacy services under a health benefit plan any copayment, fee, or any other condition that is not equally imposed upon all beneficiaries in the same benefit category, class, or copayment level under the health benefit plan when receiving services from a contract provider;

(4) impose a monetary advantage, incentive, or penalty under a health benefit plan that would affect or influence a beneficiary's choice among those pharmacies or pharmacists who have agreed to participate in the plan according to the terms offered by the insurer;

(5) require a beneficiary, as a condition of payment or reimbursement, to purchase pharmacy services, including prescription drugs, exclusively through a mail-order pharmacy or pharmacy benefit manager affiliate; or

(6) impose upon a beneficiary any copayment, amount of reimbursement, number of days of a drug supply for which reimbursement will be allowed, or any other payment, restriction, limitation, or condition relating to purchasing pharmacy services from any pharmacy, including prescription drugs, that is more costly or more restrictive than that which would be imposed upon the beneficiary if such services were purchased from a mail-order pharmacy, a pharmacy benefit manager affiliate, or any other pharmacy that is willing to provide the same services or products for the same cost and copayment as any mail-order service.

(v) A pharmacy benefit manager or a pharmacy benefit manager affiliate shall not:

(1) refer a covered person to a mail-order pharmacy or any other pharmacy benefit manager affiliate; or

(2) utilize a covered person's pharmacy service data

collected pursuant to the provision of claims processing services for the purpose referring the covered person to a mail-order pharmacy or any other pharmacy benefit manager affiliate.

As used this subsection, "refer" means:

(A) ordering a covered person to a pharmacy either orally or in writing, including online messaging;

(B) offering or implementing plan designs that require covered persons to utilize a pharmacy benefit manager affiliate or that increase plan or patient costs, including requiring covered persons to pay the full cost for a prescription when covered persons choose not to use a pharmacy benefit manager affiliate; or

(C) using person-specific advertising, marketing, direct written, electronic, or verbal communication, promotion, or other solicitation of a pharmacy by an affiliate or pharmacy benefit manager as a result of an arrangement or agreement with the pharmacy's affiliate.

(w) A pharmacy benefit manager shall not prohibit a pharmacy from participating in any given network of pharmacies within the State if the pharmacy is licensed by the Department of Financial and Professional Regulation and willing to accept the same terms and conditions that the pharmacy benefit manager has established for other pharmacies participating within the network that the pharmacy wishes to join.

(x) A pharmacy benefit manager shall not require

participation in additional networks for a pharmacy to enroll in an individual network.

(y) A pharmacy benefit manager shall not charge a participant or beneficiary of a pharmacy benefits plan or program that the pharmacy benefit manager serves a different copayment obligation or additional fee for using any pharmacy within a given network of pharmacies established by the pharmacy benefit manager to serve patients within the State.

(z) Notwithstanding any other law, when conducting a pharmacy audit, an auditing entity shall:

(1) not conduct an on-site audit of a pharmacy at any time during the first 3 business days of a month or the first 2 weeks and final 2 weeks of the calendar year or during a declared State or federal public health emergency;

(2) notify the pharmacy or its contracting agent no later than 30 days before the date of initial on-site audit; the notification to the pharmacy or its contracting agent shall be in writing and delivered either:

(A) by mail or common carrier, return receipt requested; or

(B) electronically with electronic receipt confirmation, addressed to the supervising pharmacist of record and pharmacy corporate office, if applicable, at least 30 days before the date of an initial on-site audit;

(3) limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the pharmacy benefit manager;

(4) include in the written advance notice of an on-site audit the list of specific prescription numbers to be included in the audit that may or may not include the final 2 digits of the prescription numbers;

(5) use the written and verifiable records of a hospital, physician, or other authorized practitioner that are transmitted by any means of communication to validate the pharmacy records in accordance with State and federal law;

(6) limit the number of prescriptions audited to no more than 100 randomly selected in a 12-month period and no more than one on-site audit per quarter of the calendar year, except in cases of fraud;

(7) provide the pharmacy or its contracting agent with a copy of the preliminary audit report within 45 days after the conclusion of the audit;

(8) be allowed to conduct a follow-up audit on site if a remote or desk audit reveals the necessity for a review of additional claims;

(9) accept invoice audits as validation invoices from any wholesaler registered with the Department of Financial and Professional Regulation from which the pharmacy has purchased prescription drugs or, in the case of durable

medical equipment or sickroom supplies, invoices from an authorized distributor other than a wholesaler;

(10) provide the pharmacy or its contracting agent with the ability to provide documentation to address a discrepancy or audit finding if the documentation is received by the pharmacy benefit manager no later than the 45th day after the preliminary audit report was provided to the pharmacy or its contracting agent; the pharmacy benefit manager shall consider a reasonable request from the pharmacy for an extension of time to submit documentation to address or correct any findings in the report;

(11) be required to provide the pharmacy or its contracting agent with the final audit report no later than 60 days after the initial audit report was provided to the pharmacy or its contracting agent;

(12) conduct the audit in consultation with a pharmacist if the audit involves clinical or professional judgment;

(13) not chargeback, recoup, or collect penalties from a pharmacy until the time period to file an appeal of the final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later, unless the identified discrepancy is expected to exceed $25,000, in which case the auditing entity may withhold future payments in excess of that amount until the final

resolution of the audit;

(14) not compensate the employee or contractor conducting the audit based on a percentage of the amount claimed or recouped pursuant to the audit;

(15) not use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by federal law or regulation; any amount to be charged back or recouped due to overpayment may not exceed the amount the pharmacy was overpaid;

(16) not include dispensing fees in the calculation of overpayments unless a prescription is considered a misfill; as used in this paragraph, "misfill" means a prescription that was not dispensed; a prescription that was dispensed but was an incorrect dose, amount, or type of medication; a prescription that was dispensed to the wrong person; a prescription in which the prescriber denied the authorization request; or a prescription in which an additional dispensing fee was charged; or

(17) conduct a pharmacy audit under the same standards and parameters as conducted for other similarly situated pharmacies audited by the auditing entity.

(aa) Except as otherwise provided by State or federal law, an auditing entity conducting a pharmacy audit may have access to a pharmacy's previous audit report only if the report was prepared by that auditing entity.

(bb) Information collected during a pharmacy audit shall

be confidential by law, except that the auditing entity conducting the pharmacy audit may share the information with the covered entity for which a pharmacy audit is being conducted and with any regulatory agencies and law enforcement agencies as required by law.

(cc) A pharmacy may not be subject to a chargeback or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical error or computer error, unless the error resulted in overpayment to the pharmacy.

(dd) A pharmacy shall have the right to file a written appeal of a preliminary and final pharmacy audit report in accordance with the procedures established by the entity conducting the pharmacy audit.

(ee) No interest shall accrue for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.

(ff) A contract between a pharmacy or pharmacist and a pharmacy benefit manager must contain a provision allowing, during the course of a pharmacy audit conducted by or on behalf of a pharmacy benefit manager, a pharmacy or pharmacist to withdraw and resubmit a claim within 30 days after:

(1) the preliminary written audit report is delivered if the pharmacy or pharmacist does not request an internal appeal; or

(2) the conclusion of the internal audit appeals

process if the pharmacy or pharmacist requests an internal audit appeal.

(gg) To the extent that an audit results in the identification of any clerical or recordkeeping errors, such as typographical errors, scrivener's errors, or computer errors, in a required document or record, the pharmacy shall not be subject to recoupment of funds by the pharmacy benefit manager unless the pharmacy benefit manager can provide proof of intent to commit fraud or such error results in actual financial harm to the pharmacy benefit manager, a health plan managed by the pharmacy benefit manager, or a consumer.

(hh) Any claim that was retroactively denied for a clerical error, typographical error, scrivener's error, or computer error shall be paid if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity. As used in this subsection, "clerical error" means an error that does not result in actual financial harm to the covered entity or consumer and does not include the dispensing of an incorrect dose, amount, or type of medication or dispensing a prescription drug to the wrong person.

(ii) For any claim that meets the definition of a clean claim or is deemed to not have violated the terms of the contract or the practice of pharmacy as described under the Pharmacy Practice Act, the pharmacy benefit manager shall pay

the pharmacy 5% of the total claim amount to cover audit preparation costs and time taken away from pharmacy staff in providing patient care.

(jj) This Section shall not apply to:

(1) audits in which suspected fraudulent activity or other intentional or willful misrepresentation is evidenced by a physical review, review of claims data or statements, or other investigative methods;

(2) audits of claims paid for by federally funded programs; or

(3) concurrent reviews or desk audits that occur within 3 business days after transmission of a claim and where no chargeback or recoupment is demanded.

(kk) A violation of this Section shall be an unfair and deceptive act or practice.

(ll) ~~(f)~~ This Section applies to contracts entered into or renewed on or after July 1, 2020.

(mm) ~~(g)~~ This Section applies to any group or individual policy of accident and health insurance or managed care plan that provides coverage for prescription drugs and that is amended, delivered, issued, or renewed on or after July 1, 2020.

(Source: P.A. 101-452, eff. 1-1-20.)

(215 ILCS 5/513b1.1 new)

Sec. 513b1.1. Applicability.

(a) This Article applies to a contract or health benefit plan issued, renewed, recredentialed, amended, or extended on or after the effective date of this amendatory Act of the 102nd General Assembly, including any health carrier that performs claims processing or other prescription drug or device services through a third party.

(b) As a condition of licensure, any contract in existence on the date the pharmacy benefit manager receives its license to do business in this State shall comply with the requirements of this Article.

(c) Nothing in this Article is intended or shall be construed to conflict with existing federal law.

(215 ILCS 5/513b1.3 new)

Sec. 513b1.3. Fiduciary responsibility. A pharmacy benefit manager is a fiduciary to a health carrier and shall:

(1) discharge that duty in accordance with federal and State law;

(2) notify the covered entity in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents any conflict of interest and inability to comply with the duties imposed by this Section, but in no event does this notification exempt the pharmacy benefit manager from compliance with all other Sections of this Code; and

(3) disclose all direct or indirect payments related

to the dispensation of prescription drugs or classes or brands of drugs to the covered entity.

Section 10. The Illinois Public Aid Code is amended by changing Sections 5-5.12 and 5-36 as follows:

(305 ILCS 5/5-5.12) (from Ch. 23, par. 5-5.12)

Sec. 5-5.12. Pharmacy payments.

(a) Every request submitted by a pharmacy for reimbursement under this Article for prescription drugs provided to a recipient of aid under this Article shall include the name of the prescriber or an acceptable identification number as established by the Department.

(b) Pharmacies providing prescription drugs under this Article shall be reimbursed at a rate which shall include a professional dispensing fee as determined by the Illinois Department, plus the current acquisition cost of the prescription drug dispensed. The Illinois Department shall update its information on the acquisition costs of all prescription drugs no less frequently than every 30 days. The Department shall not reimburse a pharmacy or pharmacist in this State an amount less than the current national average drug acquisition cost listing for the pharmaceutical product. ~~However, the Illinois Department may set the rate of reimbursement for the acquisition cost, by rule, at a percentage of the current average wholesale acquisition cost.~~

(b-5) The Department shall pay a pharmacy or pharmacist a professional dispensing fee at a rate not less than the amount determined by a pharmacy profession-recognized national or state survey of pharmacies for each prescription pharmaceutical product that is dispensed (on a per unit basis based on the same generic product identifier or generic code number) to the patient by the pharmacy. This dispensing fee shall be in addition to the amount that the Department reimburses a pharmacy for the cost of the pharmaceutical product that the pharmacy dispenses to the patient. If a vendor is utilized for conducting the survey or data analysis, the vendor may not be a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager or managed care organization.

(b-10) All Medicaid managed care organizations must reimburse pharmacy provider professional dispensing fees and acquisition costs at no less than the amounts established under the fee-for-service program whether the Medicaid managed care organization directly reimburses pharmacy providers or contracts with a pharmacy benefit manager to reimburse pharmacy providers. The reimbursement requirement specified in this subsection applies to all pharmacy services for persons receiving benefits under this Code, including services reimbursed under Section 5-36.

(c) (Blank).

(d) The Department shall review utilization of narcotic

medications in the medical assistance program and impose utilization controls that protect against abuse.

(e) When making determinations as to which drugs shall be on a prior approval list, the Department shall include as part of the analysis for this determination, the degree to which a drug may affect individuals in different ways based on factors including the gender of the person taking the medication.

(f) The Department shall cooperate with the Department of Public Health and the Department of Human Services Division of Mental Health in identifying psychotropic medications that, when given in a particular form, manner, duration, or frequency (including "as needed") in a dosage, or in conjunction with other psychotropic medications to a nursing home resident or to a resident of a facility licensed under the ID/DD Community Care Act or the MC/DD Act, may constitute a chemical restraint or an "unnecessary drug" as defined by the Nursing Home Care Act or Titles XVIII and XIX of the Social Security Act and the implementing rules and regulations. The Department shall require prior approval for any such medication prescribed for a nursing home resident or to a resident of a facility licensed under the ID/DD Community Care Act or the MC/DD Act, that appears to be a chemical restraint or an unnecessary drug. The Department shall consult with the Department of Human Services Division of Mental Health in developing a protocol and criteria for deciding whether to grant such prior approval.

(g) The Department may by rule provide for reimbursement of the dispensing of a 90-day supply of a generic or brand name, non-narcotic maintenance medication in circumstances where it is cost effective.

(g-5) On and after July 1, 2012, the Department may require the dispensing of drugs to nursing home residents be in a 7-day supply or other amount less than a 31-day supply. The Department shall pay only one dispensing fee per 31-day supply.

(h) Effective July 1, 2011, the Department shall discontinue coverage of select over-the-counter drugs, including analgesics and cough and cold and allergy medications.

(h-5) On and after July 1, 2012, the Department shall impose utilization controls, including, but not limited to, prior approval on specialty drugs, oncolytic drugs, drugs for the treatment of HIV or AIDS, immunosuppressant drugs, and biological products in order to maximize savings on these drugs. The Department may adjust payment methodologies for non-pharmacy billed drugs in order to incentivize the selection of lower-cost drugs. For drugs for the treatment of AIDS, the Department shall take into consideration the potential for non-adherence by certain populations, and shall develop protocols with organizations or providers primarily serving those with HIV/AIDS, as long as such measures intend to maintain cost neutrality with other utilization management

controls such as prior approval. For hemophilia, the Department shall develop a program of utilization review and control which may include, in the discretion of the Department, prior approvals. The Department may impose special standards on providers that dispense blood factors which shall include, in the discretion of the Department, staff training and education; patient outreach and education; case management; in-home patient assessments; assay management; maintenance of stock; emergency dispensing timeframes; data collection and reporting; dispensing of supplies related to blood factor infusions; cold chain management and packaging practices; care coordination; product recalls; and emergency clinical consultation. The Department may require patients to receive a comprehensive examination annually at an appropriate provider in order to be eligible to continue to receive blood factor.

(i) On and after July 1, 2012, the Department shall reduce any rate of reimbursement for services or other payments or alter any methodologies authorized by this Code to reduce any rate of reimbursement for services or other payments in accordance with Section 5-5e.

(j) On and after July 1, 2012, the Department shall impose limitations on prescription drugs such that the Department shall not provide reimbursement for more than 4 prescriptions, including 3 brand name prescriptions, for distinct drugs in a 30-day period, unless prior approval is received for all

prescriptions in excess of the 4-prescription limit. Drugs in the following therapeutic classes shall not be subject to prior approval as a result of the 4-prescription limit: immunosuppressant drugs, oncolytic drugs, anti-retroviral drugs, and, on or after July 1, 2014, antipsychotic drugs. On or after July 1, 2014, the Department may exempt children with complex medical needs enrolled in a care coordination entity contracted with the Department to solely coordinate care for such children, if the Department determines that the entity has a comprehensive drug reconciliation program.

(k) No medication therapy management program implemented by the Department shall be contrary to the provisions of the Pharmacy Practice Act.

(l) Any provider enrolled with the Department that bills the Department for outpatient drugs and is eligible to enroll in the federal Drug Pricing Program under Section 340B of the federal Public Health Service ~~Services~~ Act shall enroll in that program. No entity participating in the federal Drug Pricing Program under Section 340B of the federal Public Health Service ~~Services~~ Act may exclude Medicaid from their participation in that program, although the Department may exclude entities defined in Section 1905(l)(2)(B) of the Social Security Act from this requirement.

(Source: P.A. 98-463, eff. 8-16-13; 98-651, eff. 6-16-14; 99-180, eff. 7-29-15; revised 9-2-20.)

(305 ILCS 5/5-36)

Sec. 5-36. Pharmacy benefits.

(a)(1) The Department may enter into a contract with a third party on a fee-for-service reimbursement model for the purpose of administering pharmacy benefits as provided in this Section for members not enrolled in a Medicaid managed care organization; however, these services shall be approved by the Department. The Department shall ensure coordination of care between the third-party administrator and managed care organizations as a consideration in any contracts established in accordance with this Section. Any managed care techniques, principles, or administration of benefits utilized in accordance with this subsection shall comply with State law.

(2) The following shall apply to contracts between entities contracting relating to the Department's third-party administrators and pharmacies:

(A) the Department shall approve any contract between a third-party administrator and a pharmacy;

(B) the Department's third-party administrator shall not change the terms of a contract between a third-party administrator and a pharmacy without written approval by the Department; and

(C) the Department's third-party administrator shall not create, modify, implement, or indirectly establish any fee on a pharmacy, pharmacist, or a recipient of medical assistance without written approval by the Department.

(b) The provisions of this Section shall not apply to outpatient pharmacy services provided by a health care facility registered as a covered entity pursuant to 42 U.S.C. 256b or any pharmacy owned by or contracted with the covered entity. A Medicaid managed care organization shall, either directly or through a pharmacy benefit manager, administer and reimburse outpatient pharmacy claims submitted by a health care facility registered as a covered entity pursuant to 42 U.S.C. 256b, its owned pharmacies, and contracted pharmacies in accordance with the contractual agreements the Medicaid managed care organization or its pharmacy benefit manager has with such facilities and pharmacies. Any pharmacy benefit manager that contracts with a Medicaid managed care organization to administer and reimburse pharmacy claims as provided in this Section must be registered with the Director of Insurance in accordance with Section 513b2 of the Illinois Insurance Code.

(c) On at least an annual basis, the Director of the Department of Healthcare and Family Services shall submit a report beginning no later than one year after January 1, 2020 (the effective date of Public Act 101-452) ~~this amendatory Act of the 101st General Assembly~~ that provides an update on any contract, contract issues, formulary, dispensing fees, and maximum allowable cost concerns regarding a third-party administrator and managed care. The requirement for reporting to the General Assembly shall be satisfied by filing copies of

the report with the Speaker, the Minority Leader, and the Clerk of the House of Representatives and with the President, the Minority Leader, and the Secretary of the Senate. The Department shall take care that no proprietary information is included in the report required under this Section.

(d) A pharmacy benefit manager shall notify the Department in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager's duty to a managed care organization to exercise its contractual duties. "Conflict of interest" shall be defined by rule by the Department.

(e) A pharmacy benefit manager shall, upon request, disclose to the Department the following information:

(1) whether the pharmacy benefit manager has a contract, agreement, or other arrangement with a pharmaceutical manufacturer to exclusively dispense or provide a drug to a managed care organization's enrollees, and the aggregate amounts of consideration of economic benefits collected or received pursuant to that arrangement;

(2) the percentage of claims payments made by the pharmacy benefit manager to pharmacies owned, managed, or controlled by the pharmacy benefit manager or any of the pharmacy benefit manager's management companies, parent companies, subsidiary companies, or jointly held

companies;

(3) the aggregate amount of the fees or assessments imposed on, or collected from, pharmacy providers; and

(4) the average annualized percentage of revenue collected by the pharmacy benefit manager as a result of each contract it has executed with a managed care organization contracted by the Department to provide medical assistance benefits which is not paid by the pharmacy benefit manager to pharmacy providers and pharmaceutical manufacturers or labelers or in order to perform administrative functions pursuant to its contracts with managed care organizations.

(f) The information disclosed under subsection (e) shall include all retail, mail order, specialty, and compounded prescription products. All information made available to the Department under subsection (e) is confidential and not subject to disclosure under the Freedom of Information Act. All information made available to the Department under subsection (e) shall not be reported or distributed in any way that compromises its competitive, proprietary, or financial value. The information shall only be used by the Department to assess the contract, agreement, or other arrangements made between a pharmacy benefit manager and a pharmacy provider, pharmaceutical manufacturer or labeler, managed care organization, or other entity, as applicable.

(g) A pharmacy benefit manager shall disclose directly in

writing to a pharmacy provider or pharmacy services administrative organization contracting with the pharmacy benefit manager of any material change to a contract provision that affects the terms of the reimbursement, the process for verifying benefits and eligibility, dispute resolution, procedures for verifying drugs included on the formulary, and contract termination at least 30 days prior to the date of the change to the provision. The terms of this subsection shall be deemed met if the pharmacy benefit manager posts the information on a website, viewable by the public. A pharmacy service administration organization shall notify all contract pharmacies of any material change, as described in this subsection, within 2 days of notification. As used in this Section, "pharmacy services administrative organization" means an entity operating within the State that contracts with independent pharmacies to conduct business on their behalf with third-party payers. A pharmacy services administrative organization may provide administrative services to pharmacies and negotiate and enter into contracts with third-party payers or pharmacy benefit managers on behalf of pharmacies.

(h) A pharmacy benefit manager shall not include the following in a contract with a pharmacy provider:

(1) a provision prohibiting the provider from informing a patient of a less costly alternative to a prescribed medication; or

(2) a provision that prohibits the provider from

dispensing a particular amount of a prescribed medication, if the pharmacy benefit manager allows that amount to be dispensed through a pharmacy owned or controlled by the pharmacy benefit manager, unless the prescription drug is subject to restricted distribution by the United States Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(i) Nothing in this Section shall be construed to prohibit a pharmacy benefit manager from requiring the same reimbursement and terms and conditions for a pharmacy provider as for a pharmacy owned, controlled, or otherwise associated with the pharmacy benefit manager. Reimbursement must not be less than the dispensing fees and acquisition costs under the fee-for-service program as required under subsection (b-10) of Section 5-5.12.

(j) A pharmacy benefit manager shall establish and implement a process for the resolution of disputes arising out of this Section, which shall be approved by the Department.

(k) The Department shall adopt rules establishing reasonable dispensing fees for fee-for-service payments in accordance with guidance or guidelines from the federal Centers for Medicare and Medicaid Services.

(Source: P.A. 101-452, eff. 1-1-20; revised 10-22-19.)

INDEX

Statutes amended in order of appearance