HB0156

LRB10103973SMS48981b

101ST GENERAL ASSEMBLY

State of Illinois

2019 and 2020

HB0156

by Rep. Mary E. Flowers

SYNOPSIS AS INTRODUCED:

See Index

Creates the Prescription Drug Pricing Transparency Act. Requires health insurers to disclose certain rate and spending information concerning prescription drugs and certain prescription drug pricing information to the Department of Public Health. Requires the Department and health insurers to create annual lists of prescription drugs on which the State spends significant health care dollars and for which costs have increased at a certain rate over time. Requires the Department and health insurers to provide their lists to the Attorney General. Requires prescription drug manufacturers to notify the Attorney General if they are introducing a new prescription drug at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. Amends the Illinois Insurance Code. Requires a group or individual policy of accident and health insurance that provides coverage for prescription drugs to apply the same cost-sharing requirements to interchangeable biological products as apply to generic drugs under the policy. Amends the Pharmacy Practice Act. Provides that when a pharmacist receives a prescription for a biological product, the pharmacist shall select the lowest priced interchangeable biological product (rather than allowing a pharmacist to substitute an interchangeable biological product only if certain requirements are met). Requires that when a pharmacist receives a prescription from a Medicaid recipient, the pharmacist shall select the preferred drug or biological product from the State's preferred drug list. Makes other changes. Makes conforming changes in the Freedom of Information Act. Effective immediately.

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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 1. Short title. This Act may be cited as the Prescription Drug Pricing Transparency Act.

Section 5. Definitions. In this Act:

"Department" means the Department of Public Health.

"Manufacturer" means any entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, whether directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. "Manufacturer" does not include a wholesale distributor of prescription drugs, a retailer, or a pharmacist licensed under the Pharmacy Practice Act.

"Prescription drug" means a drug as defined in 21 U.S.C. 321.

Section 10. Disclosures to the Department.

(a) A health insurer shall disclose to the Department:

(1) for all covered prescription drugs, including generic drugs, brand-name drugs excluding specialty drugs, and specialty drugs dispensed at a pharmacy, network pharmacy, or mail-order pharmacy for outpatient use:

(A) the percentage of the premium rate attributable to prescription drug costs for the prior year for each category of prescription drugs;

(B) the year-over-year increase or decrease, expressed as a percentage, in per-member, per-month total health plan spending on each category of prescription drugs; and

(C) the year-over-year increase or decrease in per-member, per-month costs for prescription drugs compared to other components of the premium rate; and

(2) the specialty tier formulary list.

(b) The health insurer shall provide, if available, the percentage of the premium rate attributable to prescription drugs administered by a health care provider in an outpatient setting that are part of the medical benefit as separate from the pharmacy benefit.

(c) The health insurer shall include information on its use of a pharmacy benefit manager, if any, including which components of the prescription drug coverage described in subsections (a) and (b) are managed by the pharmacy benefit manager, as well as the name of the pharmacy benefit manager or pharmacy benefit managers used.

Section 15. Impact of prescription drug costs on health insurance premiums; report.

(a) Each health insurer with more than 1,000 covered lives in this State for major medical health insurance shall report to the Department for all covered prescription drugs, including generic drugs, brand-name drugs, and specialty drugs, provided in an outpatient setting or sold in a retail setting:

(1) the 25 most frequently prescribed drugs and the average wholesale price for each drug;

(2) the 25 most costly drugs by total plan spending and the average wholesale price for each drug; and

(3) the 25 drugs with the highest year-over-year price increases and the average wholesale price for each drug.

(b) A health insurer shall not be required to provide to the Department the actual price paid, net of rebates, for any prescription drug.

(c) The Department shall compile the information reported pursuant to subsection (a) into a consumer-friendly report that demonstrates the overall impact of drug costs on health insurance premiums. The data in the report shall be aggregated and shall not reveal information specific to a particular health benefit plan.

(d) The Department shall publish the report required pursuant to subsection (a) on its website on or before January 1 of each year.

Section 20. Prescription drug cost transparency.

(a) The Department shall create annually a list of 10 prescription drugs on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50% or more over the past 5 years or by 15% or more during the previous calendar year, creating a substantial public interest in understanding the development of the drugs' pricing. The list shall include at least one generic drug and one brand-name drug and shall indicate each of the drugs on the list that the Department considers to be specialty drugs. The Department shall include the percentage of the wholesale acquisition cost increase for each drug on the list; rank the drugs on the list from those with the largest increase in wholesale acquisition cost to those with the smallest increase; indicate whether each drug was included on the list based on its cost increase over the past 5 years or during the previous calendar year, or both; and provide the State's total expenditure for each drug on the list during the most recent calendar year.

(b) The Department shall create annually a list of 10 prescription drugs on which the State spends significant health care dollars and for which the cost to the State, net of rebates and other price concessions, has increased by 50% or more over the past 5 years or by 15% or more during the previous calendar year, creating a substantial public interest

in understanding the development of the drugs' pricing. The list shall include at least one generic drug and one brand-name drug and shall indicate each of the drugs on the list that the Department considers to be specialty drugs. The Department shall rank the drugs on the list from those with the greatest increase in net cost to those with the smallest increase and indicate whether each drug was included on the list based on its cost increase over the past 5 years or during the previous calendar year, or both.

(c) Each health insurer with more than 5,000 covered lives in this State for major medical health insurance shall create annually a list of 10 prescription drugs on which its health insurance plans spend significant amounts of their premium dollars and for which the cost to the plans, net of rebates and other price concessions, has increased by 50% or more over the past 5 years or by 15% or more during the previous calendar year, or both, creating a substantial public interest in understanding the development of the drugs' pricing. The list shall include at least one generic drug and one brand-name drug and shall indicate each of the drugs on the list that the health insurer considers to be specialty drugs. The health insurer shall rank the drugs on the list from those with the greatest increase in net cost to those with the smallest increase and indicate whether each drug was included on the list based on its cost increase over the past 5 years or during the previous calendar year, or both.

(d) Each health insurer creating a list pursuant to subsection (c) shall provide to the Office of the Attorney General the percentage by which the net cost to its plans increased over the applicable period or periods for each drug on the list, as well as the health insurer's total expenditure, net of rebates and other price concessions, for each drug on the list during the most recent calendar year. Information provided to the Office of the Attorney General pursuant to this subsection is exempt from public inspection and copying under the Freedom of Information Act and shall not be released.

(e) The Department and the health insurers shall provide to the Office of the Attorney General the lists of prescription drugs developed pursuant to subsections (a), (b), and (c) annually on or before June 1. The Office of the Attorney General shall make all of the information available to the public on its website.

(f) Of the prescription drugs listed by the Department and the health insurers pursuant to subsections (a), (b), and (c), the Office of the Attorney General shall:

(1) of the drugs appearing on more than one payer's list, identify the top 15 drugs on which the greatest amount of money was spent across all payers during the previous calendar year, to the extent information is available; and

(2) if fewer than 15 drugs appear on more than one payer's list, rank the remaining drugs based on the amount

of money spent by any one payer during the previous calendar year, in descending order, and select as many of the drugs at the top of the list as necessary to reach a total of 15 drugs.

(g) For the 15 drugs identified by the Office of the Attorney General pursuant to subsection (f), the Office of the Attorney General shall require the manufacturer of each such drug to provide all of the following:

(1) justification for the increase in the net cost of the drug to the Department, to one or more health insurers, or both, which shall be provided to the Office of the Attorney General in a format that the Office of the Attorney General determines to be understandable and appropriate and shall be provided in accordance with a timeline specified by the Office of the Attorney General; the manufacturer shall submit to the Office of the Attorney General all relevant information and supporting documentation necessary to justify the manufacturer's net cost increase to the Department, to one or more health insurers, or both during the identified period of time, including:

(A) each factor that specifically caused the net cost increase to the Department, to one or more health insurers, or both during the specified period of time;

(B) the percentage of the total cost increase attributable to each factor; and

(C) an explanation of the role of each factor in contributing to the cost increase; and

(2) a separate version of the information submitted pursuant to subparagraph (A) of paragraph (1), which shall be made available to the public by the Office of the Attorney General pursuant to subsection (i); if the manufacturer believes it necessary to redact certain information in the public version as proprietary or confidential, the manufacturer shall provide an explanation for each such redaction to the Office of the Attorney General; the information, format, and any redactions shall be subject to approval by the Office of the Attorney General; and

(3) additional information in response to all requests for such information by the Office of the Attorney General.

(h) Nothing in this Section shall be construed to restrict the legal ability of a prescription drug manufacturer to change prices to the extent permitted under federal law.

(i) The Attorney General shall provide a report to the General Assembly on or before December 1 of each year based on the information received from manufacturers pursuant to this Section. The report to the General Assembly shall be filed with the Clerk of the House of Representatives and the Secretary of the Senate in electronic form only, in the manner that the Clerk and the Secretary shall direct. The Attorney General shall post the report and the public version of each

manufacturer's information submitted pursuant to paragraph (2) of subsection (g) on the Office of the Attorney General's website.

(j) The Department shall post on its website the report prepared by the Attorney General pursuant to subsection (i) and the public version of each manufacturer's information submitted pursuant to paragraph (2) of subsection (g) and may inform the public of the availability of the report and the manufacturers' justification information.

(k) Information provided to the Office of the Attorney General pursuant to subsection (g) is exempt from public inspection and copying under the Freedom of Information Act and shall not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information, except for the information prepared for release to the public pursuant to paragraph (2) of subsection (g).

(l) The Attorney General may bring an action in the circuit court of Sangamon County for injunctive relief, costs, and attorney's fees and to impose on a manufacturer that fails to provide any of the information required by subsections (f) and (g), in the format requested by the Office of the Attorney General and in accordance with the timeline specified by the Office of the Attorney General, a civil penalty of not more than $10,000 per violation. Each unlawful failure to provide

information shall constitute a separate violation.

Section 25. Notice of introduction of new high-cost prescription drugs.

(a) A manufacturer shall notify the Office of the Attorney General in writing if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. The manufacturer shall provide the written notice within 3 calendar days following the release of the drug in the commercial market. A manufacturer may make the notification pending approval by the United States Food and Drug Administration if commercial availability is expected within 3 calendar days following the approval.

(b) Not later than 30 calendar days following notification pursuant to subsection (a), the manufacturer shall provide all of the following information to the Office of the Attorney General in a format that the Office of the Attorney General prescribes:

(1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

(2) the estimated volume of patients who may be prescribed the drug;

(3) whether the drug was granted breakthrough therapy designation or priority review by the United States Food

and Drug Administration prior to final approval; and

(4) the date and price of acquisition if the drug was not developed by the manufacturer.

(c) The manufacturer may limit the information reported pursuant to subsection (b) to that which is otherwise in the public domain or publicly available.

(d) The Office of the Attorney General shall publish on its website at least quarterly the information reported to it pursuant to this Section. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.

(e) The Attorney General may bring an action in the circuit court of Sangamon County for injunctive relief, costs, and attorney's fees and to impose on a manufacturer that fails to provide the information required by subsection (b) a civil penalty of not more than $1,000 per day for every day after the notification period described in subsection (a) that the required information is not reported.

Section 900. The Freedom of Information Act is amended by changing Section 7.5 as follows:

(5 ILCS 140/7.5)

Sec. 7.5. Statutory exemptions. To the extent provided for by the statutes referenced below, the following shall be exempt

from inspection and copying:

(a) All information determined to be confidential under Section 4002 of the Technology Advancement and Development Act.

(b) Library circulation and order records identifying library users with specific materials under the Library Records Confidentiality Act.

(c) Applications, related documents, and medical records received by the Experimental Organ Transplantation Procedures Board and any and all documents or other records prepared by the Experimental Organ Transplantation Procedures Board or its staff relating to applications it has received.

(d) Information and records held by the Department of Public Health and its authorized representatives relating to known or suspected cases of sexually transmissible disease or any information the disclosure of which is restricted under the Illinois Sexually Transmissible Disease Control Act.

(e) Information the disclosure of which is exempted under Section 30 of the Radon Industry Licensing Act.

(f) Firm performance evaluations under Section 55 of the Architectural, Engineering, and Land Surveying Qualifications Based Selection Act.

(g) Information the disclosure of which is restricted and exempted under Section 50 of the Illinois Prepaid

Tuition Act.

(h) Information the disclosure of which is exempted under the State Officials and Employees Ethics Act, and records of any lawfully created State or local inspector general's office that would be exempt if created or obtained by an Executive Inspector General's office under that Act.

(i) Information contained in a local emergency energy plan submitted to a municipality in accordance with a local emergency energy plan ordinance that is adopted under Section 11-21.5-5 of the Illinois Municipal Code.

(j) Information and data concerning the distribution of surcharge moneys collected and remitted by carriers under the Emergency Telephone System Act.

(k) Law enforcement officer identification information or driver identification information compiled by a law enforcement agency or the Department of Transportation under Section 11-212 of the Illinois Vehicle Code.

(l) Records and information provided to a residential health care facility resident sexual assault and death review team or the Executive Council under the Abuse Prevention Review Team Act.

(m) Information provided to the predatory lending database created pursuant to Article 3 of the Residential Real Property Disclosure Act, except to the extent authorized under that Article.

(n) Defense budgets and petitions for certification of compensation and expenses for court appointed trial counsel as provided under Sections 10 and 15 of the Capital Crimes Litigation Act. This subsection (n) shall apply until the conclusion of the trial of the case, even if the prosecution chooses not to pursue the death penalty prior to trial or sentencing.

(o) Information that is prohibited from being disclosed under Section 4 of the Illinois Health and Hazardous Substances Registry Act.

(p) Security portions of system safety program plans, investigation reports, surveys, schedules, lists, data, or information compiled, collected, or prepared by or for the Regional Transportation Authority under Section 2.11 of the Regional Transportation Authority Act or the St. Clair County Transit District under the Bi-State Transit Safety Act.

(q) Information prohibited from being disclosed by the Personnel Record ~~Records~~ Review Act.

(r) Information prohibited from being disclosed by the Illinois School Student Records Act.

(s) Information the disclosure of which is restricted under Section 5-108 of the Public Utilities Act.

(t) All identified or deidentified health information in the form of health data or medical records contained in, stored in, submitted to, transferred by, or released from

the Illinois Health Information Exchange, and identified or deidentified health information in the form of health data and medical records of the Illinois Health Information Exchange in the possession of the Illinois Health Information Exchange Authority due to its administration of the Illinois Health Information Exchange. The terms "identified" and "deidentified" shall be given the same meaning as in the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, or any subsequent amendments thereto, and any regulations promulgated thereunder.

(u) Records and information provided to an independent team of experts under the Developmental Disability and Mental Health Safety Act (also known as Brian's Law).

(v) Names and information of people who have applied for or received Firearm Owner's Identification Cards under the Firearm Owners Identification Card Act or applied for or received a concealed carry license under the Firearm Concealed Carry Act, unless otherwise authorized by the Firearm Concealed Carry Act; and databases under the Firearm Concealed Carry Act, records of the Concealed Carry Licensing Review Board under the Firearm Concealed Carry Act, and law enforcement agency objections under the Firearm Concealed Carry Act.

(w) Personally identifiable information which is exempted from disclosure under subsection (g) of Section

19.1 of the Toll Highway Act.

(x) Information which is exempted from disclosure under Section 5-1014.3 of the Counties Code or Section 8-11-21 of the Illinois Municipal Code.

(y) Confidential information under the Adult Protective Services Act and its predecessor enabling statute, the Elder Abuse and Neglect Act, including information about the identity and administrative finding against any caregiver of a verified and substantiated decision of abuse, neglect, or financial exploitation of an eligible adult maintained in the Registry established under Section 7.5 of the Adult Protective Services Act.

(z) Records and information provided to a fatality review team or the Illinois Fatality Review Team Advisory Council under Section 15 of the Adult Protective Services Act.

(aa) Information which is exempted from disclosure under Section 2.37 of the Wildlife Code.

(bb) Information which is or was prohibited from disclosure by the Juvenile Court Act of 1987.

(cc) Recordings made under the Law Enforcement Officer-Worn Body Camera Act, except to the extent authorized under that Act.

(dd) Information that is prohibited from being disclosed under Section 45 of the Condominium and Common Interest Community Ombudsperson Act.

(ee) Information that is exempted from disclosure under Section 30.1 of the Pharmacy Practice Act.

(ff) Information that is exempted from disclosure under the Revised Uniform Unclaimed Property Act.

(gg) Information that is prohibited from being disclosed under Section 7-603.5 of the Illinois Vehicle Code.

(hh) Records that are exempt from disclosure under Section 1A-16.7 of the Election Code.

(ii) Information which is exempted from disclosure under Section 2505-800 of the Department of Revenue Law of the Civil Administrative Code of Illinois.

(jj) Information and reports that are required to be submitted to the Department of Labor by registering day and temporary labor service agencies but are exempt from disclosure under subsection (a-1) of Section 45 of the Day and Temporary Labor Services Act.

(kk) Information prohibited from disclosure under the Seizure and Forfeiture Reporting Act.

(ll) Information the disclosure of which is restricted and exempted under Section 5-30.8 of the Illinois Public Aid Code.

(mm) ~~(ll)~~ Records that are exempt from disclosure under Section 4.2 of the Crime Victims Compensation Act.

(nn) ~~(ll)~~ Information that is exempt from disclosure under Section 70 of the Higher Education Student Assistance

Act.

(oo) Information provided to the Office of the Attorney General under subsections (d) and (g) of Section 20 of the Prescription Drug Pricing Transparency Act, except for the information prepared for release to the public pursuant to paragraph (2) of subsection (g) of Section 20 of the Prescription Drug Pricing Transparency Act.

(Source: P.A. 99-78, eff. 7-20-15; 99-298, eff. 8-6-15; 99-352, eff. 1-1-16; 99-642, eff. 7-28-16; 99-776, eff. 8-12-16; 99-863, eff. 8-19-16; 100-20, eff. 7-1-17; 100-22, eff. 1-1-18; 100-201, eff. 8-18-17; 100-373, eff. 1-1-18; 100-464, eff. 8-28-17; 100-465, eff. 8-31-17; 100-512, eff. 7-1-18; 100-517, eff. 6-1-18; 100-646, eff. 7-27-18; 100-690, eff. 1-1-19; 100-863, eff. 8-14-18; 100-887, eff. 8-14-18; revised 10-12-18.)

Section 905. The Illinois Insurance Code is amended by adding Section 356z.33 as follows:

(215 ILCS 5/356z.33 new)

Sec. 356z.33. Interchangeable biological products.

(a) As used in this Section, "interchangeable biological product" has the same meaning given to the term in Section 19.5 of the Pharmacy Practice Act.

(b) A group or individual policy of accident and health insurance provided by a health insurer or by a pharmacy benefit

manager on behalf of a health insurer amended, delivered, issued, or renewed after the effective date of this amendatory Act of the 101st General Assembly that provides coverage for prescription drugs shall apply the same cost-sharing requirements to interchangeable biological products as apply to generic drugs under the policy.

Section 910. The Pharmacy Practice Act is amended by changing Sections 19.5, 25, and 41 and by adding Sections 16d and 19.7 as follows:

(225 ILCS 85/16d new)

Sec. 16d. Information; labeling.

(a) Every pharmacy in the State shall have posted a sign in a prominent place that is in clear unobstructed view which shall read: "Illinois law requires pharmacists in some cases to select a less expensive generic equivalent drug or interchangeable biological product for the drug or biological product prescribed unless you or your physician direct otherwise. Ask your pharmacist.".

(b) The label of the container of all drugs and biological products dispensed by a pharmacist under this Act shall indicate the generic or proper name using an abbreviation, if necessary, the strength of the drug or biological product, if applicable, and the name or number of the manufacturer or distributor.

(225 ILCS 85/19.5)

(Section scheduled to be repealed on January 1, 2020)

Sec. 19.5. Biological products.

(a) For the purposes of this Section:

"Biological product" has the meaning given to that term in 42 U.S.C. 262.

"Interchangeable biological product" means a biological product that the United States Food and Drug Administration:

(1) has (A) licensed and (B) determined it to meet the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4); or

(2) has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

(b) When a pharmacist receives a prescription for a biological product, the pharmacist shall select the lowest priced interchangeable biological product unless otherwise instructed by the prescriber, or by the purchaser if the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced biological product. ~~A pharmacist may substitute an interchangeable~~

~~biological product for a prescribed biological product only if all of the following conditions in this subsection (b) are met:~~

~~(1) the substituted product has been determined by the United States Food and Drug Administration to be interchangeable, as defined in subsection (a) of this Section, with the prescribed biological product;~~

~~(2) the prescribing physician does not designate orally, in writing, or electronically that substitution is prohibited in a manner consistent with Section 25 of this Act; and~~

~~(3) the pharmacy informs the patient of the substitution.~~

(c) Within 5 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through:

(1) an interoperable electronic medical records system;

(2) an electronic prescribing technology;

(3) a pharmacy benefit management system; or

(4) a pharmacy record.

Entry into an electronic records system as described in this subsection (c) is presumed to provide notice in accordance

with this subsection (c). Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required where:

(A) there is no United States Food and Drug Administration-approved interchangeable biological product for the product prescribed; or

(B) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(d) The pharmacy shall retain a record of the biological product dispensed for a period of 5 years.

(e) The Department shall maintain a link on its Internet website to the current list of all biological products determined by the United States Food and Drug Administration to be interchangeable with a specific biological product.

(f) The Department may adopt rules for compliance with this Section.

(Source: P.A. 99-200, eff. 1-1-16.)

(225 ILCS 85/19.7 new)

Sec. 19.7. State's preferred drug list. Notwithstanding Section 19.5, when a pharmacist receives a prescription from a recipient of medical assistance under Article V of the Illinois Public Aid Code, the pharmacist shall select the preferred brand-name or generic drug or biological product from the

State's preferred drug list.

(225 ILCS 85/25) (from Ch. 111, par. 4145)

(Section scheduled to be repealed on January 1, 2020)

Sec. 25. No person shall compound, or sell or offer for sale, or cause to be compounded, sold or offered for sale any medicine or preparation under or by a name recognized in the United States Pharmacopoeia National Formulary, for internal or external use, which differs from the standard of strength, quality or purity as determined by the test laid down in the United States Pharmacopoeia National Formulary official at the time of such compounding, sale or offering for sale. Nor shall any person compound, sell or offer for sale, or cause to be compounded, sold, or offered for sale, any drug, medicine, poison, chemical or pharmaceutical preparation, the strength or purity of which shall fall below the professed standard of strength or purity under which it is sold. Except as set forth in Section 26 of this Act, if the physician or other authorized prescriber, when transmitting an oral or written prescription, does not prohibit drug product selection, a different brand name or nonbrand name drug product of the same generic name or interchangeable biological product may be dispensed by the pharmacist, provided that the selected drug or interchangeable biological product has a unit price less than the drug product or interchangeable biological product specified in the prescription. A generic drug or interchangeable biological

product determined to be therapeutically equivalent by the United States Food and Drug Administration (FDA) shall be available for substitution in Illinois in accordance with this Act and the Illinois Food, Drug and Cosmetic Act, provided that each manufacturer submits to the Director of the Department of Public Health a notification containing product technical bioequivalence information as a prerequisite to product substitution when they have completed all required testing to support FDA product approval and, in any event, the information shall be submitted no later than 60 days prior to product substitution in the State. On the prescription forms of prescribers, shall be placed a signature line and the words "may not substitute". The prescriber, in his or her own handwriting, shall place a mark beside "may not substitute" to direct the pharmacist in the dispensing of the prescription. Preprinted or rubber stamped marks, or other deviations from the above prescription format shall not be permitted. The prescriber shall sign the form in his or her own handwriting to authorize the issuance of the prescription.

In every case in which a selection is made as permitted by the Illinois Food, Drug and Cosmetic Act, the pharmacist shall indicate on the pharmacy record of the filled prescription the name or other identification of the manufacturer of the drug or interchangeable biological product which has been dispensed.

The selection of any drug product or interchangeable biological product by a pharmacist shall not constitute

evidence of negligence if the selected nonlegend drug product or interchangeable biological product was of the same dosage form and each of its active ingredients did not vary by more than 1 percent from the active ingredients of the prescribed, brand name, nonlegend drug product or interchangeable biological product. Failure of a prescribing physician to specify that drug product or interchangeable biological product selection is prohibited does not constitute evidence of negligence unless that practitioner has reasonable cause to believe that the health condition of the patient for whom the physician is prescribing warrants the use of the brand name drug product or interchangeable biological product and not another.

The Department is authorized to employ an analyst or chemist of recognized or approved standing whose duty it shall be to examine into any claimed adulteration, illegal substitution, improper selection, alteration, or other violation hereof, and report the result of his investigation, and if such report justify such action the Department shall cause the offender to be prosecuted.

(Source: P.A. 94-936, eff. 6-26-06; 95-689, eff. 10-29-07.)

(225 ILCS 85/41)

(Section scheduled to be repealed on January 1, 2020)

Sec. 41. Current usual and customary retail price disclosure. Upon request, a pharmacy must disclose the current

usual and customary retail price of any brand or generic prescription drug, interchangeable biological product, or medical device that the pharmacy offers for sale to the public. This disclosure requirement applies only to requests made in person or by telephone for the prices of no more than 10 prescription drugs, interchangeable biological products, or medical devices for which the person making the request has a prescription. Prices quoted are for informational purposes only and are valid only on the day of inquiry. The requests must specify the name, strength and quantity of the prescription drug or interchangeable biological product.

(Source: P.A. 94-459, eff. 1-1-06.)

Section 999. Effective date. This Act takes effect upon becoming law.

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Statutes amended in order of appearance