HOUSE HEALTH COMMITTEE

VOTING MEETING

Wednesday, June 12th, 2024

9:30am

G-50, Irvis Office Building

Harrisburg, PA

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1. Call to Order

2. Attendance

3. **HB1993 PN2833 (Benham)**

An Act amending the act of November 21, 2016 (P.L.1318, No.169), known as the Pharmacy Audit Integrity and Transparency Act, further providing for title of act; in preliminary provisions, further providing for short title and for definitions; in pharmacy audits, further providing for limitations; and providing for pharmacy benefits manager contract requirements and prohibited acts.

Amendment A04888 (Benham)

Provides new regulatory oversight, transparency reporting, enforcements and penalties.

HB2339 PN3172 (Khan)

An Act amending the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, providing for hospital price transparency and for prohibition on collection action of debt against patients for noncompliant hospitals.

HB2363 PN31985 (Cutler)

An Act amending the act of May 13, 2008 (P.L.139, No.14), known as the Cancer Drug Repository Program Act, further providing for title and short title of act, for definitions, for establishment of program, for restocking and dispensing of cancer drugs, for storage, distribution and fees and for immunity, providing for annual report and for list of approved participating pharmacies and further providing for regulations.

Amendment A04851 (Frankel)

Expands the entities that can donate prescriptions and ensures compliance to state and federal laws.

HR464 PN3239 (Mehaffie)

A Resolution designating the month of July 2024 as "MECP2 Duplication Syndrome Awareness Month" in Pennsylvania.

HR471 PN3269 (Kinsey)

A Resolution recognizing the month of June 2024 as "Scleroderma Awareness Month" and June 29, 2024, as "World Scleroderma Day" in Pennsylvania.

HR476 PN3286 (N. Nelson)

A Resolution recognizing June 25, 2024, as "World Vitiligo Day" in Pennsylvania.

4. Any other business that may come before the committee.

5. Adjournment

HOUSE OF REPRESENTATIVES
DEMOCRATIC COMMITTEE BILL ANALYSIS

Bill No:	HB1993 PN2833	**Prepared By:**	Erika Fricke (412) 422-1774
Committee:	Health		
Sponsor:	Benham, Jessica	**Executive Director:**	Erika Fricke
Date:	5/28/2024		

A. Brief Concept

Amends the Pharmacy Audit Integrity and Transparency Act to provide for the oversight of pharmacy benefit manager contracts with pharmacies in Pennsylvania.

C. Analysis of the Bill

HB1993 creates new regulatory oversight of pharmacy benefit manager contracts with pharmacies and renames the Pharmacy Audit Integrity and Transparency Act to the Community Pharmacy Protection Act.

Existing limits on the audits the pharmacy benefit managers conduct on pharmacies by stopping PBMs from completely taking back the entire cost of a drug that's already been dispensed due to a technical error that was unintentional. PBMs can still demand the dispensing fee be returned.

Creates a new chapter "Pharmacy Benefit Manager Contract Requirements and Prohibited Acts."

Under the new chapter, contracts between PBMs and pharmacies shall not:

- Require contract participation to be contingent on signing an effective rate contract (a contract that sets a specific discount rate for all prescriptions filled by a member pharmacy during the term contract) or a National Average Drug Acquisition Cost (average price that pharmacies pay for prescription drugs) guidelines contract.
- Include demands for retroactive recoupment of money to the PBM unless both parties agree.
- Base reimbursement on effective rate (costs of drugs) unless both parties agree. Any other fees such as transaction fees, chargebacks due to recalculation of costs, or direct or indirect remuneration fees, must be disclosed when claims are adjudicated. The reimbursement for drugs will be based on costs of drugs at effective date of agreement unless both parties agree. Any additional fees such as transaction fees, chargebacks due to recalculation of costs, or direct or indirect remuneration fees, need to be clearly disclosed when claims are processed.

PBMs cannot use "spread pricing," the practice of charging insurance companies more than the PBM pays a pharmacy for the drug cost, and pocketing the difference.

PBMs cannot create closed networks of pharmacies, excluding some pharmacies from their network. Additionally, they cannot price co-pays differently in order to direct patients to affiliated pharmacies.

Responsibilities of the department:

The department shall:

The department must create a new oversight process to oversee the contracts between PBMs and pharmacies, including creating a complaints' process, and a means to evaluate and resolve complaints.

The department will set the fees PBMs are allowed to charge for processing claims and for administrative fees.

The department will create it's own National Average Drug Acquisition Cost (NADAC) guideline for the state, basing it on the invoices of all the manufacturers who ship drugs to Pennsylvania.

Requirements for Pharmacy Benefit Managers (PBMs)

- PBMs must approve all requests of pharmacies that want to join a network, and must do so within 30 days; and must provide contact information (a dedicated telephone number and email address) for those who want to enter a network.

State Employee Health Plan

PBM's hired for State Employee Health Plan must use the state version of the NADAC (the average cost of all the prices manufacturers charge distributors, and distributors charge pharmacies) and must pay the highest amount for drug dispensing in the state.

Reporting

PBM's must report the amount of rebates and payments received from drug manufacturers for inclusion on formularies, and how those were distributed.

Effective Date:

60 days.

G. Relevant Existing Laws

The Pharmacy Audit Integrity and Transparency Act sets limits on pharmacy audits, requires the registration of Pharmacy Benefit Managers (PBMs) and creates some drug transparency and pricing within the PACE and PACENETprograms.

Act 98 of 2022 provided that the auditor general can audit any pharmacy benefit manager that contracts with the medical assistance program.

Act 120 of 2020 requires that a PBM must contract with any pharmacy that is willing to agree to their rates. It prevents spread pricing within the Medicaid program and requires that any transmission fees are made clear when claims are paid. It allows DHS to audit contracts with PBMs and also requires a study by the Legislative Budget and Finance Committee of PBM payments.

The Federal "Patient Right to Know Drug Prices Act" ensures that pharmacists are allowed to tell patients when the cost for purchasing medication without insurance could be less expensive than their cost-sharing requirement with insurance, but does not *require* the pharmacist to inform patients.

E. Prior Session (Previous Bill Numbers & House/Senate Votes)

SB 1000, Senator Ward, passed out of the Health and Human Services Committee

HB882 from 2021-2022 provided for PBM price transparency.

This document is a summary of proposed legislation and is prepared only as general information for use by the Democratic Members and Staff of the Pennsylvania House of Representatives.The document does not represent the legislative intent of the Pennsylvania House of Representatives and may not be utilized as such.

LEGISLATIVE REFERENCE BUREAU

AMENDMENTS TO HOUSE BILL NO. 1993

Sponsor: Benham #36

Printer's No. 2833

Amend Bill, page 1, line 9, by striking out "and" and inserting

in registration, further providing for PBM and auditing entity registration;

Amend Bill, page 1, line 10, by striking out the period after "acts" and inserting

; in PBM cost transparency requirements, providing for transparency report required; and, in enforcements, further providing for scope of enforcement authority and providing for regulations and for construction.

Amend Bill, page 2, line 7, by striking out "Community Pharmacy Protection" and inserting

Pharmacy Benefit Reform

Amend Bill, page 2, lines 9 and 10, by striking out all of said lines and inserting

Section 2. The definitions of "covered entity" and "health insurance policy" in section 103 of the act are amended and the section is amended by adding definitions to read:

Amend Bill, page 2, by inserting between lines 20 and 21

"Covered entity." A contract holder or policy holder providing pharmacy benefits to a covered individual under a health [insurance policy] benefit plan pursuant to a contract administered by a pharmacy benefit manager.

* * *

Amend Bill, page 2, line 30; page 3, lines 1 through 11; by striking out all of said lines on said pages and inserting

"Health benefit plan." A policy, contract, certificate or agreement entered into, offered, issued or renewed by a health insurer to provide, deliver, arrange for, pay for or reimburse

any of the costs of physical, mental or behavioral health care services. The term does not include Medicare supplement or Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) supplement insurance.

* * *

["Health insurance policy." A policy, subscriber contract, certificate or plan that provides prescription drug coverage. The term includes both comprehensive and limited benefit health policies.]

* * *

"Licensee." An entity subject to oversight of the department under this act. The term includes:

(1) An auditing entity.

(2) A health insurer.

(3) A pharmacy benefit manager.

* * *

"Monetary advantage or penalty." An incentive or deterrent imposed under a health benefit plan that affects a beneficiary's choice of pharmacy. The term includes, but is not limited to, a higher copayment, a waiver of a copayment, a reduction in reimbursement for services, a requirement or limit on the number of days of a drug supply for which reimbursement will be allowed or a promotion of one participating pharmacy over another by these methods.

* * *

"Spread pricing." A model of prescription drug pricing in which the PBM charges a health benefit plan or health insurer a contracted price for prescription drugs and the contracted price for the prescription drugs differs from the amount the PBM directly or indirectly pays the pharmacist or pharmacy for prescription drugs and related pharmacist services.

Amend Bill, page 3, line 16, by striking out "Scrivener error.--A scrivener" and inserting

Scrivener's error.--A scrivener's

Amend Bill, page 3, line 20, by striking out "of" and inserting

for

Amend Bill, page 3, by inserting between lines 21 and 22

Section 4. Section 501(b)(3) of the act is amended to read:

Section 501. PBM and auditing entity registration.

* * *

(b) Term and fee.--

* * *

(3) The amount of the initial application fee and renewal application fee shall be sufficient to fund the department's duties in relation to its responsibilities under

this chapter but may not exceed [$1,000] $10,000.

* * *

Amend Bill, page 3, line 22, by striking out "4" and inserting

5

Amend Bill, page 3, line 27, by striking out "pharmacy benefit manager" and inserting

PBM

Amend Bill, page 3, line 28, by striking out "pharmacy benefit manager" and inserting

PBM

Amend Bill, page 4, line 17, by striking out "participation"

Amend Bill, page 4, lines 18 through 30; page 5, lines 1 through 20; by striking out all of said lines on said pages and inserting

A health benefit plan, health insurer or PBM contracting with a health benefit plan or health insurer may not utilize any form of spread pricing in this Commonwealth.

Section 603. Patient steering prohibited.

A health benefit plan, health insurer or PBM contracting with a health benefit plan or health insurer may not:

(1) Require a covered individual, as a condition of payment or reimbursement, to purchase pharmacist services, including, but not limited to, prescription drugs, exclusively through a mail-order pharmacy or PBM affiliate.

(2) Prohibit or limit any covered individual from selecting an in-network pharmacy or in-network pharmacist of the covered individual's choice who meets and agrees to the terms and conditions, including reimbursements, in the PBM's contract.

(3) Impose a monetary advantage or penalty under a health benefit plan that affects a covered individual's choice of pharmacy among those pharmacies that have chosen to contract with the PBM under the same terms and conditions, including reimbursements.

(4) Use a covered individual's pharmacy services data collected under claims processing services for the purpose of soliciting, marketing or referring the covered individual to a mail-order pharmacy or PBM affiliate, except that a health benefit plan or health insurer may use pharmacy services data for the purpose of administering the health benefit plan.

Section 604. Clawbacks prohibited.

(a) General rule.--A health benefit plan, health insurer or PBM contracting with a health benefit plan or health insurer may not require cost-sharing in an amount or direct a pharmacy to collect cost-sharing in an amount, greater than the lesser of either of the following from an individual purchasing a prescription drug:

(1) The amount an individual would pay for the prescription drug if the prescription drug were to be purchased without coverage under a health benefit plan.

(2) The net reimbursement paid to the pharmacy for the prescription drug by the health insurer or PBM.

(b) Duty when filling a prescription.--When filling a prescription, if a pharmacist, pharmacy intern or technician determines that information indicating that the cost-sharing amount required by the patient's health benefit plan exceeds the amount that may otherwise be charged for the same prescription drug, both of the following shall apply:

(1) The pharmacist, pharmacy intern or technician shall notify the patient.

(2) The patient may not be charged the higher amount.

Section 605. Network adequacy.

(a) General rule.--A PBM shall establish a reasonably adequate and accessible PBM network for the provision of prescription drugs under a health benefit plan that shall provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence in accordance with the following requirements:

(1) A mail-order pharmacy shall not be included in the calculations determining PBM network adequacy.

(2) The network may not be limited to affiliated pharmacies only.

(3) The network shall meet or exceed the requirements of 42 CFR 423.120(a)(1) (relating to access to covered Part D drugs) or successor regulation.

(b) Report requirement.--Beginning April 1, 2026, and annually thereafter, a PBM shall file with the department a network adequacy report describing the PBM network and the PBM network's accessibility in this Commonwealth on a form prescribed by the department, which shall be posted on the department's publicly accessible Internet website.

Section 606. Regulations.

The department may promulgate regulations as necessary and appropriate to carry out this chapter.

Section 607. Applicability.

If a contract is in effect on the effective date of this section that conflicts with this chapter, the provision of this chapter shall not apply until the date the contract is amended, extended or renewed.

Section 6. The act is amended by adding a section to read:

Section 703.1. Transparency report required.

(a) General rule.--Beginning July 1, 2026, and annually thereafter, each licensed PBM shall submit a transparency report containing data from the prior calendar year to the department. The transparency report shall contain the following information:

(1) The aggregate amount of all rebates that the PBM received from all pharmaceutical manufacturers for all health benefit plan and health insurer clients and for each health benefit plan or health insurer client.

(2) The aggregate administrative fees that the PBM received from all manufacturers for all health benefit plan and health insurer clients and for each health benefit plan or health insurer client.

(3) The aggregate retained rebates that the PBM received from all pharmaceutical manufacturers and did not pass through to health benefit plan or health insurer clients.

(4) The highest, lowest and mean aggregate retained rebate percentage for all health benefit plan or health insurer clients and for each health benefit plan or health insurer client.

(5) For a PBM that controls or is affiliated with a pharmacy, a description of any differences between what the PBM reimburses or charges affiliated and nonaffiliated pharmacies.

(b) Publication.--Within 60 days of receipt, the department shall publish the transparency report under this section on the department's publicly accessible Internet website in a form that does not disclose the identity of a specific health benefit plan or health insurer, the prices charged for specific drugs or classes of drugs or the amount of any rebates provided for specific drugs or classes of drugs.

(c) Additional categories.--The department may, by regulation, direct PBMs to include additional categories for aggregated data from health benefit plan or health insurer clients in the annual transparency report submitted under this section.

Section 7. Section 901 of the act is amended to read:

Section 901. Scope of enforcement authority.

(a) Scope.--The department may investigate and enforce the provisions of this act only insofar as the actions or inactions being investigated relate to prescription drug coverage under a health [insurance policy] benefit plan.

[(b) Remedy.--Actions or inactions within the scope of the department's investigative and enforcement authority under subsection (a) found to violate this act constitute "unfair methods of competition" and "unfair or deceptive acts or practices" within the meaning of section 5 of the act of July 22, 1974 (P.L.589, No.205), known as the Unfair Insurance Practices Act. A proceeding under this section shall be conducted in accordance with 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of Commonwealth agencies).]

(b.1) Examination and access to records.--

(1) The department may order a PBM, a health insurer and a PBM's or health insurer's affiliates to produce records, books or other information as reasonably necessary to ascertain compliance with this act.

(2) The department may examine or audit the books and records of a PBM, a health insurer and a PBM's or health insurer's affiliates to ascertain compliance with this act. The examination shall be conducted in accordance with Article IX of the act of May 17, 1921 (P.L.789, No.285), known as the Insurance Department Act of 1921.

(c) Penalties.--Upon the determination, after notice and hearing, that this act has been violated, the commissioner may impose the following penalties:

(1) Suspension or revocation of the licensee's license, authorization to operate or registration.

(2) Refusal to issue or renew a license, authorization to operate or registration.

(3) A cease and desist order.

(4) Order reimbursement to an insured, pharmacy or dispenser that has incurred a monetary loss as a result of a violation of this act.

(5) For each violation of this act that a licensee knew or reasonably should have known was a violation, a penalty of not more than $100,000, not to exceed an aggregate penalty of $1,000,000 in a single calendar year.

(6) For each violation of this act that a licensee did not know nor reasonably should have known was a violation, a penalty of not more than $50,000, not to exceed an aggregate penalty of $500,000 in a single calendar year.

Section 8. The act is amended by adding sections to read:

Section 902. Regulations.

The department may promulgate regulations as necessary and appropriate to carry out this chapter.

Section 903. Construction.

Nothing in this act shall be construed to apply to the conduct of a PBM in connection with a contract with a self-funded group health plan subject to 29 U.S.C. Ch. 18 (relating to Employee Retirement Income Security Program).

Amend Bill, page 5, line 21, by striking out "5" and inserting

9

PRINTER'S NO. 2833

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1993 Session of 2024

INTRODUCED BY BENHAM, GAYDOS, KENYATTA, BURGOS, HARKINS, DONAHUE, MADDEN, MAJOR, SANCHEZ, CERRATO, HILL-EVANS, D'ORSIE, CIRESI, GREEN, DALEY, MATZIE, SOLOMON, MIHALEK, ECKER, McNEILL, SCHLOSSBERG, PICKETT, PISCIOTTANO, WEBSTER, HOHENSTEIN, KRUEGER, BOROWSKI, NEILSON, FEE, KIM, KHAN, BERNSTINE, MENTZER, O'MARA, FLEMING, GROVE, MULLINS, KOSIEROWSKI, ISAACSON, HEFFLEY, OBERLANDER, ARMANINI, GREGORY, E. NELSON, STAATS, WAXMAN, STEELE, SALISBURY, KINKEAD, McANDREW, KAUFFMAN, GIRAL, DELOZIER AND FRITZ, APRIL 3, 2024

REFERRED TO COMMITTEE ON HEALTH, APRIL 3, 2024

AN ACT

Amending the act of November 21, 2016 (P.L.1318, No.169), entitled "An act providing for pharmacy audit procedures, for registration of pharmacy benefits managers and auditing entities, for maximum allowable cost transparency and for prescription drugs reimbursed under the PACE and PACENET program; and making related repeals," further providing for title of act; in preliminary provisions, further providing for short title and for definitions; in pharmacy audits, further providing for limitations; and providing for pharmacy benefits manager contract requirements and prohibited acts.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The title and section 101 of the act of November 21, 2016 (P.L.1318, No.169), known as the Pharmacy Audit Integrity and Transparency Act, are amended to read:

AN ACT

Providing for pharmacy audit procedures, for registration of pharmacy benefits managers and auditing entities, for maximum

allowable cost transparency and for prescription drugs reimbursed under the PACE and PACENET program and for pharmacy benefit managers contract requirements and prohibited activities; and making related repeals.

Section 101. Short title.

This act shall be known and may be cited as the [Pharmacy Audit Integrity and Transparency] Community Pharmacy Protection Act.

Section 2. Section 103 of the act is amended by adding definitions to read:

Section 103. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

* * *

"Brand effective rate." The reimbursement rate paid to the pharmacy based on a percentage of the average wholesale cost for brand-name drugs dispensed by the pharmacy under the contract with the pharmacy benefit manager.

* * *

"Effective rate contract." A contract that sets a specific discount rate for all prescriptions filled by a member pharmacy during the term of the contract.

* * *

"Generic effective rate." The reimbursement rate paid to the pharmacy based on a percentage of the average wholesale cost for generic drugs dispensed by the pharmacy under the contract with the pharmacy benefit manager.

* * *

"Patient steering." One of the following:

(1) When a pharmacy benefit manager directs a patient to use a preferred pharmacy through mandatory mail order requirements or the creation by the PBM of a restricted network that consists only of pharmacies approved by the PBM.

(2) The use of co-pay differentials between PBM-affiliated pharmacies and nonaffiliated pharmacies.

* * *

"Spread pricing." An act of a pharmacy benefit manager reimbursing a pharmacy for a prescription and then billing an insurer or an employer that provides health insurance at a higher price for the same prescription.

Section 3. Section 303 of the act is amended by adding a subsection to read:

Section 303. Limitations.

* * *

(c) Scrivener error.--A scrivener error made by a pharmacy not attributed to fraud, waste or abuse that is discovered during an audit of the pharmacy by the PBM shall result in the PBM recouping the dispensing fee for that particular transaction, not the entire amount of the medication received by the patient.

Section 4. The act is amended by adding a chapter to read:

CHAPTER 6

PHARMACY BENEFITS MANAGER CONTRACT

REQUIREMENTS AND PROHIBITED ACTS

Section 601. Contract provisions.

A contract between a pharmacy benefit manager or a designee of the pharmacy benefit manager and a pharmacy may not:

(1) Require participation in the PBM's network contingent on the pharmacy signing either an effective rate

contract or a contract based on the National Average Drug Acquisition Cost guidelines.

(2) Include provisions allowing for retroactive recoupment of money paid to a pharmacy by the PBM, unless both parties agree to that provision.

(3) Base reimbursement upon general effective rate or the brand effective rate as a condition of entering a network, unless both parties agree to that provision. Any additional fees must be disclosed and applied at the time of the adjudication of the claim. Fees may include:

(i) Transaction fees.

(ii) Chargebacks due to recalculation of the cost of the ingredients used in a prescription drug.

(iii) Adjustments in the general effective rate, brand effective rates or direct and indirect remuneration fees made by the PBM.

Section 602. Spread pricing participation prohibited.

A pharmacy benefit manager may not conduct or participate in spread pricing.

Section 603. Patient steering prohibited.

A pharmacy benefit manager may not conduct or participate in patient steering.

Section 604. Duties of the department.

The department shall:

(1) Develop a process for receiving, hearing and resolving complaints a pharmacy filed against a PBM.

(2) Have the ability to set fixed amounts for PBM claim processing fees and administrative fees.

(3) Develop a Statewide National Average Drug Acquisition Cost guideline that uses wholesale pricing based

on manufacturer's invoices of those manufacturers who ship drugs to this Commonwealth.

Section 605. Duties of pharmacy benefit managers.

Pharmacy benefit managers shall:

(1) Approve a request from a pharmacy to be a member of the PBM's network within 30 days of the initial request to join the network.

(2) Provide a dedicated telephone number and email address for handling network admission requests.

Section 606. PBM for State Employee Health Plan.

A PBM hired for the State Employee Health Plan shall have a transparent reimbursement methodology based on the National Average Drug Acquisition Cost guidelines developed under section 604(3) and a dispensing fee equal to or greater than the maximum prevailing fee for service or PACE rate in this Commonwealth.

Section 607. Reports by PBM.

A PBM shall report to the department the amount of rebates and payments received from drug manufacturers and how the rebates and payments were distributed by the PBM.

Section 5. This act shall take effect in 60 days.

HOUSE OF REPRESENTATIVES
DEMOCRATIC COMMITTEE BILL ANALYSIS

Bill No:	HB2339 PN3172	**Prepared By:**	Erika Fricke (717) 787-4296,6711
Committee:	Health		
Sponsor:	Khan, Tarik	**Executive Director:**	Erika Fricke
Date:	5/30/2024		

A. Brief Concept

Ensures that the costs for hospital services are publicly available in accordance with federal law. Provides patients information about facility fees in advance of procedures.

C. Analysis of the Bill

House Bill 2339 restates the federal law requiring hospitals to make public their actual charges to insurance companies, and to do so in a way that is easy to access and understand, as well as providing patients a simple way to determine the cost of procedures for which they might shop. Additionally, it provides patients information about the extra charges hospitals add on to procedures as facility costs up front.

Standard charges for all hospital services

Each individual hospital location is expected to follow federal law and make the different prices they charge different entities for each service publicly available including:

(1) The gross charge. (The amount that a hospital states is their regular price on the "chargemaster", the list of all items or services for which the hospital has a set charge.)

(2) The charge for each individual insurance company or payor.

(3) The smallest amount that a hospital charges an insurer or payor, without naming the payor.

(4) The highest amount that the insurer charges, without naming who they are charging the most.

(5) What the hospital charges someone who is paying out of pocket.

The document must include a commonly used code format, such as CPT codes (Current Procedural Terminology), DRG codes (Diagnosis Related Group), the HCPCS (Healthcare Common Procedure Coding System), or the NDC (National Drug Code) but must also include a description of what each of the codes represents. Additionally, the document must make clear which insurance companies are charged which rates.

	A	B	C	D	E	F	G	H	I	
1	**Einstein Medical Center Montgomery Summary Sheet**						IBC Indemnity	IBC PPO	IBC HMO	IBC Pro
2										
3										
4	**Inpatient**									
5	MS-DRG		Description	Min Negotiated Charge	Max Negotiated Charge					
7	2	-	HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM WITHOUT MCC	$96,383	$308,925		$146,325	$173,916	$173,916	$14
8	3	-	ECMO OR TRACHEOSTOMY WITH MV >96 HOURS OR PRINCIPAL DIAGNOSIS EXCEPT FACE, MOUTH	$144,689	$491,478		$199,465	$237,076	$237,076	$19
9	4	-	TRACHEOSTOMY WITH MV >96 HOURS OR PRINCIPAL DIAGNOSIS EXCEPT FACE, MOUTH AND NECI	$98,230	$314,854		$124,484	$147,957	$147,957	$12
10	5	-	LIVER TRANSPLANT WITH MCC OR INTESTINAL TRANSPLANT	$81,627	$373,698		$111,787	$132,866	$132,866	$10
11	6	-	LIVER TRANSPLANT WITHOUT MCC	$34,509	$373,698		$53,040	$63,041	$63,041	$51
12	7	-	LUNG TRANSPLANT	$87,343	$279,901		$116,110	$138,003	$138,003	$11
13	8	-	SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANT	$40,092	$167,213		$57,221	$68,010	$68,010	$56
14	10	-	PANCREAS TRANSPLANT	$29,778	$147,229		$49,207	$58,486	$58,486	$48
15	11	-	TRACHEOSTOMY FOR FACE, MOUTH AND NECK DIAGNOSES OR LARYNGECTOMY WITH MCC	$34,700	$131,658		$53,552	$63,649	$63,649	$52
16	12	-	TRACHEOSTOMY FOR FACE, MOUTH AND NECK DIAGNOSES OR LARYNGECTOMY WITH CC	$28,083	$89,984		$41,574	$49,413	$49,413	$40
17	13	-	TRACHEOSTOMY FOR FACE, MOUTH AND NECK DIAGNOSES OR LARYNGECTOMY WITHOUT CC/MC	$20,362	$64,850		$25,362	$30,144	$30,144	$24
18	14	-	ALLOGENEIC BONE MARROW TRANSPLANT	$80,099	$256,644		$130,274	$154,838	$154,838	$12
19	16	-	AUTOLOGOUS BONE MARROW TRANSPLANT WITH CC/MCC	$43,615	$179,882		$71,288	$84,730	$84,730	$69
20	17	-	AUTOLOGOUS BONE MARROW TRANSPLANT WITHOUT CC/MCC	$31,373	$179,882		$47,760	$56,765	$56,765	$46
21	18	-	CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL IMMUNOTHERAPY	$183,931	$1,043,602		$406,934	$483,666	$483,666	$39
22	19	-	SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANT WITH HEMODIALYSIS	$51,116	$167,213		$57,221	$68,010	$68,010	$56
23	20	-	INTRACRANIAL VASCULAR PROCEDURES WITH PRINCIPAL DIAGNOSIS HEMORRHAGE WITH MCC	$66,604	$261,658		$113,649	$135,079	$135,079	$11
24	21	-	INTRACRANIAL VASCULAR PROCEDURES WITH PRINCIPAL DIAGNOSIS HEMORRHAGE WITH CC	$48,649	$179,622		$86,181	$102,432	$102,432	$84
25	22	-	INTRACRANIAL VASCULAR PROCEDURES WITH PRINCIPAL DIAGNOSIS HEMORRHAGE WITHOUT CC	$31,290	$131,287		$56,223	$66,825	$66,825	$55
26	23	-	CRANIOTOMY WITH MAJOR DEVICE IMPLANT OR ACUTE COMPLEX CNS PRINCIPAL DIAGNOSIS WI	$41,094	$143,755		$59,522	$70,746	$70,746	$58
27	24	-	CRANIOTOMY WITH MAJOR DEVICE IMPLANT OR ACUTE COMPLEX CNS PRINCIPAL DIAGNOSIS WI	$28,364	$103,443		$42,727	$50,783	$50,783	$41
28	25	-	CRANIOTOMY AND ENDOVASCULAR INTRACRANIAL PROCEDURES WITH MCC	$32,345	$123,788		$46,630	$55,423	$55,423	$45

(Example of Compliant Hospital System/ Einstein Medical Center)

The list must be published in an easy-to-use computer format that doesn't require additional technology and instructions to use. Users should be able to get the file off the home page of a hospital's website for free without using special passcodes, log-ins or identifying information.

The list must be updated at least annually, and the last three versions should be made available.

Consumer friendly list of common procedures for patients comparing prices

Hospitals must publish all the charges (gross charges, negotiated rates, minimum charges, maximum charges and out-of-pocket rates) for 300 of the services or procedures most often performed or that patients might schedule in advance.

Hospitals can choose which 300 services to publish, but at a minimum hospitals must report the 70 services that the Center for Medicare and Medicaid Services requires hospitals to publish. (If a hospital doesn't provide that care, they must instead include all those services within the 70 outlined that the hospital does provide.)

This list must also be updated yearly, with the three most recent reports made available.

Facility Fees

Facility fees were originally charged at hospitals as a way of paying for the overhead costs of staying open and available on a 24-hour basis, regardless of utilization. However, as hospitals have purchased ambulatory surgical facilities and doctors' offices, they are increasingly being used for all procedures, not only those related to emergencies.

Patients must be informed about any extra facility fees charged by a hospital affiliated office when an appointment is scheduled. Facility fees include any fee charged by a hospital for outpatient services in a non-hospital building that doesn't pay for actual services provided, but that compensates the hospital globally.

Reporting requirements from hospitals to DOH

Each of the lists above - both standard charges and shoppable services - must be updated at least annually, with the three most recent reports made available to the public. When the updates are made, the new lists, plus a report on the list, must be sent to the Department of Health, which must keep the lists and make them publicly available.

Each hospital must have a separate report.

The lists must be 95 percent complete in order to be considered compliant.

Hospitals must report on all facility fees charged or billed during the previous year, including the names and locations of hospitals charging facility fees, number of patients billed, the total amount billed, and types of facility fees paid by Medicare, Medical Assistance and private insurance, the revenue received from facility fees, and the 10 procedures for which facility fees were most often charged and provided the most revenue.

An authorized executive must attest that the provided information is correct.

All reports must be publicly available on the Department of Health web site.

Reporting requirements to legislature

DOH must report on the progress of price transparency availability and submit it to the majority and minority committee chairs for the relevant committees: Appropriations, Health and Human Services, Health, and Human Services.

Enforcement - Civil penalties, Tobacco Settlement Funds and Medical Debt

The Department of Health shall accept complaints for reported violations on its website and via a telephone number.

If the Department of Health determines that a hospital is non-compliant, they can require a correction, immediately or within 30 days.

If a hospital fails to correct, then the department can, but is not required, to issue civil penalties, under the following fine schedule:

- up to $2,500 for first infraction
- up to $5,000 for second infraction
- Up to $10,000 for third infraction
- up to $15,000 for any further infractions

Civil penalties must be applied in accordance with normal requirements for administrative proceedings and judicial appeals. Funds generated would go back to the Department of Health.

A hospital receiving three or more sanctions cannot receive any funds from the uncompensated care payment program of the Tobacco Settlement Act.

Additionally, non-compliant hospitals may not collect medical debt from patients who received services when the hospital was non-compliant. If they attempt to do so, the patient may take civil action against them and can have any payments refunded and the debt removed from their credit report.

Department of Health Regulations and Duties

The Department must develop templates for hospitals to follow for the publication of information, and the templates should follow the guidelines for federal templates as much as possible.

The Department may audit hospital websites to ensure compliance and must have mechanisms to receive complaints.

The Department must draft temporary regulations within six months, which will expire two years following the publication of the regulations in the Pennsylvania Bulletin.

The Department must promulgate regulations before the expiration of the temporary regulations (within 2.5 years after effective date of bill.)

Effective Date:

180 days.

G. Relevant Existing Laws

Federal requirements for hospital price transparency:

Federal hospital price transparency regulations (effective 2021) require hospitals to post chargemaster/gross prices, prices negotiated with each insurer, and discounted self-pay prices for each service in a machine readable format. Additionally hospitals must publish prices for shoppable services (scheduled in advance) in a consumer friendly format.

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-E/part-180

In 2022 the penalty for noncompliance changed from $100,000 to $2 million annually.

As of July 2022, CMS will require a standard format for reporting.

Federal requirements for insurers:

Transparency in coverage regulations (effective 2022) require insurers to publish negotiated rates for all items and services provided by all in-network providers.

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-B/part-147/section-147.210

Federal law regarding facility fees - No federal or state law exists related to facility fees that are applied to hospital-owned outpatient locations like doctors offices and ambulatory surgical facilities. Some Medical Assistance providers and large insurers refuse to pay for facility fees in outpatient clinics unless hospital services (such as nursing) are provided.

E. Prior Session (Previous Bill Numbers & House/Senate Votes)

House Bill 1723, session 21-22, addressed facility fee reporting

SB1322 of 2022 addressed Hospital Price Transparency

This document is a summary of proposed legislation and is prepared only as general information for use by the Democratic Members and Staff of the Pennsylvania House of Representatives.The document does not represent the legislative intent of the Pennsylvania House of Representatives and may not be utilized as such.

PRINTER'S NO. 3172

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2339 Session of 2024

INTRODUCED BY KHAN, ROWE, SANCHEZ, TOMLINSON, PROKOPIAK, KEEFER, GIRAL, HILL-EVANS, HOWARD, BURGOS, OTTEN, ZIMMERMAN, HAMM, DELLOSO, WARREN, LEADBETER, NEILSON AND CIRESI, MAY 28, 2024

REFERRED TO COMMITTEE ON HEALTH, MAY 28, 2024

AN ACT

Amending the act of July 19, 1979 (P.L.130, No.48), entitled "An act relating to health care; prescribing the powers and duties of the Department of Health; establishing and providing the powers and duties of the State Health Coordinating Council, health systems agencies and Health Care Policy Board in the Department of Health, and State Health Facility Hearing Board in the Department of Justice; providing for certification of need of health care providers and prescribing penalties," providing for hospital price transparency and for prohibition on collection action of debt against patients for noncompliant hospitals.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, is amended by adding chapters to read:

CHAPTER 8-C

HOSPITAL PRICE TRANSPARENCY

Section 801-C. Purpose.

The purpose of this chapter is to require hospitals to disclose prices for certain items and services provided by hospitals and to provide for enforcement by the department.

Section 802-C. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Ancillary service." A hospital item or service that a hospital customarily provides as part of a shoppable service.

"Chargemaster." The list of all hospital items or services maintained by a hospital for which the hospital has established a charge.

"CMS." The Centers for Medicare and Medicaid Services.

"De-identified maximum negotiated charge." The highest charge that a hospital has negotiated with all third-party payors for a hospital item or service.

"De-identified minimum negotiated charge." The lowest charge that a hospital has negotiated with all third-party payors for a hospital item or service.

"Discounted cash price." The charge that applies to an individual who pays cash or a cash equivalent for a hospital item or service.

"Facility fee." A fee charged or billed by a hospital for outpatient services provided in an off-campus health care facility, regardless of the modality through which the health care service is provided, that is:

(1) Intended to compensate the health system or hospital for health care expenses.

(2) Separate and distinct from a professional fee.

"Gross charge." The charge for a hospital item or service that is reflected on the hospital's chargemaster, absent any discount.

"Health care facility." As defined in section 802.1.

"Health system." As defined in section 809.2.

"Hospital." As defined in section 802.1.

"Item or service." An item or service, including an individual items or services package, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge, including any of the following:

(1) A supply or procedure.

(2) Room and board.

(3) The use of the hospital or other item, which is generally described as a facility fee.

(4) The service of a health care practitioner, which is generally described as a professional fee.

(5) Any other item or service for which a hospital has established a standard charge.

"Machine-readable format." A digital representation of information in a file that can be easily imported or read into a computer system for further processing without any additional preparation.

"Payor-specific negotiated charge." The charge that a hospital has negotiated with a third-party payor for a hospital item or service.

"Professional fee." A fee charged by a health care practitioner for medical services.

"Shoppable service." A service that may be scheduled by an individual in advance.

"Standard charge." The regular rate established by the hospital for a hospital item or service provided to a specific group of paying patients. The term includes any of the

following:

(1) The gross charge.

(2) The payor-specific negotiated charge.

(3) The de-identified minimum negotiated charge.

(4) The de-identified maximum negotiated charge.

(5) The discounted cash price.

"Third-party payor." An entity that is legally responsible for payment of a claim for a hospital item or service.

Section 803-C. Public availability of price information required.

Notwithstanding any other provision of law, a hospital shall publish all of the following on its publicly accessible Internet website and provide hard copies upon request:

(1) A digital file in a machine-readable format and printable format that contains a list of all standard charges for all hospital items or services as specified under section 804-C.

(2) A consumer-friendly and printable list of standard charges for a limited set of shoppable services as provided for under section 805-C.

Section 804-C. List of standard charges.

(a) List.--A hospital shall have the following duties:

(1) Maintain a list of all standard charges for all hospital items or services in accordance with this chapter.

(2) Ensure that the list is always available to the public, including publishing the list electronically in the manner specified under section 803-C.

(b) Standard charges.--The standard charges contained in the list under subsection (a) shall reflect the standard charges applicable to the location of the hospital, regardless of

whether the hospital operates in more than one location or operates under the same license as another hospital.

(c) Contents.--A hospital shall include all of the following information in the list under subsection (a):

(1) A description of each hospital item or service provided by the hospital.

(2) The following charges for each individual hospital item or service when provided in either an inpatient setting or an outpatient department setting, as applicable, including:

(i) The gross charge.

(ii) The de-identified minimum negotiated charge.

(iii) The de-identified maximum negotiated charge.

(iv) The discounted cash price.

(v) The payor-specific negotiated charge, delineated by the name of the third-party payor and plan associated with the charge and displayed in a manner that clearly associates the charge with the third-party payor and plan. A hospital must include all payors and all plans accepted by the hospital in a manner clearly associated with the name of the third-party payor and specific plan.

(vi) A code used by the hospital for the purpose of accounting or billing for the hospital item or service, including the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG) code, the National Drug Code (NDC) or other common identifier.

(d) Format.--A hospital shall publish the information contained in the list under subsection (a) in a single digital file that is in a machine-readable format.

(e) Display.--A hospital shall display the list under subsection (a) by posting the list in a prominent location on the home page of the hospital's publicly accessible Internet website or making the list accessible by a dedicated link that is prominently displayed on the home page of the hospital's publicly accessible Internet website. If the hospital operates multiple locations and maintains a single Internet website, the hospital shall post the list for each location that the hospital operates in a manner that clearly associates the list with the applicable location of the hospital and includes charges specific to each individual hospital location.

(f) Availability.--

(1) A hospital shall ensure that the list under subsection (a) complies with the following requirements:

(i) Be available free of charge.

(ii) Be accessible to a common commercial operator of an Internet search engine to the extent necessary for the search engine to index the list and display the list in response to a search query of a user of the search engine.

(iii) Be formatted in a manner specified under this chapter and by the department via a notice submitted to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

(iv) Be digitally searchable and printable by service description, billing code and third-party payor.

(v) Use a format and a naming convention specified by the department via a notice submitted to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin. The department shall consider a

naming convention as may be specified by CMS.

(2) The department shall ensure the list under subsection (a) does not require any of the following:

(i) The establishment of a user account or password or other information of the user.

(ii) The submission of personal identifying information.

(iii) Any other impediment, including entering a code to access the list.

(g) Template.--In determining the format of the list under subsection (a) as required under subsection (f)(1), the department shall develop a template that each hospital shall use in formatting the list and publish the template via a notice submitted to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin. In developing the template as required under this subsection, the department shall have the following duties:

(1) Take into consideration applicable Federal guidelines for formatting similar lists required by Federal law and ensure that the design of the template enables an individual to compare the charges contained in the lists maintained by each hospital.

(2) Design the template to be substantially like the template used by CMS for the purposes specified in this chapter.

(h) Updates.--A hospital shall update the list under subsection (a) no less than once each year. The hospital shall clearly indicate the date when the list was most recently updated, either on the list or in a manner that is clearly associated with the list. The hospital shall make available no

less than the three most recent versions of the list as required under this chapter.

Section 805-C. List of shoppable services.

(a) List.--Except as provided under subsection (c), a hospital shall maintain and make publicly available a list of the standard charges for each of at least 300 shoppable services provided by the hospital with charges specific to that individual hospital location. The hospital may select the shoppable services to be included in the list, except that the list shall include the 70 services specified as shoppable services by CMS. If the hospital does not provide all the shoppable services specified by CMS, the hospital shall include all the shoppable services provided by the hospital.

(b) Selection.--In selecting a shoppable service for the purpose of inclusion in the list under subsection (a), a hospital shall have following duties:

(1) Consider how frequently the hospital provides the service and the hospital's billing rate for the service.

(2) Prioritize the selection of services that are among the services most frequently provided by the hospital.

(c) Exception.--If a hospital does not provide 300 shoppable services in the list under subsection (a), the hospital shall include the total number of shoppable services that the hospital provides in a manner that otherwise complies with the requirements of subsection (a).

(d) Contents.--A hospital shall include all of the following information in the list under subsection (a):

(1) A plain-language description of each shoppable service included on the list.

(2) The payor-specific negotiated charge that applies to

each shoppable service included on the list and any ancillary service, delineated by the name of the third-party payor and plan associated with the charge and displayed in a manner that clearly associates the charge with the third-party payor and plan.

(3) The discounted cash price that applies to each shoppable service included on the list and any ancillary service or, if the hospital does not offer a discounted cash price for a shoppable service or an ancillary service on the list, the gross charge for the shoppable service or ancillary service, as applicable.

(4) The de-identified minimum negotiated charge that applies to each shoppable service included on the list and any ancillary service.

(5) The de-identified maximum negotiated charge that applies to each shoppable service included on the list and any ancillary service.

(6) A code used by the hospital for purposes of accounting or billing for each shoppable service included on the list and any ancillary service, including the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG) code, the National Drug Code (NDC) or other common identifier.

(7) If applicable, each location where the hospital provides a shoppable service and whether the standard charges included in the list apply at the location to the provision of the shoppable service in an inpatient setting or an outpatient department setting.

(8) If applicable, an indication if a shoppable service

specified by CMS is not provided by the hospital.

(e) Availability.--

(1) A hospital shall ensure that the list under subsection (a) complies with the following requirements:

(i) Be available free of charge.

(ii) Be accessible to a common commercial operator of an Internet search engine to the extent necessary for the search engine to index the list and display the list in response to a search query of a user of the search engine.

(iii) Be formatted in a manner specified under this chapter and by the department via a notice submitted to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

(iv) Be digitally searchable and printable by service description, billing code and third-party payor.

(v) Use a format and a naming convention specified by the department via a notice submitted to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin. The department shall consider a naming convention as may be specified by CMS.

(vi) Nothing in this section shall preclude a hospital from using a price estimator tool as provided for in 45 CFR 180.60 (relating to requirements for displaying shoppable services in a consumer-friendly manner) in addition to the list of shoppable services.

(2) The department shall ensure that the list under subsection (a) does not require any of the following:

(i) The establishment of a user account or password or other information of the user.

(ii) The submission of personal identifying information.

(iii) Any other impediment, including entering a code to access the list.

(f) Template.--In determining the format of the list under subsection (a) as required under subsection (e)(1), the department shall develop a template that each hospital shall use in formatting the list and publish the template via a notice submitted to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin. In developing the template as required under this subsection, the department shall have the following duties:

(1) Take into consideration applicable Federal guidelines for formatting similar lists required by Federal law and ensure that the design of the template enables an individual to compare the charges contained in the lists maintained by each hospital.

(2) Design the template to be substantially like the template used by CMS for the purposes specified in this chapter.

(g) Updates.--A hospital shall update the list under subsection (a) no less than once each year. The hospital shall clearly indicate the date when the list was most recently updated, either on the list or in a manner that is clearly associated with the list. The hospital shall make available no less than the three most recent versions of the list as required under this chapter.

Section 806-C. Reporting requirements.

(a) Frequency.--Each time a hospital creates or updates a list as required under section 804-C or 805-C, the hospital

shall submit the list, along with a report on the list, to the department. The department shall determine the form of the report via a notice submitted to the Legislation Reference Bureau for publication in the Pennsylvania Bulletin.

(b) Complete data.--To be considered in compliance, any list received by the department shall include a minimum of 95% of all values required under section 804-C or 805-C.

(c) Annual report.--By July 1 of each year, a hospital shall report to the department on facility fees charged or billed during the preceding calendar year. The department shall determine the form of the report and transmit notice to the Legislative Reference Bureau for publication in the next available issue of the Pennsylvania Bulletin. The report shall include, at a minimum:

(1) The name and location of each health care facility owned or operated by the hospital that provides services for which a facility fee is charged or billed.

(2) The number of patient visits at each health care facility for which a facility fee was charged or billed.

(3) The number, total amount and types of allowable facility fees paid at each health care facility by Medicare, Medical Assistance and private insurance.

(4) For each health care facility, the total number of facility fees charged and the total amount of revenue received by the hospital or health system derived from facility fees.

(5) The total amount of facility fees charged and the total amount of revenue received by the hospital or health system from all health care facilities derived from facility fees.

(6) The 10 most frequent procedures or services, identified by current procedural terminology Category I codes, provided by the hospital that generated the largest amount of facility fee gross revenue, including:

(i) The volume of each procedure or service.

(ii) The gross and net revenue totals for each procedure or service.

(iii) The total net amount of revenue received by the hospital or health system derived from facility fees for each procedure or service.

(7) The 10 most frequent procedures or services, identified by current procedural terminology Category I codes, based on patient volume, provided by the hospital for which facility fees were billed or charged, including the gross and net revenue totals received for each procedure or service.

(8) Any other information related to facility fees the department may require.

(d) Attestation.--An authorized executive of a hospital or health system shall attest, subject to 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities), that any report or list submitted to the department is complete and accurate to the best of the authorized executive's knowledge and belief.

(e) Public availability.--The department shall make all reports and lists available on its publicly accessible Internet website within 60 days of receipt of each report.

(f) Applicability.--A health system may make the report for each hospital that it owns or operates, provided that each hospital has its own separate report.

Section 807-C. Submission of complaints.

The department shall establish an electronic form for individuals to submit complaints for alleged violations of this chapter. The department shall post the electronic form on its publicly accessible Internet website. The department shall also accept complaints via a department customer service telephone number.

Section 808-C. Plans of correction.

Upon determining that a hospital has violated the provisions of this chapter or the regulations promulgated under section 813-C, the department may issue a written notice to the hospital stating that a violation has been committed by the hospital. The following shall apply:

(1) The department shall state in the written notice that the hospital is required to take immediate action to remedy the violation or, if the hospital is unable to immediately remedy the violation, submit a plan of correction to the department.

(2) If the hospital is required to submit a plan of correction to the department under paragraph (1), the department may direct that the violation be remedied within a specified period of time. The hospital must submit the plan of correction within 30 days of the department's issuance of the written notice.

(3) If the department determines that the hospital is required to take immediate corrective action, the department shall state in the written notice that the hospital is required to provide prompt confirmation to the department that the corrective action has been taken.

Section 809-C. Sanctions and penalties.

(a) Grounds for sanctions.--The department may sanction a hospital for any of the following reasons:

(1) Violating the provisions of this chapter or the regulations promulgated under section 813-C.

(2) Failing to take immediate action to remedy a violation of the provisions of this chapter or regulations promulgated under section 813-C.

(3) Failing to submit a plan of correction to the department or failing to comply with a plan of correction in accordance with section 808-C.

(4) Violating an order previously issued by the department in a disciplinary matter.

(5) Any other reason specified in this chapter or the regulations promulgated by the department under section 813-C as necessary to implement this chapter.

(b) Civil penalties.--The department may impose a civil penalty for conduct prohibited under subsection (a), with each day when a hospital engages in the conduct constituting a separate and distinct incident, as follows:

(1) No more than $2,500 for a first incident.

(2) No more than $5,000 for a second incident.

(3) No more than $10,000 for a third incident.

(4) No more than $15,000 for a fourth or subsequent incident.

(c) Ineligibility.--A hospital that is sanctioned under subsection (a) for a third or subsequent offense shall be ineligible to receive a payment from the uncompensated care payment program under Chapter 11 of the act of June 26, 2001 (P.L.755, No.77), known as the Tobacco Settlement Act, for the fiscal year following the third or subsequent offense.

(d) Audits.--The department may audit the publicly accessible Internet websites of hospitals to ensure compliance with this chapter.

(e) General government appropriations.--Money received from civil penalties imposed by the department on a hospital shall be paid into the State Treasury and shall be credited to the general government appropriations of the department for administering and enforcing the provisions of this chapter.

(f) Administrative proceedings.--The department shall hold hearings and issue adjudications for proceedings conducted under this chapter in accordance with 2 Pa.C.S. (relating to administrative law and procedure) and shall conduct the proceedings in accordance with 1 Pa. Code Pt. II (relating to general rules of administrative practice and procedure).

(g) Judicial appeals.--Department adjudications issued under this chapter may be appealed to Commonwealth Court under 42 Pa.C.S. § 763 (relating to direct appeals from government agencies).

Section 810-C. Machine-readable format requirements.

For purposes of this chapter, the following shall apply to a hospital providing digital files in a machine-readable format:

(1) The hospital shall format the file without additional rows or spacing between data.

(2) The file shall be readily usable without any additional instructions.

(3) The file shall be in a machine-readable format that is widely used by other hospitals for cross-comparison purposes, including a spreadsheet format that an individual with average computer skills can open, read and comprehend.

Section 811-C. Disclosure of facility fees.

(a) Notice.--A health care facility affiliated with or owned by a hospital that charges a facility fee shall disclose to a patient at the time an appointment is scheduled, and at the time medical services are rendered, that a facility fee may be charged.

(b) Disclosure.--Disclosure of facility fees shall occur on a plain language notice as determined by the department. The department shall transmit the notice to the Legislative Reference Bureau for publication in the next available issue of the Pennsylvania Bulletin. The notice shall include, at a minimum:

(1) The dollar amount of the patient's potential financial liability for a facility fee if a diagnosis and extent of medical treatment is known.

(2) An estimated range in dollars of the patient's potential financial liability for a facility fee if the diagnosis and extent of medical treatment is unknown.

(3) If applicable, a statement that the patient may incur a financial liability to the health care facility that the patient would not incur if the patient was receiving medical services and treatment on the campus of the hospital.

Section 812-C. Reports.

The department shall report annually on the progress in implementing and administering this chapter and submit the report to:

(1) The chairperson and minority chairperson of the Appropriations Committee of the Senate.

(2) The chairperson and minority chairperson of the Appropriations Committee of the House of Representatives.

(3) The chairperson and minority chairperson of the

Health and Human Services Committee of the Senate.

(4) The chairperson and minority chairperson of the Health Committee of the House of Representatives.

(5) The chairperson and minority chairperson of the Human Services Committee of the House of Representatives.

Section 813-C. Regulations.

(a) Temporary regulations.--In order to facilitate the prompt implementation of this chapter, regulations promulgated by the department shall be deemed temporary regulations that shall expire no later than two years following publication. Temporary regulations promulgated under this subsection shall not be subject to:

(1) Section 612 of the act of April 9, 1929 (P.L.177, No.175), known as The Administrative Code of 1929.

(2) Sections 201, 202, 203, 204 and 205 of the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law.

(3) Sections 204(b) and 301(10) of the act of October 15, 1980 (P.L.950, No.164), known as the Commonwealth Attorneys Act.

(4) The act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

(b) Expiration.--Notwithstanding any other provision of law, the department's authority to adopt temporary regulations under subsection (a) shall expire two years after the effective date of this subsection. Regulations adopted after this period shall be promulgated as provided by law.

(c) Publication.--The department shall begin submitting the temporary regulations to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin no later than six

months after the effective date of this subsection.

(d) Regulations.--The department shall promulgate regulations as provided by law prior to the expiration of the temporary regulations as necessary to implement this chapter.

CHAPTER 8-D

PROHIBITION ON COLLECTION ACTION OF DEBT AGAINST PATIENTS FOR NONCOMPLIANT HOSPITALS

Section 801-D. Purpose.

The purpose of this chapter is to provide for the prohibition on collection action of debt for noncompliant hospitals.

Section 802-D. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"CMS." The Centers for Medicare and Medicaid Services.

"Collection action." Any of the following actions taken with respect to a debt for an item or service that was purchased from or provided to a patient by a hospital on a date during which the hospital was not in material compliance with Chapter 8-C:

(1) Attempting to collect a debt from a patient or patient guarantor by referring the debt, directly or indirectly, to a debt collector, a collection agency or other third-party retained by or on behalf of the hospital.

(2) Suing the patient or patient guarantor or enforcing an arbitration or mediation clause in a hospital document, including any contract, agreement, statement or bill.

(3) Directly or indirectly causing a report to be made to a consumer reporting agency.

"Collection agency." Any of the following:

(1) A person that engages in a business for the

principal purpose of collecting debts.

(2) A person that does any of the following:

(i) Regularly collects or attempts to collect, directly or indirectly, debts owed or due or asserted to be owed or due to another.

(ii) Takes assignment of debts for collection purposes.

(iii) Directly or indirectly solicits for collection debts owed or due or asserted to be owed or due to another.

"Consumer reporting agency." A person that, for monetary fees, dues or on a cooperative nonprofit basis, regularly engages, in whole or in part, in the practice of assembling or evaluating consumer credit information or other information on consumers for the purpose of furnishing consumer reports to third parties. The term includes "consumer reporting agency" as defined in 15 U.S.C. § 1681a(f) (relating to definitions and rules of construction). The term does not include a business entity that only provides check verification or check guarantee services.

"Debt." An obligation or alleged obligation of a consumer to pay money arising out of a transaction, whether or not the obligation has been reduced to judgment. The term does not include a debt for business, investment, commercial or agricultural purposes or a debt incurred by a business.

"Debt collector." A person employed or engaged by a collection agency to perform the collection of debts owed or due, or asserted to be owed or due, to another.

"Hospital." As defined in section 802.1.

"Item or service." As defined in section 802-C.

Section 803-D. Failure to comply with hospital price transparency.

(a) Prohibition.--Except as provided under subsection (d), a hospital that is in violation of the requirements under Chapter 8-C on the date when an item or service is purchased from or provided to a patient by the hospital may not initiate or pursue a collection action against the patient or patient guarantor for a debt owed for the item or service.

(b) Civil action.--If a patient believes that a hospital is in violation of the requirements under Chapter 8-C on the date when an item or service is purchased from or provided to the patient and the hospital takes a collection action against the patient or patient guarantor, the patient or patient guarantor may initiate a civil action in a court of competent jurisdiction to determine if the hospital is in violation of Chapter 8-C and the noncompliance is related to the item or service. The hospital may not take a collection action against the patient or patient guarantor or submit a report to a patient's or patient guarantor's credit report while the civil action is pending.

(c) Noncompliance.--A hospital that has been determined to be in violation of the requirements under Chapter 8-C shall:

(1) refund the payor an amount of the debt the payor has paid and pay a penalty to the patient or patient guarantor in an amount equal to the total amount of the debt;

(2) dismiss or cause to be dismissed a civil action under subsection (b) with prejudice and pay any attorney fees and costs incurred by the patient or patient guarantor relating to the action; and

(3) remove or cause to be removed from the patient's or patient guarantor's credit report a report made to a consumer

reporting agency relating to the debt.

(d) Construction.--Nothing in this section shall be construed to:

(1) prohibit a hospital from billing a patient, patient guarantor or third-party payor, including a health insurer, for an item or service provided to the patient in a manner that is not in violation of this chapter; or

(2) require a hospital to refund a payment made to the hospital for an item or service provided to the patient if no collection action is taken in violation of this chapter.

Section 2. This act shall take effect in 180 days.

HOUSE OF REPRESENTATIVES
DEMOCRATIC COMMITTEE BILL ANALYSIS

Bill No:	HB2363 PN3195	**Prepared By:**	Dylan Lindberg (717) 705-1875,6240
Committee:	Health		
Sponsor:	Cutler, Bryan	**Executive Director:**	Erika Fricke
Date:	6/3/2024		

A. Brief Concept

Establishes the Prescription Drug Repository Program.

C. Analysis of the Bill

House Bill 2363 amends Act 14 of 2008 to replace the Pennsylvania Cancer Drug Repository Program with the Pennsylvania Prescription Drug Repository Program.

State Board of Pharmacy Duties

Program

The Pennsylvania Prescription Drug Repository Program would allow unused prescription drugs to be returned to participating pharmacies and then redispensed to indigent residents. Prescriptions under this program cannot be resold to the consumers, but the pharmacies can charge a handling fee in an amount determined by the board. Income eligibility to receive redispensed prescriptions is determined by DHS in consultation with the board.

The board determines which prescriptions the program will accept and not accept, informed consent procedures, provisions for recalls, and procedures to minimize theft and diversion.

Individuals, health care facilities, hospitals, or health clinics are allowed to donate unused prescriptions through the program. It is voluntary and pharmacies must be approved by the board to participate.

A pharmacy may redispense a prescription if:

- the prescription is unused;
- it is in the original, unopened packaging;
- the expiration date is longer 6 months or longer;
- the prescription is not adulterated or misbranded;
- the prescription is not a controlled substance.

The board must list on its website each approved participating pharmacy, including its address and phone number, and update it within 30 days of any changes.

Both the donator and the pharmacist are required to record the quantity, name, and strength of the drug.

Report

The board is required to annually report the following:

- the name and address of each participating pharmacy by county;
- number of pharmacies participating in the program by county;
- number of pharmacies that have withdrawn from the program;
- number of pharmacies that the board has refused to approve, revoked, or has suspended participation;
- recommendations for improvements or changes to the law.

The report is issued to the chairs of the Senate Health and Human Services Committee, House Health Committee, Senate Consumer Protection and Professional Licensure Committee, and the House Professional Licensure Committee.

The prescription drugs may be distributed to another participating physician's office, pharmacy, hospital, or health clinic for dispensing by a pharmacist.

Regulations

The board must promulgate temporary regulations within 8 months of enactment, which will expire two years after adoption. Permanent regulations must be promulgated before the expiration of temporary regs.

Regulations governing the Cancer Drug Repository Program continue until temporary regulations are promulgated.

Pharmacy Duties

To participate in the program, a pharmacy must:

- be approved by the board;
- comply with all federal and state laws regarding storage, distribution, and dispensing;
- inspect all prescription drugs prior to dispensing to determine if they are adulterated or misbranded;
- Dispense only pursuant to a prescription by a prescribing practitioner.

Immunity

A participant in this program who exercises in good faith is immune from civil or criminal liability and professional disciplinary action.

Effective Date:

60 days.

G. Relevant Existing Laws

Act 14 of 2008 established the Cancer Drug Repository Program, which allows a pharmacy, health care facility, drug manufacturer or wholesale drug distributor to donate unused drugs to pharamcies who can redispense them.

House Bill 2363 is largely consistent with Act 14 but with a couple of key changes. First, it expands the program to include all types of prescription drugs instead of cancer-specific (excluding controlled substances). Second, it allows individuals to donate their unused drugs, whereas Act 14 limits donations to those in a closed drug delivery system. Lastly, it adds reporting requirements of the program by the board.

The Controlled Substances Act limits who can handle or transfer controlled substances and for what purposes.

Title 49, Chapter 27 of Pa Code provides for the storage, distribution and dispensing of drugs.

Drug Supply Chain Security Act (DSCSA) requires electronic tracing of drugs throughout the supply chain.

E. Prior Session (Previous Bill Numbers & House/Senate Votes)

N/A.

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the Pennsylvania House of Representatives and may not be utilized as such.

LEGISLATIVE REFERENCE BUREAU

AMENDMENTS TO HOUSE BILL NO. 2363

Sponsor: Frankel #23

Printer's No. 3195

Amend Bill, page 3, by inserting between lines 10 and 11

"Manufacturer." As defined in section 2 of The Controlled Substance, Drug, Device and Cosmetic Act.

Amend Bill, page 3, by inserting between lines 27 and 28

"Wholesale distributor of prescription drugs." As defined in section 3 of the act of December 14, 1992 (P.L.1116, No.145), known as the Wholesale Prescription Drug Distributors License Act.

Amend Bill, page 4, line 11, by striking out "or" and inserting a comma

Amend Bill, page 4, line 11, by inserting after "clinic"

, manufacturer or wholesale distributor of prescription drugs

Amend Bill, page 4, line 12, by inserting after "return"

or donate

Amend Bill, page 5, by inserting between lines 1 and 2

(5) Subject to this act and except as otherwise prohibited by Federal or State law, an unused prescription drug dispensed under a State medical assistance program may be accepted and dispensed by an approved participating pharmacy.

Amend Bill, page 5, line 6, by inserting a bracket before "relating"

Amend Bill, page 5, line 6, by inserting after "to"

], including

PRINTER'S NO. 3195

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2363 Session of 2024

INTRODUCED BY CUTLER, GREINER, PICKETT, KINSEY, MOUL, STAATS, ROWE, STENDER, SCHEUREN, GILLEN, HADDOCK, E. NELSON AND MENTZER, JUNE 3, 2024

REFERRED TO COMMITTEE ON HEALTH, JUNE 3, 2024

AN ACT

Amending the act of May 13, 2008 (P.L.139, No.14), entitled "An act establishing the Cancer Drug Repository Program for accepting donated cancer drugs and dispensing cancer drugs; and providing for the powers and duties of the State Board of Pharmacy," further providing for title and short title of act, for definitions, for establishment of program, for restocking and dispensing of cancer drugs, for storage, distribution and fees and for immunity, providing for annual report and for list of approved participating pharmacies and further providing for regulations.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The title and sections 1, 2, 3, 4, 5(a) and (b) and 6 of the act of May 13, 2008 (P.L.139, No.14), known as the Cancer Drug Repository Program Act, are amended to read:

AN ACT

Establishing the [Cancer] Prescription Drug Repository Program for accepting donated [cancer] prescription drugs and dispensing [cancer] prescription drugs; and providing for the powers and duties of the State Board of Pharmacy.

Section 1. Short title.

This act shall be known and may be cited as the [Cancer] Prescription Drug Repository Program Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Adulterated." As specified under section 7 of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

"Approved participating pharmacy." A pharmacy approved by the State Board of Pharmacy for the purpose of dispensing unused [cancer] prescription drugs to participating entities and to patients who are indigent.

"Board." The State Board of Pharmacy of the Commonwealth.

"Cancer drug." A prescription drug used to treat any of the following:

(1) Cancer or its side effects.

(2) The side effects of a prescription drug used to treat cancer or its side effects.

["Closed drug delivery system." A system in which the actual control of a unit dose medication is maintained by a health care facility, health clinic, hospital, pharmacy or physician's office rather than an individual patient.]

"Controlled substance." As defined in section 2 of The Controlled Substance, Drug, Device and Cosmetic Act.

"Health care facility." [A for-profit or nonprofit entity providing clinically related health services, including those operated by the Commonwealth or its political subdivisions and including a general or special hospital, including psychiatric hospitals, rehabilitation hospitals, ambulatory surgical

facilities, long-term care nursing facilities, a hospice, a cancer treatment center using radiation therapy on an ambulatory basis and an inpatient drug and alcohol treatment facility.] As defined in section 802.1 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

"Health clinic." A for-profit or nonprofit clinic providing health services.

"Hospital." An entity licensed as a hospital under the [act of July 19, 1979 (P.L.130, No.48), known as the] Health Care Facilities Act.

"Misbranded." As specified under section 8 of The Controlled Substance, Drug, Device and Cosmetic Act.

"Pharmacist." A pharmacist licensed by the Commonwealth.

"Pharmacy." A pharmacy licensed by the Commonwealth.

"Physician's office." The office of a person licensed to practice medicine and surgery or osteopathic medicine and surgery.

"Prescribing practitioner." A health care practitioner licensed under the laws of this Commonwealth who is authorized to prescribe [cancer] prescription drugs.

"Prescription drug." A drug requiring a prescription in this Commonwealth. The term includes cancer drugs. The term does not include a controlled substance.

"Program." The [Cancer] Prescription Drug Repository Program established in section 3.

["Unit dose system." A system wherein all individually sealed unit doses are physically connected as a unit.]

Section 3. Establishment.

The board shall establish a [Cancer] Prescription Drug Repository Program consistent with public health and safety

standards through which unused [cancer] prescription drugs may be redispensed to [cancer] patients by pharmacies approved by the board for the purpose of dispensing unused [cancer] prescription drugs to residents who are indigent. The board shall develop and promulgate rules and regulations to establish procedures necessary to implement the program. Participation in the program shall be voluntary.

Section 4. Restocking and dispensing of [cancer] prescription drugs.

An [entity that is part of a closed drug delivery system] individual, health care facility, hospital or health clinic may return to an approved participating pharmacy an unused [cancer] prescription drug under the following conditions:

(1) [If the cancer] The prescription drug is in its original unopened, sealed and tamper-evident [unit dose] packaging. A [cancer] prescription drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened.

(2) The [cancer] prescription drug may not be accepted or dispensed by the approved participating pharmacy if the [cancer] prescription drug bears an expiration date that is earlier than six months after the date the [cancer] prescription drug was restocked or the [cancer] prescription drug is adulterated or misbranded.

[(3) Except as provided in this subsection, an unused cancer drug dispensed under a State medical assistance program may be accepted and dispensed by the approved participating pharmacy.

(4) In the case of controlled substances, as it is

allowed by Federal law.]

Section 5. Storage, distribution and fees.

(a) General rule.--An approved participating pharmacy that accepts donated [cancer] prescription drugs under the [Cancer] Prescription Drug Repository Program shall comply with all applicable provisions of Federal and State law relating to the storage, distribution and dispensing of [cancer] prescription drugs and shall inspect all [cancer] prescription drugs prior to dispensing to determine if they are adulterated or misbranded. The [cancer] prescription drugs shall only be dispensed by a pharmacist according to State law pursuant to a prescription issued by a prescribing practitioner. The [cancer] prescription drugs may be distributed to another participating physician's office, pharmacy, hospital or health clinic for dispensing by a pharmacist as allowed by Federal or State law.

(b) Handling fee.--An approved participating pharmacy may charge a handling fee for distributing or dispensing [cancer] prescription drugs under the program. The fee shall be established in regulations promulgated by the board. [Cancer] Prescription drugs donated under the program shall not be resold.

* * *

Section 6. Immunity.

Any person or entity, acting in good faith, who exercises reasonable care in donating, accepting, distributing, dispensing or manufacturing [cancer] prescription drugs donated and utilized under the program shall be immune from civil or criminal liability or professional disciplinary action for any injury, death or loss to a person or property relating to activities under the program. Immunity granted under this

section is solely applicable to the donation, acceptance, distribution, dispensing or manufacture of the actual medications donated to the program and is explicitly not a general waiver of liability.

Section 2. The act is amended by adding sections to read:

Section 6.1. Annual report.

(a) Report.--The board shall report annually by December 31 of each year on the progress in implementing and administering this act and submit the report to all of the following:

(1) The chairperson and minority chairperson of the Health and Human Services Committee of the Senate.

(2) The chairperson and minority chairperson of the Health Committee of the House of Representatives.

(3) The chairperson and minority chairperson of the Consumer Protection and Professional Licensure Committee of the Senate.

(4) The chairperson and minority chairperson of the Professional Licensure Committee of the House of Representatives.

(b) Contents.--A report under subsection (a) shall include all of the following information:

(1) The name and address of each approved participating pharmacy in the program.

(2) The number of approved participating pharmacies in the program by county.

(3) The number of approved participating pharmacies that have withdrawn from the program.

(4) The number of pharmacies that the board has refused to approve, has revoked or has suspended from participating in the program.

(5) Recommendations to the General Assembly for improvements or changes to the program as the board deems necessary.

Section 6.2. List of approved participating pharmacies.

The board shall post on the board's publicly accessible Internet website a list of each approved participating pharmacy, including the address and telephone number of each approved participating pharmacy. The board shall update the list under this section within 30 days of a change in the list and note the change from the previous list on the board's publicly accessible Internet website.

Section 3. Section 7 of the act is amended to read:

Section 7. Regulations.

[The board shall promulgate regulations to carry out the purposes of this act within 90 days of the effective date of this section.]

(a) Authority.--In order to facilitate the prompt implementation of this act, the board may promulgate temporary regulations that shall expire no later than two years following the publication of the temporary regulations. The board must promulgate the temporary regulations within 180 days of the effective date of this subsection. The board may promulgate temporary regulations not subject to:

(1) Section 612 of the act of April 9, 1929 (P.L.177, No.175), known as The Administrative Code of 1929.

(2) Sections 201, 202, 203, 204 and 205 of the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law.

(3) Sections 204(b) and 301(10) of the act of October 15, 1980 (P.L.950, No.164), known as the Commonwealth

Attorneys Act.

(4) The act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

(b) Expiration.--The board's authority to adopt temporary regulations under subsection (a) shall expire two years after the effective date of this subsection. Regulations adopted after this period shall be promulgated as provided by law before the expiration of the temporary regulations under subsection (a).

(c) Contents.--The regulations shall include:

(1) Income eligibility criteria and other standards and procedures for individuals participating in the program, determined by the Department of [Public Welfare] Human Services in conjunction with the board.

(2) Eligibility criteria and other standards and procedures for entities participating in the program that restock and distribute or dispense donated [cancer] prescription drugs.

(3) Necessary forms for administration of the program, including forms for use by entities permitted to accept, distribute or dispense [cancer] prescription drugs under the program.

(4) The maximum handling fee that may be charged by entities permitted to restock and distribute or dispense donated [cancer] prescription drugs.

(5) Categories of [cancer] prescription drugs that the program will accept for dispensing and categories of [cancer] prescription drugs that the program will not accept for dispensing and the reason that the [cancer] prescription drugs will not be accepted.

(6) Informed consent provision for patients

participating in the program indicating that the [cancer] prescription drug has been restocked and redistributed.

(7) Provisions for recalls of the drug if necessary.

(8) Procedures for entities participating in the program to minimize theft and diversion.

(d) Applicability.--The regulations promulgated by the board as published in the Pennsylvania Bulletin at 43 Pa.B. 7011 (November 27, 2013) and effective November 30, 2013, shall remain in full force and effect until the promulgation of the temporary regulations under subsection (a).

Section 4. This act shall take effect in 60 days.

HOUSE OF REPRESENTATIVES
DEMOCRATIC COMMITTEE BILL ANALYSIS

Bill No:	HR0464 PN3239	**Prepared By:**	Patrick O'Rourke (717) 787-4296,6711
Committee:	Health		
Sponsor:	Mehaffie, Thomas	**Executive Director:**	Erika Fricke
Date:	6/5/2024		

A. Brief Concept

House Resolution 464 designates July 2024 as "MECP2 Duplication Syndrome Awareness Month."

B. Committee Votes

N/A.

C. Analysis of the Bill

The following points are referenced in support by the resolution:

- MECP2 duplication syndrome is usually caused by duplication of DNA on the Xq28 region of the chromosomes.
- Despite MECP2 duplication syndrome being a neurodevelopmental disorder, it causes multisystemic health problems, such as severe gastrointestinal symptoms, frequent respiratory infections and treatment-resistant seizures.
- MECP2 duplication syndrome is a condition that occurs almost exclusively in boys.
- Some boys have large duplications which include many other genes, and the full extent of phenotypes due to duplication of other genes is not completely understood at this time.
- Recent studies have shown a link between MECP2 duplication syndrome and autism, and most boys with this syndrome do have distinct features of autism.
- Patients with MECP2 duplication syndrome are highly responsive to proper stimulation such as schooling, exercise, music, age-appropriate social interactions and related activities.
- MECP2 duplication syndrome can cause significant anxiety, depression and emotional exhaustion on caregivers.
- MECP2 duplication syndrome was not formally recognized until 2005.
- MECP2 duplication syndrome is most commonly inherited in an X-linked manner, with affected males most commonly inheriting the MECP2 duplication from the carrier mother, but spontaneous duplications have been reported.
- To date, no cases of a father transmitting the duplication have been reported.
- MECP2 duplication syndrome research, which has shown that symptoms of the disorder can be reversed in mice using a small antisense oligonucleotide, gives hope for the future development of effective treatments for humans with this disorder.
- Clinical readiness studies have been done to identify ways to monitor response to therapy and ensure safety as a preparation for future clinical trials.
- Natural history studies are ongoing to define the natural course of MECP2 duplication syndrome over the span of 12 to 18 months to prepare for the start of clinical trials.

Effective Date:

N/A.

D. Third Party Feedback

N/A.

E. Prior Session (Previous Bill Numbers & House/Senate Votes)

2019-2020 Legislative Session

- HR 367 (Hickernell)
  - Adopted June 10, 2019 (198-0)
- HR 917 (Hickernell)
  - Adopted Nov 18, 2020 (202-0)

F. Key Points

Per the Children's Hospital of Philadelphia:

- MECP2 duplication syndrome is a rare neurodevelopmental condition caused by an extra copy (duplication) of the MECP2 gene. The disorder can cause a wide range of symptoms with varying severity. The most common symptoms include differences in muscle tone, epilepsy and neurodevelopmental impairment that affects cognitive, motor and speech function.

- The MECP2 gene creates a protein (methyl-CpG-binding protein 2) that regulates the activity of other genes in the body. When the protein level is altered either because of a faulty gene or an extra copy of the gene, it causes other genes in the body to malfunction, and ultimately affects normal brain development. MECP2 duplication syndrome primarily affects males, but in rare cases, females may also be affected. The MECP2 gene is located on the X chromosome, one of the two chromosomes that determine a person's sex.

- Children with MECP2 duplication syndrome are typically followed by multiple providers, including dedicated specialists in neurogenetics, genetic counseling, gastroenterology, rehabilitation medicine, orthopaedics, pulmonology, immunology and physiotherapy. For children with seizures, anti-seizure medications are used. Seizure control in MECP2 duplication syndrome is challenging, and seizures are often the most difficult health issue to manage. No single anti-seizure medication has been found to be uniformly effective to treat MECP2 duplication syndrome.

G. Relevant Existing Laws

N/A.

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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 464 Session of 2024

INTRODUCED BY MEHAFFIE, BARTON, BENNINGHOFF, CABELL, COOK, CUTLER, DAVANZO, DIAMOND, FLICK, JOZWIAK, KAUFFMAN, KINSEY, KRUPA, KUTZ, LABS, M. MACKENZIE, MALAGARI, MARCELL, MERCURI, MOUL, MUSTELLO, NEILSON, E. NELSON, SCHEUREN, SCHLOSSBERG, STEHR, STRUZZI, TOPPER AND WATRO, JUNE 4, 2024

REFERRED TO COMMITTEE ON HEALTH, JUNE 4, 2024

A RESOLUTION

Designating the month of July 2024 as "MECP2 Duplication Syndrome Awareness Month" in Pennsylvania.

WHEREAS, MECP2 duplication syndrome is usually caused by duplication of DNA on the Xq28 region of the chromosomes; and

WHEREAS, Despite MECP2 duplication syndrome being a neurodevelopmental disorder, it causes multisystemic health problems, such as severe gastrointestinal symptoms, frequent respiratory infections and treatment-resistant seizures; and

WHEREAS, MECP2 duplication syndrome is a condition that occurs almost exclusively in boys; and

WHEREAS, Some boys have large duplications which include many other genes, and the full extent of phenotypes due to duplication of other genes is not completely understood at this time; and

WHEREAS, Recent studies have shown a link between MECP2 duplication syndrome and autism, and most boys with this

syndrome do have distinct features of autism; and

WHEREAS, Patients with MECP2 duplication syndrome are highly responsive to proper stimulation such as schooling, exercise, music, age-appropriate social interactions and related activities; and

WHEREAS, MECP2 duplication syndrome can cause significant anxiety, depression and emotional exhaustion on caregivers; and

WHEREAS, MECP2 duplication syndrome was not formally recognized until 2005; and

WHEREAS, MECP2 duplication syndrome is most commonly inherited in an X-linked manner, with affected males most commonly inheriting the MECP2 duplication from the carrier mother, but spontaneous duplications have been reported; and

WHEREAS, To date, no cases of a father transmitting the duplication have been reported; and

WHEREAS, MECP2 duplication syndrome research, which has shown that symptoms of the disorder can be reversed in mice using a small antisense oligonucleotide, gives hope for the future development of effective treatments for humans with this disorder; and

WHEREAS, Clinical readiness studies have been done to identify ways to monitor response to therapy and ensure safety as a preparation for future clinical trials; and

WHEREAS, Natural history studies are ongoing to define the natural course of MECP2 duplication syndrome over the span of 12 to 18 months to prepare for the start of clinical trials; therefore be it

RESOLVED, That the House of Representatives designate the month of July 2024 as "MECP2 Duplication Syndrome Awareness Month" in Pennsylvania.

HOUSE OF REPRESENTATIVES
DEMOCRATIC COMMITTEE BILL ANALYSIS

Bill No:	HR0471 PN3269	**Prepared By:**	Patrick O'Rourke (717) 787-4296,6711
Committee:	Health		
Sponsor:	Kinsey, Stephen	**Executive Director:**	Erika Fricke
Date:	6/10/2024		

A. Brief Concept

Recognizes June 2024 as "Scleroderma Awareness Month" and June 29, 2024, as "World Scleroderma Day" in Pennsylvania.

B. Committee Votes

N/A.

C. Analysis of the Bill

To raise awareness about scleroderma, the Federation of European Scleroderma Associations first recognized June 29, 2009 as World Scleroderma Day to commemorate Paul Klee, a Swiss artist that died of systemic scleroderma on June 29, 1940. For June 2024, the theme is "Every Journey Matters," which recognizes how the experiences of individuals with scleroderma differ.

Scleroderma is a rare group of autoimmune diseases that affects 2.5 million individuals in the world and approximately 300,000 individuals in the U.S. It makes the skin harden and tighten, affecting the face, feet, fingers, and hands first. Systemic scleroderma affects the skin and internal organs, while localized scleroderma only affects the skin.

Effective Date:

N/A.

D. Third Party Feedback

N/A.

E. Prior Session (Previous Bill Numbers & House/Senate Votes)

2023-24 Legislative Session

- HR 123, PN 1340 (Malagari)
  - Adopted June 13, 2023 (202-1)

2019-20 Legislative Session

- HR 971, PN 4283 (Malagari)
  - Adopted Sep. 16, 2020 (202-0)

F. Key Points

Scleroderma is a group of rare autoimmune diseases which vary in type and involves the hardening and tightening of the skin and connective tissues. Scleroderma results from an overproduction and accumulation of collagen in body tissues, with one of the earliest signs of systemic scleroderma being Raynaud's disease.

It is estimated that approximately 300,000 Americans have scleroderma, with it affecting women more often than men and occurring between the ages of 30 and 50.

Scleroderma can be managed with treatment but currently is uncurable. Mutiple Pennsylvania university hospitals are researching ways to solve this. Treatment includes medications, physical and occupational therapy, and in severe cases, transplantations.

It is vitally important for all Pennsylvanians to be aware of the signs, symptoms, educational resources and treatment options for scleroderma.

G. Relevant Existing Laws

Act 14 of 2017 created the Pennsylvania Rare Disease Advisory Council.

H. Messaging

Scleroderma is a rare group of autoimmune diseases that makes the skin harden and tighten. By increasing awareness to rare diseases such as scleroderma, we may enhance Pennsylvanians' knowledge about symptoms, research to treat scleroderma, and support individuals living with rare diseases.

In Pennsylvania, Thomas Jefferson University, the University of Pennsylvania, and the University of Pittsburgh research scleroderma, assisting individuals with receiving treatment to mitigate their symptoms.

There is not a cure to scleroderma, but medications may ease symptoms by dilating blood vessels, suppressing the immune system, reducing stomach acid, preventing infections in ulcers caused by Raynaud's phenomenon, and alleviating pain. Physical and occupational therapies and stem cell and organ transplants may mitigate symptoms for individuals diagnosed with scleroderma. By increasing awareness to scleroderma, we may assist in advancing research for a cure.

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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 471 Session of 2024

INTRODUCED BY KINSEY, MALAGARI, GIRAL, HILL-EVANS, SCHLOSSBERG, CURRY, SANCHEZ, DALEY AND BELLMON, JUNE 7, 2024

REFERRED TO COMMITTEE ON HEALTH, JUNE 7, 2024

A RESOLUTION

Recognizing the month of June 2024 as "Scleroderma Awareness Month" and June 29, 2024, as "World Scleroderma Day" in Pennsylvania.

WHEREAS, Scleroderma is a rare group of autoimmune diseases that makes the skin harden and tighten, which may cause issues in the blood vessels, gastrointestinal tract, heart and lungs; and

WHEREAS, Across the world, 2.5 million individuals have scleroderma, including approximately 300,000 individuals in the United States; and

WHEREAS, Systemic scleroderma affects the skin as well as the internal organs; and

WHEREAS, One-third of those with scleroderma have systemic scleroderma, 80% of which are women; and

WHEREAS, African Americans have a high risk of systemic scleroderma, and 70% of individuals with systemic scleroderma are African Americans; and

WHEREAS, Scleroderma commonly occurs between the ages of 25

and 55; and

WHEREAS, Symptoms commonly affect the face, feet, fingers, and hands first, and early symptoms include hardening and tightening of the skin, swelling and itchiness; and

WHEREAS, Diagnosis may include physical exams, laboratory tests for antibodies, skin biopsies, computerized tomography, echocardiograms and pulmonary function tests; and

WHEREAS, There is not a cure for scleroderma, but treatment may include medications to dilate blood vessels, suppress the immune system, reduce stomach acid, prevent infections of ulcers caused by Raynaud's phenomenon and alleviate pain, in addition to physical and occupational therapies and stem cell and organ transplants; and

WHEREAS, Symptoms associated with scleroderma may decrease on their own in two to five years, while systemic scleroderma, which damages the internal organs, continues to worsen; and

WHEREAS, Thomas Jefferson University, the University of Pennsylvania, the University of Pittsburgh and other entities in Pennsylvania continue to research scleroderma, enabling individuals to receive treatment to mitigate their symptoms; and

WHEREAS, Awareness of rare diseases such as scleroderma assists in individuals' knowledge about the symptoms, research to treat these rare diseases and providing supports to individuals with rare diseases; therefore be it

RESOLVED, That the House of Representatives recognize the month of June 2024 as "Scleroderma Awareness Month" and June 29, 2024, as "World Scleroderma Day" in Pennsylvania.

HOUSE OF REPRESENTATIVES
DEMOCRATIC COMMITTEE BILL ANALYSIS

Bill No:	HR0476 PN3286	**Prepared By:**	Patrick O'Rourke (717) 787-4296,6711
Committee:	Health		
Sponsor:	Nelson, Napoleon	**Executive Director:**	Erika Fricke
Date:	6/10/2024		

A. Brief Concept

House Resolution 476 recognizes June 25, 2024, as "World Vitiligo Day."

B. Committee Votes

N/A.

C. Analysis of the Bill

HR 476 references the following points in support of recognizing "World Vitiligo Day" in Pennsylvania:

- Vitiligo is an autoimmune condition causing loss of pigment from areas of the skin and resulting in irregular white spots or patches.
- Approximately 1% of the global population is affected by vitiligo, highlighting its universal prevalence and the need for enhanced awareness.
- Vitiligo affects two million to five million Americans and can affect people of any age, gender, race or ethnicity.
- While vitiligo is not contagious and usually not physically painful, the psychological and social effects are well-documented and especially devastating to children.
- Many individuals with vitiligo experience stigmatization, discrimination, and bullying due to a lack of public understanding about the condition.
- Embracing acceptance and self-love can be essential components for some individuals living with vitiligo.
- Having knowledge of and access to treatment options should be discussed between patients and their providers.
- Despite clinical consensus that vitiligo is not a cosmetic condition, some insurance providers are denying coverage of Food and Drug Administration-approved treatments for vitiligo patients.
- The precise causes of vitiligo remain largely unknown, requiring further research to better understand and treat this condition.
- The Food and Drug Administration approved the first-ever drug to treat vitiligo in 2022.
- June 25 is recognized as "World Vitiligo Day," a day dedicated to raising awareness and understanding about this condition.

Effective Date:

N/A.

D. Third Party Feedback

N/A.

E. Prior Session (Previous Bill Numbers & House/Senate Votes)

N/A.

F. Key Points

Per the Mayo Clinic:

Vitiligo (vit-ih-LIE-go) is a disease that causes loss of skin color in patches. The discolored areas usually get bigger with time. The condition can affect the skin on any part of the body. It can also affect hair and the inside of the mouth.

Normally, the color of hair and skin is determined by melanin. Vitiligo occurs when cells that produce melanin die or stop functioning. Vitiligo affects people of all skin types, but it may be more noticeable in people with brown or Black skin. The condition is not life-threatening or contagious. It can be stressful or make you feel bad about yourself.

Treatment for vitiligo may restore color to the affected skin. But it doesn't prevent continued loss of skin color or a recurrence.

G. Relevant Existing Laws

N/A.

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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 476 Session of 2024

INTRODUCED BY N. NELSON, JUNE 10, 2024

REFERRED TO COMMITTEE ON HEALTH, JUNE 10, 2024

A RESOLUTION

Recognizing June 25, 2024, as "World Vitiligo Day" in Pennsylvania.

WHEREAS, Vitiligo is an autoimmune condition causing loss of pigment from areas of the skin and resulting in irregular white spots or patches; and

WHEREAS, Approximately 1% of the global population is affected by vitiligo, highlighting its universal prevalence and the need for enhanced awareness; and

WHEREAS, Vitiligo affects two million to five million Americans and can affect people of any age, gender, race or ethnicity; and

WHEREAS, While vitiligo is not contagious and usually not physically painful, the psychological and social effects are well-documented and especially devastating to children; and

WHEREAS, Many individuals with vitiligo experience stigmatization, discrimination and bullying due to a lack of public understanding about the condition; and

WHEREAS, Embracing acceptance and self-love can be essential

components for some individuals living with vitiligo; and

WHEREAS, Having knowledge of and access to treatment options should be discussed between patients and their providers; and

WHEREAS, The clinical consensus identifies vitiligo as an autoimmune condition, not a cosmetic condition; and

WHEREAS, The precise causes of vitiligo remain largely unknown, requiring further research to better understand and treat this condition; and

WHEREAS, The Food and Drug Administration approved the first ever drug to treat vitiligo in 2022; and

WHEREAS, June 25 is recognized as "World Vitiligo Day," a day dedicated to raising awareness and understanding about this condition; therefore be it

RESOLVED, That the House of Representatives recognize June 25, 2024, as "World Vitiligo Day" in Pennsylvania; and be it further

RESOLVED, That the House of Representatives encourage all Pennsylvanians to promote public awareness about vitiligo, dispel myths and foster empathy and support for those affected by the condition; and be it further

RESOLVED, That the House of Representatives acknowledge the importance of ongoing research into the causes and potential treatments for vitiligo and call on both the Commonwealth and the private sector to continue to prioritize and increase funding for vitiligo research within this Commonwealth; and be it further

RESOLVED, That the House of Representatives stand with the medical community in recognizing vitiligo as a serious autoimmune condition deserving of parity in recognition alongside other autoimmune conditions that impact

Pennsylvanians.