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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1052 Session of 2005

INTRODUCED BY S. H. SMITH, ARMSTRONG, BAKER, BOYD, CALTAGIRONE, CAPPELLI, CAUSER, CREIGHTON, DALLY, DENLINGER, BALDWIN, CRAHALLA, FAIRCHILD, FORCIER, FREEMAN, GEIST, HERMAN, HESS, GINGRICH, HARRIS, MARSICO, MACKERETH, JAMES, McGILL, McILHATTAN, McILHINNEY, MICOZZIE, R. MILLER, NICKOL, PAYNE, PHILLIPS, READSHAW, ROSS, RUBLEY, MUSTIO, O'NEILL, SAYLOR, B. SMITH, STERN, R. STEVENSON, T. STEVENSON, STURLA, E. Z. TAYLOR, TIGUE, WALKO, WATSON, YOUNGBLOOD, RAPP, REED, REICHLEY, TRUE, GOOD, THOMAS, CIVERA AND BROWNE, MARCH 21, 2005

AS REPORTED FROM COMMITTEE ON HEALTH AND HUMAN SERVICES, HOUSE OF REPRESENTATIVES, AS AMENDED, MAY 3, 2005

AN ACT

Providing for the Commonwealth pharmacy program procedures and policies; imposing powers and duties on the Governor's Office of Administration; and providing for a review system.

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Section 11. Effective date.

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

Section 1. Short title.

This act shall be known and may be cited as the Commonwealth Pharmacy Program Procedures and Policies Act.

Section 2. Legislative intent (Reserved).

Section 3. 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:

"Commonwealth pharmacy program." The term shall include: medical assistance, GENERAL ASSISTANCE, PACE, PACENET, the <— Special Pharmaceutical Benefit Program in the Department of Public Welfare, the End Stage Renal Program in the Department of Health and any other pharmacy program administered by the Commonwealth that is recognized by the Centers for Medicare and Medicaid as a State pharmaceutical assistance program.

"Disease management program." A system of coordinated health care interventions and communications designed for enhanced health outcomes and managing costs for populations with conditions where self-care efforts are significant. This program promotes the physician-patient relationship and plan of care, emphasizes the prevention of exacerbations and complications of disease states utilizing patient empowerment strategies, and evaluates clinical, humanistic and economic outcomes on an ongoing basis with the goal of improving overall health.

"Health care facility." A general or specific hospital, including State centers for the mentally retarded and psychiatric hospitals, skilled nursing facilities and

intermediate care facilities, regardless of whether such a facility is for profit, nonprofit or governmental.

~~"Hospital." An institution licensed or regulated as a hospital by the Department of Health or the Department of Public Welfare or a facility owned or operated by the Federal Government and accredited by the Joint Commission on Accreditation of Hospitals as a hospital.~~ <—

"Less expensive." The lowest net cost to the Commonwealth for a Commonwealth pharmacy program. The net cost shall include the amount paid by the Commonwealth to a pharmacy for a drug under current retail pharmacy reimbursement formula less any discounts or rebates, including those paid during the previous calendar quarter and inclusive of all dispensing fees.

"Manufacturer." An entity which is engaged in any of the following:

(1) The production, preparation, propagation, compounding, conversion or processing of prescription drug products directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.

(2) The packaging, repackaging, labeling or relabeling or distribution of prescription drug products. The term shall also include the entity holding legal title to or possession of the national drug code number for the covered prescription drug. The term does not include a wholesale distributor of drugs, drugstore chain organization or retail pharmacy licensed by the Commonwealth.

"National drug code number." The identifying drug number maintained by the Food and Drug Administration. The complete 11-

digit number must include the labeler code, product code and package size code.

"Office of Administration." The Governor's Office of Administration.

"Preferred pharmacy program." Any pharmacy program exclusive of Commonwealth pharmacy programs through which the Commonwealth, or its affiliates or designees, through a contractual agreement purchases or reimburses its affiliates or designees for a pharmacy benefit. The term may include, but shall not be limited to, the Public Employees Benefit Trust Fund, Children's Health Insurance Program, Workers' Compensation Program and the Department of Corrections. The Office of Administration shall publish in the Pennsylvania Bulletin a listing of pharmacy programs that shall be designated preferred pharmacy programs within 90 days of the effective date of this act.

Section 4. Rebates.

(a) Procedures requirement.--Any Commonwealth pharmacy or preferred pharmacy program that requires a manufacturer to remit a rebate to the program as a condition of participating in it shall have a clearly defined remittance procedure. The procedure shall include a process for the efficient collection of rebates that are not in dispute and a dispute resolution process.

(b) Uniformity.--The Office of Administration in coordination with the corresponding departmental oversight entity shall develop and publish in the Pennsylvania Bulletin a clearly defined remittance procedure for any Commonwealth pharmacy and preferred pharmacy program that does not already have a procedure in place. The procedure shall include a process for the efficient collection of rebates that are not in dispute

and a dispute resolution process. The development of the procedure shall include the consideration of need for uniform procedures. Nothing shall preclude the Office of Administration from implementing a uniform procedure for all programs, including those with procedures already in place.

(c) Past due rebates.--The Office of Administration shall have the authority to levy a surcharge penalty on any manufacturer for the collection of past due rebates that are not in dispute. The penalty may be levied on any rebate more than one year past due. The surcharge shall be in addition to any interest and penalties authorized under existing law or contractual agreement.

(1) The surcharge shall be equal to 15% of the principal owed for each year that the rebate is past due. The calculation of the surcharge shall be prorated for any portion of the year that the rebate is past due.

(2) The Office of Administration shall not apply the surcharge to any past due manufacturer's rebates prior to notifying the manufacturer of its intent to levy the surcharge. The notice shall provide the manufacturer with ~~90~~ 30 days to satisfy any past due claims. <—— <——

(d) Prohibition.--Nothing in this section shall be interpreted to authorize or require the implementation of rebates or supplemental rebates as a condition of participation in any Commonwealth pharmacy or preferred pharmacy program.

Section 5. Cost containment.

(a) Auditing procedures.--The Office of Administration in coordination with the corresponding departmental oversight entity shall ensure that a uniform, coordinated and standardized auditing procedure be adopted for all Commonwealth pharmacy and

preferred pharmacy programs.

(b) Claims adjudication.--The Office of Administration in coordination with the corresponding departmental oversight entity shall ensure that a state-of-the-art, online claims adjudication system is established for all appropriate Commonwealth pharmacy and preferred pharmacy programs. Nothing shall preclude the Office of Administration from adopting successful systems currently utilized in a Commonwealth pharmacy program as a uniform procedure for all programs, including those with procedures already in place.

(c) Drug utilization review system.--The Office of Administration in coordination with the corresponding departmental oversight entity shall ensure that a state-of-the-art, outcome-based, regulatory modeled, therapeutic drug utilization review system is established to monitor and correct misutilization of drug therapies for all appropriate Commonwealth pharmacy and preferred pharmacy programs. The system shall provide prospective and retrospective analysis of potentially dangerous drug interactions, duplicative therapies, maximum allowable dosing, therapy duration, acute to maintenance therapy and drug utilization. Nothing shall preclude the Office of Administration from adopting successful systems currently utilized in a Commonwealth pharmacy program as a uniform procedure for all programs, including those with procedures already in place.

(d) Surveillance utilization review system.--The Office of Administration in coordination with the corresponding departmental oversight entity shall ensure that a surveillance utilization review system is established to monitor, identify and investigate potential misutilization or deficiencies in the

level of care. The system shall monitor potential fraud and abuse by enrollees, providers and prescribers for all appropriate Commonwealth pharmacy and preferred pharmacy programs. Nothing shall preclude the Office of Administration from adopting successful systems currently utilized in a Commonwealth pharmacy program as a uniform procedure for all programs, including those with procedures already in place.

(e) Mandatory generic substitution.--The Office of Administration in consultation with the Department of Health and in coordination with the appropriate corresponding departmental oversight entity shall provide for a procedure to ensure that, notwithstanding provisions of the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug ~~Law, and the act of August 26, 1971 (P.L.351, No.91), known as the State Lottery Law, to the contrary, a generic drug equivalent shall only be dispensed when it is less expensive for a Commonwealth pharmacy program.~~ <—

~~(f) Access restrictions.--Except as provided for in this section, the Commonwealth shall not institute or adopt any new restrictions, drug formulary, preferred drug list or any other substitution process for the purchase of or reimbursement for pharmaceuticals by a Commonwealth pharmacy program on or before January 1, 2007. This restriction shall include:~~ LAW, A BRAND NAME PRODUCT SHALL BE DISPENSED AND NOT SUBSTITUTED WITH AN A-RATED GENERIC THERAPEUTICALLY EQUIVALENT DRUG IF IT IS LESS EXPENSIVE TO THE COMMONWEALTH PHARMACY PROGRAM. <—

(F) ACCESS RESTRICTIONS.--EXCEPT AS PROVIDED IN THIS SECTION, A COMMONWEALTH PHARMACY PROGRAM SHALL NOT INSTITUTE ANY NEW ACCESS RESTRICTIONS FOR ENROLLEES. THIS LIMITATION SHALL INCLUDE THE IMPLEMENTATION OF SCRIPT LIMITATIONS, DRUG

FORMULARIES OR PREFERRED DRUG LISTS ON OR BEFORE JANUARY 1, 2007. THIS RESTRICTION SHALL ALSO INCLUDE:

(1) Any policy modifications to existing prior authorization procedures.

(2) The application for any approval of modifications to its State plan as provided for in the Social Security Act (49 Stat. 620, 42 U.S.C. § 301 et seq.) pertaining to the ~~reimbursement for,~~ rebate on or access to pharmaceuticals in a Commonwealth pharmacy program. <—

(3) The implementation of any approval of modifications to its State plan as provided for in Ch. 7 Subch. XIX of the Social Security Act pertaining to the ~~reimbursement for,~~ rebate on or access to pharmaceuticals in a Commonwealth pharmacy program. <—

(4) Nothing in this section shall preclude the adoption of a new or revised procedure for the reimbursement for, rebate on or access to pharmaceuticals in a Commonwealth pharmacy program provided that the adoption of such change is required by Federal law.

(g) Access restrictions after January 1, 2007.--~~If other cost-saving measures are not identified, the~~ <—

(1) THE Commonwealth may institute or adopt any new restrictions, drug formulary, preferred drug list or any other substitution process for the purchase of ~~or reimbursement for~~ pharmaceuticals by a Commonwealth pharmacy program after January 1, 2007, provided that the General Assembly does not object to the adoption of such a procedure. <—

~~(h) Notice and procedure.--~~ <—

(2) The Office of Administration in coordination with the corresponding departmental oversight entity shall notify <—

the Majority Leader and the Minority Leader of the Senate and the Majority Leader and the Minority Leader of the House of Representatives upon the adoption of any access restriction as outlined in subsection (f). Upon receipt of the notification, the General Assembly may overturn the restriction, provided that it adopts a concurrent resolution within 25 legislative days of receiving notice.

(3) THE DEPARTMENT SHALL NOT IMPLEMENT A PREFERRED DRUG LIST, FORMULARY, SUBSTITUTION PROCESS OR PRIOR AUTHORIZATION PROCEDURE FOR THE FOLLOWING: <—

(I) A CENTRAL NERVOUS SYSTEM PRESCRIPTION DRUG THAT IS CLASSIFIED AS AN ANTICONVULSANT, ANTIDEPRESSANT, ANTIPSYCHOTIC OR A NONCONTROLLED SUBSTANCE ANTI-ANXIETY DRUG IN A GENERALLY ACCEPTED STANDARD MEDICAL REFERENCE.

(II) A PRESCRIPTION DRUG THAT IS CROSS-INDICATED FOR A CENTRAL NERVOUS SYSTEM DRUG EXEMPTED UNDER CLAUSE (I) AS DOCUMENTED IN A GENERALLY ACCEPTED STANDARD MEDICAL REFERENCE.

(III) A PRESCRIPTION DRUG THAT IS USED AS AN IMMUNOSUPPRESSANT.

(IV) UNLESS THE PRESCRIPTION DRUG IS A CONTROLLED SUBSTANCE OR THE PRESCRIPTION DRUG IS BEING PRESCRIBED TO TREAT A CONDITION THAT IS EXCLUDED FROM COVERAGE UNDER THIS ACT, A PRESCRIPTION DRUG THAT IS RECOGNIZED IN A GENERALLY ACCEPTED STANDARD MEDICAL REFERENCE AS EFFECTIVE IN THE TREATMENT OF CONDITIONS SPECIFIED IN THE MOST RECENT DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS PUBLISHED BY THE AMERICAN PSYCHIATRIC ASSOCIATION. THE DEPARTMENT OR THE DEPARTMENT'S AGENT SHALL NOT DENY A REQUEST FOR PRIOR AUTHORIZATION OF A

CONTROLLED SUBSTANCE UNDER THIS SUBSECTION UNLESS THE DEPARTMENT OR THE DEPARTMENT'S AGENT DETERMINES THAT THE CONTROLLED SUBSTANCE OR THE DOSAGE OF THE CONTROLLED SUBSTANCE BEING PRESCRIBED IS NOT CONSISTENT WITH ITS LICENSED INDICATIONS OR WITH GENERALLY ACCEPTED MEDICAL PRACTICE AS DOCUMENTED IN A STANDARD MEDICAL REFERENCE.

(V) A PRESCRIPTION DRUG THAT IS RECOGNIZED IN A GENERALLY ACCEPTED STANDARD MEDICAL REFERENCE FOR THE TREATMENT OF AND IS BEING PRESCRIBED TO A PATIENT FOR THE TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS, ACQUIRED IMMUNE DEFICIENCY SYNDROME OR OPPORTUNISTIC INFECTIONS.

Section 6. Disease management.

(a) Authorization.--The Office of Administration in coordination with the corresponding departmental oversight entity shall evaluate the feasibility and fiscal impact of implementing a disease management program for Commonwealth pharmacy and preferred pharmacy programs. When appropriate, the Office of Administration shall provide for the contracting for, the implementation of and the administration of disease management programs. The contracting for the services may include the bundling of multiple Commonwealth pharmacy and preferred pharmacy programs.

(b) Program.--A disease management program shall include:

(1) A population identification process; collaborative practice models to include physicians and support-service providers; patient self-management education, including primary prevention, behavior modification programs and compliance-surveillance; process and outcomes measurement, evaluation and management; and periodic reporting, including communication with patient, physician, health plan and

ancillary providers and practice profiling.

(2) A disease management program may be established to include any of the following conditions: asthma, diabetes, mental health, congestive heart failure, chronic obstructive pulmonary disease, coronary artery disease, chronic kidney disease and high-risk pregnancies.

Section 7. Recycling.

(a) Authorization.--The Office of Administration in coordination with the corresponding departmental oversight entity shall evaluate the feasibility and fiscal impact of implementing a pharmaceutical recycling program for the redistribution of prescription drugs at health care facilities or State correctional facilities for enrollees of Commonwealth pharmacy and preferred pharmacy programs. The Office of Administration shall have the immediate authority to provide for the contracting for, the implementation of and the administration of a pharmaceutical recycling pilot program in State correctional facilities. Upon the completion of the studies provided for in subsection (f), the Office of Administration may expand the recycling program to other health care facilities. The establishment of such a program may be limited to specific classes of enrollees or specific categories of health care facilities.

(b) Program.--Each health care facility or State correctional facility may be required to return to the appropriate vendor pharmacy, for initial repackaging by that vendor pharmacy and redistribution to that health care facility or State correctional facility, prescription drug products which are suitable for redistribution. The redistribution of prescription drug products shall only occur if the products are:

(1) Not controlled substances.

(2) Sealed in individually packaged units.

(3) Returned to the vendor pharmacy at least 90 days prior to the expiration of the recommended period of shelf life for the purpose of redispensing such drug products.

(4) Oral and parenteral medication in single-dose sealed containers approved by the FDA, topical or inhalant drug products in units of use containers approved by the FDA or parenteral medications in multiple-dose sealed containers approved by the FDA from which no doses have been withdrawn.

(5) Subject to a stringent pedigree papers process which documents the product's chain of possession, when it was last repackaged, the drug product's lot number and the drug product's expiration date.

(c) Scope.--The determination of which products and facilities that may be included in the program shall include a specific costs benefit analysis for each category of health care facility and class of a pharmacy program enrollee. In order to enhance the cost-effectiveness of the recycling program and maximize patient safety, the scope of prescription drugs covered may be limited.

(d) Fees.--The program shall establish by regulation or contract an appropriate fee schedule for vendors utilized in the collection, redistribution and tracking of pharmaceuticals included within the program.

(e) Prohibition.--Nothing in this section shall require a pharmaceutical manufacturer to provide a rebate based on the reuse and redistribution of any unused drug as authorized in this section.

(f) Liability.--No pharmaceutical manufacturer shall be

liable for any claim or injury arising from the transfer of any prescription drug pursuant to the provision of this act, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

(g) Studies.--

(1) No sooner than one year after the initial implementation of the recycling pilot program authorized by subsection (a) the Office of Administration shall evaluate the fiscal impact of the pilot program and determine the feasibility of establishing such a program in other health care facilities.

(2) In conjunction with the pilot program's analysis, the Office of Administration in consultation with representatives of the pharmaceutical manufacturers and dispensing pharmacists shall provide recommendations on suggested revisions to the practices and protocols for the packaging and distribution of pharmaceuticals that could further enhance the cost-effectiveness of a recycling program.

(3) Upon the completion of the studies provided for in this section, copies of the studies shall be transmitted to the chairman and minority chairman of the Appropriations Committee of the Senate, the chairman and minority chairman of the Public Health and Welfare Committee of the Senate, the chairman and minority chairman of the Appropriations Committee of the House of Representatives and the chairman and minority chairman of the Health and Human Services Committee of the House of Representatives.

Section 8. Reporting.

No later than two years from the effective date of this act, the Office of Administration in coordination with the corresponding departmental oversight entities shall submit a report to the chairman and minority chairman of the Appropriations Committee of the Senate, the chairman and minority chairman of the Public Health and Welfare Committee of the Senate, the chairman and minority chairman of the Appropriations Committee of the House of Representatives and the chairman and minority chairman of the Health and Human Services Committee of the House of Representatives evaluating the fiscal impact of implementing the various provisions of this act and making recommendations to the General Assembly for enhancing the efficacy of this act.

Section 9. Rules and regulations.

The Office of Administration shall promulgate ~~rules and~~ regulations to administer this act. <—

Section 10. Severability.

The provisions of this act are severable. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application.

Section 11. Effective date.

This act shall take effect immediately.