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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 199 Session of 2001

INTRODUCED BY RHOADES, GERLACH, SCHWARTZ, COSTA, WENGER, KUKOVICH, TOMLINSON, MUSTO, STOUT, WAGNER, HELFRICK, LAVALLE, MADIGAN, BELL, GREENLEAF, BOSCOLA, O'PAKE AND TARTAGLIONE, JANUARY 30, 2001

REFERRED TO PUBLIC HEALTH AND WELFARE, JANUARY 30, 2001

AN ACT

Providing for a single pharmacy benefits manager to administer outpatient pharmacy services provided through the medical assistance program.

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 Medical Assistance Single Pharmacy Benefits Manager 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:

"A-rated generically equivalent drug." A drug product that the Commissioner of Food and Drugs of the Food and Drug Administration has approved as safe and effective and has determined to be equivalent as listed in "The Approved Drug Products with Therapeutic Equivalence Evaluations" (Food and

Drug Administration "Orange Book"), with a specific "A" code designation only.

"Committee" or "DURC." The Drug Utilization Review Committee created in section 5.

"Department." The Department of Public Welfare of the Commonwealth.

"DESI drug." A drug product for which Federal financial participation is not available under 42 CFR 441.25 (relating to prohibition on FFP for certain prescribed drugs).

"Experimental drug." A drug or product currently being investigated under an investigational or new drug application filed with the Food and Drug Administration to determine its safety and effectiveness.

"Licensed prescriber." A person currently licensed under the law of a state to order medication for patient treatment.

"Pharmaceutical manufacturer." A company which participates under the pharmaceutical services medical assistance program as a manufacturer of prescription drugs, insulin, insulin needles or insulin syringes.

"Pharmacy." A pharmacy licensed by the Commonwealth.

"Pharmacy benefits manager" or "PBM." An entity under contract with the Department of Public Welfare to administer the departmental program to provide outpatient pharmacy services to eligible medical assistance recipients.

"Pharmacy services." Medically necessary prescription drugs and other pharmacy services furnished directly to eligible recipients by pharmacies enrolled as providers in the medical assistance program.

"Prescription drug." A drug requiring a prescription in this Commonwealth, insulin, insulin syringes and insulin needles.

Experimental drugs or drugs prescribed for wrinkle removal or hair growth are excluded.

"Prior authorization." A procedure established by the Department of Public Welfare under which the delivery of a pharmacy service is either conditioned upon or delayed by a prior determination by the department or its agent that an eligible medical assistance recipient is eligible for a particular pharmacy service, that there is medical necessity for a particular pharmacy service or that a particular pharmacy service is suitable to a particular recipient.

"Provider." A pharmacy or licensed prescriber who has signed an agreement with the Department of Public Welfare to participate in the medical assistance program.

"Recipient." A person determined to be eligible for medical assistance pharmacy services.

"Wholesaler." A licensed person or entity within this Commonwealth which legally purchases pharmaceuticals for resale or distribution to persons other than recipients or consumers.

Section 3. Single medical assistance pharmacy benefits manager.

The department shall administer a single pharmacy benefits manager program for all eligible medical assistance recipients. To that end, no later than 90 days from the effective date of this section, the department shall issue a request for proposal for a three-year contract with a pharmacy benefits manager to administer outpatient pharmacy services for recipients. The proposal shall require the PBM to perform prospective, concurrent and retrospective drug utilization review and education of licensed providers and benefit recipients. No person, partnership, corporation or entity which holds a 5% or greater interest in one or more pharmacies, a chain of

pharmacies, a pharmacists association, an organization of pharmacies, a drug wholesaler or drug manufacturer and no person, partnership, corporation or entity in which one or more pharmacies, a chain of pharmacies, a pharmacists association, an organization of pharmacies, a drug wholesaler or drug manufacturer has a 5% or greater interest shall be considered eligible to bid. Such contract shall be executed within six months from the effective date of this section.

Section 4. Pharmacy benefits manager functions.

(a) Requirements.--The department shall require the PBM to:

(1) Develop and update a formulary of drugs with the advice of the DURC utilizing disease and care management.

(2) Manage a drug formulary.

(3) Ensure that any pharmacy licensed in this Commonwealth is eligible to provide pharmacy services in this program according to those regulations in effect on the effective date of this section regulating pharmacy providers participating in the fee-for-service program of the medical assistance program of the department.

(4) Negotiate drug rebates with manufacturers.

(5) In accordance with the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law, make provisions for generic substitutions and require pharmacists to disclose any affiliation with a generic manufacturer.

(6) Provide for prospective drug utilization review which precludes overriding alerts without intervention.

(7) Provide for prior authorization in accordance with departmental regulations.

(8) Provide for prospective and concurrent and

retrospective drug utilization review to ensure that prescriptions are appropriate, medically necessary and not likely to result in adverse medical results and to educate providers and recipients and to correct and report misutilization and abuse by licensed prescribers and recipients and provide for fraud and abuse audits, coordinating its activities with the department to support compliance with applicable laws and regulations.

(9) Educate providers on disease and care management.

(10) Provide educational materials for recipients on disease and care management.

(11) In accordance with the provisions of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508, 104 Stat. 1388), bill, recoup and relay to the department manufacturers' drug rebates and excessive consumer price inflation discounts and resolve disputes, as defined in the Omnibus Budget Reconciliation Act of 1990.

(12) Adjudicate claims through a Statewide point-of-sale electronic verification and claims processing system which will allow for intervention upon receipt of a prospective drug utilization review alert and will allow for an emergency supply of prescribed medication in the event of equipment failures.

(13) Create an audit and recoupment system for providers and recipients, and third-party medical resources.

(14) Reimburse pharmacies on a fee-for-service basis.

(15) Provide administrative support for the department's appeals process for providers and recipients.

(b) Preparation of a formulary.--The PBM, with the advice of the Drug Utilization Review Committee created in section 5,

shall prepare a formulary of drugs and, in accordance with the Generic Equivalent Drug Law, include generically equivalent drugs to be used in the pharmacy services program. In evaluating drugs for the formulary, the PBM shall consider their therapeutic efficacy and take into consideration all discounts, rebates or other concessions provided by manufacturers. The formulary must indicate that drugs will not be reimbursed if they are experimental or on the Drug Efficacy Study Implementation list (DESI) prepared by the Health Care Financing Administration. The formulary shall provide for a medical exception for a drug on the latter list upon a handwritten declaration of its necessity on the prescription by the treating prescriber.

(c) Conflict of interest.--In developing the formulary, the single PBM shall demonstrate how it will avoid a conflict of interest with any pharmaceutical manufacturer, wholesaler or drug store chain that holds a less-than-5% interest in the PBM or in which the PBM has a less-than-5% interest and shall indicate how it will prevent the sharing of nonpublic information concerning other drug manufacturers' bids, proposals, contracts, prices, rebates or discounts.

(d) Considerations.--In preparing and managing the formulary, the PBM shall ensure that it will consider all discounts, rebates or other concessions offered by manufacturers, drug chains or wholesale drug companies.

(e) Changes to the formulary.--Upon making changes to the formulary the PBM shall allow a benefit recipient to continue to receive a drug which is part of an ongoing treatment regimen for a period of up to 60 days.

Section 5. Drug Utilization Review Committee (DURC).

(a) Creation of Drug Utilization Review Committee.--The department shall require the PBM to create a Drug Utilization Review Committee.

(b) Composition and number.--The committee shall be comprised of nine members, five of whom shall be actively practicing physicians licensed in this Commonwealth and four of whom shall be actively practicing pharmacists licensed in this Commonwealth. None of the members may hold a 5% or greater interest in the PBM, its parent company or companies, or in a company or companies owned by the PBM.

(c) Quality of care.--

(1) The DURC shall develop a system that provides prospective, concurrent and retrospective review of drug utilization to ensure that pharmacy services provided are or were appropriate and medically necessary and not likely to result in adverse medical results. The review program shall be designed to educate licensed prescribers and pharmacists as provided in paragraph (4) on the proper utilization of drugs in disease and care management. In reviewing drug utilization, the committee shall assess data on drug use against predetermined standards consistent with the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, American Medical Association Drug Evaluations or peer-reviewed medical literature.

(2) The committee shall develop a system to utilize the compendia and literature referred to in paragraph (1) as its source of standards to screen for potential drug problems before a prescription is filled or delivered to a recipient. Prospective drug use review shall include consultation with

recipients by pharmacists.

(3) The department and the PBM shall provide data to the committee, through mechanized drug claims processing and retrieval systems, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse or inappropriate or medically unnecessary care among licensed prescribers, pharmacists and recipients or associated with specific drugs or groups of drugs. The committee shall, on an ongoing basis, assess data on drug use against explicit predetermined standards using the compendia and literature referred to in this subsection and to introduce, as necessary, remedial strategies to improve the quality of care and to conserve program funds or patient expenditures.

(4) The committee shall, using drug use data on common therapy problems, develop active and ongoing educational outreach programs to disseminate information to providers on common drug therapy problems with the aim of improving prescribing or dispensing practices. The educational programs shall include interventions for providers targeting therapy problems or individuals identified in the course of retrospective drug reviews. The committee shall reevaluate interventions from time to time to determine if the interventions were successful in improving the quality of drug therapy and shall make modifications as necessary. Intervention programs shall include:

(i) Information dissemination sufficient to ensure the ready availability to providers of information concerning the committee's duties, powers and basis for its standards.

(ii) Written, oral or electronic reminders containing patient-specific and/or drug-specific information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information.

(iii) Use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing or pharmacy care practices and follow-up face-to-face discussions.

(iv) Intensified review or monitoring of selected prescribers or dispensers.

(d) Corrective actions.--Should licensed prescribers or recipients continue to misutilize drugs or abuse the system, the committee shall provide information to the department for corrective action. In the case of prescribers, the committee shall submit a report and recommendations to the department for appropriate action. The department shall inform the PBM and the appropriate Commonwealth licensing body of any final administrative sanctions.

(e) Nonliability.--Any person rendering service as a member of a utilization review committee for this program shall not be liable for any civil damages as a result of any acts or omissions in rendering the service as a member of any such committee except any acts or omissions intentionally designed to harm or any grossly negligent acts or omissions which result in harm to the person receiving such service.

(f) Annual report.--The department shall require the committee to provide an annual report describing the committee's

activities, including the nature and scope of the prospective, concurrent and retrospective drug reviews, a summary of interventions used, an assessment of the impact of these educational interventions on quality of care and an estimate of the cost savings generated as a result of the program.

Section 6. Reimbursement.

(a) General rule.--The PBM shall reimburse pharmacies on a fee-for-service basis, using formulas established by departmental regulation. Pharmacies reimbursed under this act shall be paid at fee-for-service rates no less than the rates in effect on the effective date of this act. Pharmacies shall be paid within 21 days of the PBM's receipt of appropriate substantiation of the transaction. Pharmacies shall be entitled to interest at a rate approved by the department for any payment not made within the 21-day period. The department shall not reimburse the PBM for interest paid.

(b) Copayments.--Except for services which are excluded under the Commonwealth's medical assistance program, a recipient is liable for a copayment in an amount set by the department, and collection of the copayment by pharmacies shall be mandatory. The amount of the copayment paid to pharmacy providers by recipients shall be deducted from the Commonwealth's medical assistance fee to pharmacy providers.

Section 7. Administration by department.

(a) Administration of contract.--The department shall administer the contract with the PBM and shall promulgate rules and regulations, as necessary, to carry out the provisions of this act.

(b) Provision of data.--The department and the PBM shall provide data necessary to the committee to develop provider

prescribing profiles and recipient utilization profiles to perform utilization review and disease and care management through the coordination of health care and pharmacy services to ensure that recipients are receiving and complying with appropriate therapies.

Section 8. Studies required.

(a) Selection of contractor.--The department shall select a competent contractor to analyze and compare expenditures, utilization rates and utilization patterns for pharmacy services for medical assistance recipients in the managed care plans under current contracts with the department and in the single pharmacy benefits management program established under this act. To effectuate the purposes of this act, all participating pharmacy providers, manufacturers, drug chains and wholesalers shall, as a condition of participation, be required to cooperate with the department in preparing the required report. The department shall report preliminary findings to the President pro tempore of the Senate and the Speaker of the House of Representatives by September 30, 2003. The department shall report finally on June 30, 2004. That report shall include recommendations to the General Assembly on whether to continue the single medical assistance pharmacy benefits manager program which shall terminate on December 31, 2004.

(b) Report.--The Legislative Budget and Finance Committee shall evaluate and prepare a report to be submitted no later than June 30, 2004, to the General Assembly on the single pharmacy benefits manager selected under this act.

Section 9. Applicability.

This act shall apply to the provision of all pharmacy benefits under the medical assistance program to eligible

recipients by any managed health care plan, pharmaceutical manufacturer, licensed pharmacy, chain of pharmacies or wholesaler.

Section 10. Prohibited activities.

It shall be unlawful for any individual, partnership or corporation to solicit, receive, offer or pay any kickback, bribe or rebate in cash or in-kind from or to any person in connection with the furnishing of services under this act.

Section 11. Repeals.

All acts and parts of acts are repealed insofar as they are inconsistent with this act.

Section 12. Effective date.

This act shall take effect in 60 days.