RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

COAL AND CLAY MINE SUBSIDENCE INSURANCE BOARD

[25 PA. CODE CH. 401]

Corrective Amendment to 25 Pa. Code § 401.13

The Department of Environmental Protection has discovered a discrepancy between the agency text of 25 Pa. Code § 401.13 (relating to coverage limits and premiums for insurance) as deposited with the Legislative Reference Bureau, and the official text published at 35 Pa.B. 2628, 2630 (April 30, 2005) and as currently codified in the *Pennsylvania Code*. Subsections (c) and (d) were rescinded and should not have been printed.

Therefore, under 45 Pa.C.S. § 901: The Department of Environmental Protection has deposited with the Legislative Reference Bureau a corrective amendment to 25 Pa. Code § 401.13. The corrective amendment to 25 Pa. Code § 401.13 is effective as of April 30, 2005, the date the defective text was printed in the *Pennsylvania Bulletin*.

The correct version of 25 Pa. Code § 401.13 appears in Annex A.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART III. COAL AND CLAY MINE SUBSIDENCE INSURANCE BOARD

CHAPTER 401. MINE SUBSIDENCE FUND

INSURANCE POLICIES

§ 401.13. Coverage limits and premiums for insurance.

(a) The maximum amount of insurance for a single covered structure, the term or duration of the policy, and the premium rate shall be determined by the Board.

(b) An insurance policy is effective upon the date a complete application is received by the Board or its agent provided the premium associated with that application is received by the Board or its agent within the next 80 days and provided that the applicant and structure meet the eligibility requirements in the act and in § 401.11 (relating to eligibility for insurance).

[Pa.B. Doc. No. 05-1477. Filed for public inspection August 5, 2005, 9:00 a.m.]

Title 55—PUBLIC WELFARE

DEPARTMENT OF PUBLIC WELFARE

[55 PA. CODE CHS. 1101, 1121 AND 1150]

Revisions to Pharmaceutical Services Payment Methods, General Assistance Pharmacy Benefits, Payment Levels and Rate Setting Notification

The Department of Public Welfare (Department), under the authority of sections 201(2), 403(b), 443.4 and 454 of the Public Welfare Code (code) (62 P. S. §§ 201(2), 403(b), 443.4 and 454), as amended by the act of July 7, 2005 (P. L. 177, No. 42) (Act 42), amends Chapters 1101, 1121 and 1150 (relating to general provisions; pharmaceutical services; and MA program payment polices) to read as set forth in Annex A.

Omission of Proposed Rulemaking

Act 42 amended the code by adding section 454. Section 454 of the code specifies that until December 31, 2005, notwithstanding any other provision of law, the Department must promulgate regulations to establish benefit packages for adults eligible for Medical Assistance (MA) in General Assistance (GA)-related categories and provider payment rates under section 204(1)(iv) of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. § 1204(1)(iv)), known as the Commonwealth Documents Law (CDL). That section authorizes an agency to omit or modify notice of proposed rulemaking when the regulation relates to Commonwealth grants or benefits. In addition, section 454 of the code expressly exempts regulations for GA-related benefit packages and provider payment rates from review under the Regulatory Review Act (71 P. S. §§ 745.1—745.15), and from review by the Attorney General under section 205 of the CDL (45 P. S. § 1205) and section 204(b) of the Commonwealth Attorneys Act (71 P. S. § 732-204(b)). Finally, section 454(a) and (b) of the code provides that the regulations specify the effective date for provider payment rates.

The Department is adopting this final-omitted rulemaking in accordance with section 454 of the code because the amendments pertain to the benefit package for GA-related recipients and provider payment rates. The final-omitted rulemaking also provides for the effective date for the provider payment rates.

Purpose

The purpose of this final-omitted rulemaking is to:

1. Amend the current MA fee-for-service (FFS) payment methodology in Chapter 1121 for the drug cost component of brand name drugs. The Department will establish the Estimated Acquisition Cost (EAC) for the brand name drugs as follows:

(i) The lowest wholesale acquisition cost (WAC) listed for the drug in available Nationally recognized pricing services, plus 7%.

(ii) If WAC data for the drug are not available from a Nationally recognized pricing service, the lowest average wholesale price (AWP) listed for the drug in available Nationally recognized pricing services, minus 14%.

(iii) If both WAC and AWP cost data are available for the drug from a Nationally recognized pricing service, the lower of the two amounts.

2. Amend the current MA FFS payment methodology in Chapter 1121 for the drug cost component of generic drugs. The Department will establish the EAC for the generic drugs as follows:

(i) The lowest WAC listed for the drug in available Nationally recognized pricing services, plus 66%.

(ii) If WAC data for the drug are not available from a Nationally recognized pricing service, the lowest AWP listed for the drug in available Nationally recognized pricing services, minus 25%.

(iii) If both WAC and AWP cost data are available for the drug from a Nationally recognized pricing service, the lower of the two amounts.

3. Amend the current MA pharmacy benefit package for GA-related recipients who are eligible for the pharmacy services in Chapter 1121 to permit payment for over-the-counter (OTC) medications when the Department determines that the OTC medication is the preferred medication within a therapeutic class.

4. Amend the current payment level and public notice requirements for announcing changes to Statewide methods and standards for setting payment rates in Chapters 1101 and 1150 to reflect current Federal requirements.

Background

The Pennsylvania MA Program assures the availability of a wide array of medically necessary health care services, supplies and equipment to approximately 1.8 million indigent and disabled persons. Prescription drugs are among the health care services that the Commonwealth has opted to include in the MA benefit package. The prescription drug benefit contains two types of drugs: 1) drugs available from only one manufacturer that holds or held the patent for the drug, commonly referred to as brand name drugs; and 2) drugs available from multiple manufacturers and distributors, commonly referred to as multisource drugs. A multisource drug typically includes both the brand name and the generic versions of the drug.

Under Federal law, the drug cost component of pharmacy reimbursement is based on the EAC, which is defined as the state Medicaid "agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of the drug most frequently purchased by providers." See 42 CFR 447.301 (relating to definitions). Since 1995, the Department has calculated the EAC for all drugs at the lower of AWP minus 10% and has paid the lower of the EAC or the State Maximum Allowable Cost (MAC) plus a $4 dispensing fee. See §§ 1121.55 and 1121.56 (relating to method of payment; and drug cost determination). Yet the MA program continues to have one of the highest payment rates for prescription drugs in this Commonwealth. The Pharmaceutical Assistance Contract for the Elderly (PACE) Program is the only publicly funded prescription drug program in this Commonwealth whose payment rates for drugs are as generous as those of the MA Program. The payment rates established by the Pennsylvania Employee Benefits Trust Fund and nearly all of the commercial third-party prescription drug programs in this Commonwealth, as well as the HealthChoices managed care organizations (MCOs) under contract to the Department to provide services to some 65% of the MA population, are significantly lower than those in the FFS delivery system.

States across the country are struggling to maintain their Medicaid programs as health care costs are increasing at a faster rate than state revenues, while the caseload of persons eligible for the program continues to grow. Rising drug costs play a major, if not the primary, role in escalating Medicaid costs. All three of these trends are affecting the Pennsylvania MA Program. The MA Program caseload is projected to increase by 5.9% in State Fiscal Year (SFY) 2005-2006. MA costs for the SFY are projected to increase by 6.7% while projected State revenues for the same period are projected to increase by only 2.8%. Expenditures for pharmaceutical services increased from $730,090,896 in calendar year 2002 to close to $1 billion in calendar year 2004, an increase of almost 37%.

The MA Program has responded to these challenges by aggressively improving the management of the MA Program's drug benefit. For example, the program has:

1. Issued a Request for Proposals to implement a preferred drug list (PDL) in SFY 2005-2006 designed to increase the use of the most cost-effective drugs within a drug class and enable the Department to collect supplemental rebates from drug manufacturers.

2. Implemented a disease management program for recipients with chronic diseases as part of its new ACCESS Plus Program, the primary care case management program expanded in March 2005 to include MA recipients 21 years of age and older in counties that are not included in HealthChoices, the Department's mandatory managed care program.

3. Increased the use of prior authorization (PA) to minimize the use of unnecessary drug regimens.

4. Instituted a Statewide pharmacy auditing program to insure the appropriate dispensing of drugs.

5. Improved the calculation of the EAC of drugs by basing the EAC on the lowest AWP listed in any of the Nationally recognized pricing services, rather than just one pricing service.

Each of these initiatives is designed to enhance the efficiency and cost-effectiveness of the program while maintaining access to quality care for MA recipients. Notwithstanding the savings associated with the success of these initiatives, in the face of ever-skyrocketing pharmacy expenditures, the Department cannot ignore the trends occurring in other State Medicaid programs and private third-party plans or the payment rates accepted by pharmacies in this Commonwealth, which show that the Department's pharmacy payment rates for both brand name and generic drugs are higher than those of virtually any other payor in this Commonwealth and many comparable Medicaid programs.

In setting payment rates for pharmacy services in the MA Program, the Department seeks to assure that high quality pharmacy services are available to MA recipients to the same extent as to the general population in the same geographic area at the best possible price. As a prudent buyer of medical care for its recipients, the Department must be able to obtain rates similar to those extended to other third-party payors and other state Medicaid agencies. Pharmacy providers generally complain that the lower payment rates offered by third-party payors are unfair to them and have an adverse impact on recipient access. The pharmacy industry has on two occasions in the past voiced a similar complaint to the Department, predicting that reduced payment rates would restrict recipient access and diminish the quality of care on two occasions: in 1995, when the Department revised the pharmacy payment methodology from AWP to AWP minus 10% and again in 1998 when the HealthChoices MCOs lowered their pharmacy payment rates to below AWP minus 10%. At neither time did the revised payment rates result in less access for MA recipients to pharmacy services of high quality anywhere in the State; they certainly did not result in less access than that enjoyed by the general public.

For all of these reasons, the Department is revising the EAC for both brand name and generic drugs. The Department also intends to revise the method for determining the MAC for multisource drugs but has delayed implementation of a revised State MAC after receiving comments in response to the public notice published at 35 Pa.B. 3268 (June 4, 2005) to allow for additional public

comment on the proposed MAC methodology. The dispensing fee of $4 for both brand name and generic drugs will remain the same.

Brand Name Drugs

In the public notice published at 35 Pa.B. 3268, the Department announced its intent to revise its calculation of the drug cost component of brand name drugs both by basing the EAC on the WAC when it is available, rather than relying only on the AWP for the drug, and by increasing the discount off AWP from 10% to 15%. Since publication of the public notice and in partial response to objections from pharmacy providers to the proposed methodology, the Department decided to modify the payment methodology for brand name drugs from that proposed in the public notice. The upward adjustment is intended to address the pharmacists' concerns but enable the Department to continue to meet its goal of operating an efficient and economical pharmacy benefit program that affords MA recipients access to quality care.

Having considered the comments received in response to the public notice, the Department will revise the payment rates for the drug cost component of brand name drugs to be either the lowest WAC listed for the drug in available Nationally recognized pricing services, plus 7% or, if WAC data for the drug are not available from a Nationally recognized pricing service, the lowest AWP listed for the drug in available Nationally recognized pricing services, minus 14%. In addition, consistent with its existing policy of availing itself of the best price listed in any of the Nationally recognized pricing services, which are currently First Data Bank, Medi-Span and Micromedix, if both WAC and AWP data are available for a drug, the Department will calculate the EAC using the lower of the two amounts.

This final-omitted rulemaking aligns the payment methodology for brand name pharmaceuticals in the FFS delivery system with the payment methodology adopted by other third-party prescription plans and MCOs throughout this Commonwealth, in addition to the payment methodologies of comparable state Medicaid programs. Each of these payors base their pharmacy payment rates on a discounted AWP significantly deeper than AWP minus 10% and pay a dispensing fee considerably lower than $4. For example, HealthChoices MCOs are currently paying between AWP minus 14% and AWP minus 16% for brand name drugs, plus a dispensing fee that ranges from $1.50 to $2. The weighted average of the MCOs' payment rates is AWP minus 15.22%. Rate information from 58 private prescription plans shows similar discounts from AWP: 24% of the plans discount AWP by 13%; 14% of the plans discount AWP by 14%; 19% of the plans discount AWP by 15%; and 19% of the plans discount AWP by 16%. Fifty of these private prescription plans pay a dispensing fee of $2.75 or less per prescription.

The MA Program is not the only state Medicaid program that has recognized the need to reassess the drug cost component of its pharmacy payment methodology to address not only the appropriate payment rate but the basis on which to calculate the drug cost. Most third-party payors and state Medicaid programs have historically based the calculation of the drug cost component on AWP, which is the price assigned to a drug by its manufacturers and compiled by the various drug pricing services. More recently, state Medicaid programs in particular have started using WAC to calculate their EACs. As the cost at which wholesalers purchase drug products from manufacturers, WAC is considered to be a more accurate gauge of the actual cost of the drug products.

Other state Medicaid programs comparable to the MA Program in size and scope or bordering this Commonwealth have lowered their EACs and abandoned use of AWP as the sole basis for determining drug costs, using WAC either as the only basis for determining drug costs or as a companion basis along with AWP. States that use WAC include Florida, Massachusetts, Maryland, Texas, Ohio and Rhode Island. In Massachusetts and Rhode Island, WAC is the sole basis for determining the EAC. Specific examples of rates paid by other State Medicaid programs for brand name drugs are:

Florida—the lower of WAC plus 5.75% or AWP minus 15.45% plus a $4.23 dispensing fee.

Maryland—the lower of WAC plus 12% or AWP minus 12% plus a $2.69 dispensing fee.

Texas—the lower of WAC plus 12% or AWP minus 15% plus a $5.14 dispensing fee.

Ohio—the lower of WAC plus 9% or AWP minus 12.8% plus a $3.70 dispensing fee.

Massachusetts—WAC plus 5% plus a $3.50 dispensing fee.

Rhode Island—WAC plus 5% plus a $3.40 dispensing fee.

Illinois—AWP minus 12% plus a $3.40 dispensing fee.

Michigan—AWP minus 13.5% for pharmacies owning one to four stores and AWP minus 15.1% for pharmacies owning five or more stores and for pharmacies solely serving patients in long-term-care facilities, plus a $2.50 dispensing fee.

New York—AWP minus 12% plus a $3.50 dispensing fee.

Virginia—AWP minus 10.25% plus a $3.75 dispensing fee.

Delaware—AWP minus 14% plus a $3.65 dispensing fee.

West Virginia—AWP minus 12% plus a $3.90 dispensing fee.

The Department's revised EAC for brand name drugs, together with the $4 dispensing fee, is well within the range of pharmacy payment rates of these other state Medicaid programs, which have been approved by the Centers for Medicare and Medicaid Services (CMS).

Several studies conducted in recent years confirm that the reduced payment rates offered by both private third-party payors and state Medicaid agencies more accurately reflect the prices that pharmacies pay for drugs. Of particular note regarding the cost of brand name drugs is the series of reports issued by the Office of Inspector General (OIG) of the United States Department of Health and Human Services beginning in 1997. The first report, issued in April 1997, was entitled "Medicaid Pharmacy—Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs" (Report No. A-06-96-00030). From a randomly selected sample of ten states (California, Delaware, Florida, Maryland, Missouri, Montana, Nebraska, New Jersey, North Carolina and Virginia) and the District of Columbia, the OIG analyzed the actual invoice price of brand name drugs for four categories of pharmacies, including rural-chain, rural-independent, urban-chain and urban-independent pharmacies. Combining the results of its analysis of the four categories of pharmacies, the OIG

estimated that pharmacies' actual acquisition cost for brand name prescription drugs was a National average of AWP minus 18.3%.

In August 2001, the OIG issued the results of another study, entitled "Medicaid Pharmacy—Actual Acquisition Costs of Brand Name Prescription Drug Products" (Report No. A-06-00-00023), which reviewed an eight-state sample (Montana, Florida, Colorado, Indiana, Texas, Washington, West Virginia and Wisconsin) of the same types of pharmacies as in the 1997 study, plus "nontraditional pharmacies" (that is, nursing home pharmacies and hospital pharmacies). The nontraditional pharmacies were sampled separately. The OIG estimated that Nationally, the invoice price for brand name drugs was an average of 21.84% below AWP for traditional pharmacies and 31.18% below AWP for nontraditional pharmacies.

In September 2002, the OIG issued a follow-up report to the August 2001 study entitled "Medicaid Pharmacy—Additional Analysis of the Actual Acquisition Cost of Prescription Drug Products" (Report No. A-06-02-00041). In this study, the OIG reviewed not only brand name drugs, but also all drugs without Federal upper limits, multisource drugs without Federal upper limits and multisource drugs with Federal upper limits. The OIG estimated that pharmacies were able to purchase brand name drugs at an average of 17.2% below AWP, and all drugs without Federal upper limits at an average of 27.2% below AWP.

In addition to the reports issued by the OIG, Pricewaterhouse Coopers (PwC) released a pharmacy services study in November 1998 which it conducted for the Department and the Department of Aging at the direction of the General Assembly by the act of June 12, 1996 (P. L. 337, No. 53) (Act 53), codified in section 2313-A of The Administrative Code of 1929 (71 P. S. § 581-13). The purpose of the study, as prescribed by the General Assembly, was to "determine the full cost of filling a prescription and providing pharmacy services, including reasonable profits, in the Pennsylvania Medicaid and PACE programs."

The authors of the PwC study concluded that the existing MA payment rates did not place independent pharmacies at a disadvantage in relation to the cost of acquiring drugs. Although the study estimated that pharmacy net income for dispensing MA FFS claims in 1997 was minus 1¢ per claim or −0% of acquisition costs, the estimate did not reflect additional income pharmacies receive from manufacturers in the form of rebates and discounts as well as the sale of nonprescription items. The study noted that third-party payors, other than state Medicaid programs at the time, paid AWP minus 12% to 14% for most brand name drugs.

The conclusion that emerges from all of these studies, as well as a study by the Congressional Budget Office, released December 1, 2004, is that the Department is currently paying more than it costs providers to buy brand name drugs. In discharging its obligation to set payment rates for brand name drugs at a level that will maximize the efficient and economical operation of the MA Program while maintaining recipient access to quality pharmacy services, the Department has considered the concerns expressed by pharmacies that current payments for pharmacy services nonetheless do not reflect the "costs" they incur in providing those services. The Department has also taken into account the previously noted studies and reports and their review of drug costs and the "profitability" of providing services, as well as the need to account for rebates, discounts, manufacturer's promotions and the mix of prescriptions by payor, along with the profitability from total pharmacy revenues such as nonprescription sales. Given the price ranges reflected in the studies, and taking into account the providers' claims relating to the costs of providing services, the Department believes that its decision to pay for brand name drugs at the lower of WAC plus 7% or AWP minus 14% with no reduction in the dispensing fee per prescription is consistent with its duty to assure that MA recipients have access to quality pharmacy services at rates that compare most favorably with those of other major payors, both public and private, of pharmacy services.

Generic Drugs

Generic versions of brand name drugs are reviewed and approved by the United States Food and Drug Administration (FDA). The FDA uses the same strict guidelines and inspections to evaluate and approve both generic and brand name drugs. Generic drugs that meet the same standards for strength, quality and purity as the brand name drugs are given an "A rating" by the FDA and are considered to be equivalent to the brand name counterparts. Generically equivalent drugs contain the same active ingredients and come in the same strengths and dosage forms as the brand name counterparts. Therefore, the FDA assures that all "A-rated" generically equivalent drugs can be substituted for the brand name drug with the full expectation that the generic product will produce the same clinical effect and safety profile as the brand name product.

The Department has to date established the same EAC for brand name and generic drugs, subject only to the maximum allowable cost, or State MAC, established by the Department. See § 1121.55(c). The State MAC is currently comprised of: 1) multisource drugs for which the Federal government has established a Federal upper limit as set forth in 42 CFR 447.332(a) (relating to upper limits for multiple source drugs); and 2) several other multisource drugs that do not have Federal upper limits. See § 1121.56(d).

Many A-rated generically equivalent drugs have become available in the market place for brand name drugs for which the Federal government has not yet assigned a Federal upper limit and the Department has not yet established a baseline price. Therefore, no State MAC has been established and the Department has been paying for these drugs at the rate of AWP minus 10%, rather than a rate that more accurately reflects the reported cost of the drug. For example, in its 2002 report previously discussed, the OIG concluded that pharmacies were able to purchase multisource drugs without Federal upper limits at an estimated discount of 44.2% below AWP and multisource drugs with Federal upper limits at an estimated discount of 72.1% below AWP. By not calculating a different EAC for generic drugs based on the actual costs of the generic drug, the Department has not taken full advantage of all the generic savings that exist in the current market place.

Other State Medicaid programs as well as private and public third-party payors in this Commonwealth have also begun to adopt separate EACs for generic drugs in addition to their MACs. For example, Arkansas, Colorado, Connecticut, Illinois and Kansas have adopted generic EACs ranging from AWP minus 20% to AWP minus 40%. All of these EACs have been approved by the CMS. MCOs under contract with the Department have adopted EACs for generic drugs ranging from AWP minus 15% to AWP minus 40%, depending on the drug. MCOs in this Commonwealth that participate in the Children's Health

Insurance Program have likewise adopted EACs for generic drugs, ranging from AWP minus 55% to AWP minus 30%.

After reviewing the emerging generic pricing methodologies of other state Medicaid programs and public third-party payors in this Commonwealth, the Department will revise its payment methodology for the drug cost component of generic drugs to establish a separate EAC for those drugs as proposed in the public notice published at 35 Pa.B. 3268, as follows: the lowest WAC listed for the drug in available Nationally recognized pricing services, plus 66% or, if WAC data for the drug are not available from a Nationally recognized pricing service, the lowest AWP listed for the drug in available Nationally recognized pricing services, minus 25%. As with the brand name EAC and consistent with its existing pricing policy, if both WAC and AWP data are available for a drug, the Department will calculate the EAC using the lower of the two amounts. Together with the revisions to the State MAC methodology that the Department has proposed to make in the near future, this amendment not only aligns the Department's payment methodology for generic drugs with those of other public payors but also more closely approximates the reported cost of generic drugs, thereby enabling the Department to afford MA recipients access to generic drugs at the best possible price.

GA Pharmacy Benefit Package

The MA Program currently limits the pharmacy benefit package for GA recipients who are eligible for pharmacy benefits. One limit is that OTC medications, with the exception of insulin, are not covered for these eligibility groups. This restriction was imposed as part of a Stipulation of Settlement approved by the United States District Court for the Eastern District of Pennsylvania in *Felix v. Casey* No. 92-CV-7376 (E.D. Pa.). See 23 Pa.B. 4585 (September 25, 1993).

As previously noted, the Department has begun to require PA of specified drugs within a therapeutic class, while other drugs within the same therapeutic class do not require PA (preferred drugs). In some cases, the preferred drugs are OTC medications. The Department is revising the coverage preclusion of OTC medications for GA recipients to permit coverage of OTC medications that the Department identifies as preferred drugs. This amendment will enable the Department to take advantage of the cost savings associated with the PA enhancements and extend to eligible recipients the benefits of preferred drugs that are OTC medications.

Payment Level and Public Notice of Rate-Setting Changes

Finally, the Department is amending outdated public notice requirements to conform to current corresponding Federal requirements. Section 1101.70 referred to 42 CFR 447.205 (relating to public notice of changes in Statewide methods and standards for setting payment rates) as requiring 60-day public notice of proposed Statewide changes in methods or levels of MA payment in certain circumstances and subject to certain conditions. Section 1101.70 merely recites the Federal requirements in effect at the time that regulation was promulgated. Since then, the Federal regulation has been amended to remove any reference to the timing of the public notice, but the Department has not amended its regulation to conform to the Federal amendment. The Department is rescinding § 1101.70 and amending § 1150.62 (relating to payment levels and notice of rate-setting changes) to reflect the current Federal requirement. The Department is also amending § 1150.62 to delete provisions that are duplicative of current Federal requirements regarding payment levels.

Requirements

Section 1101.21 (relating to definitions) is amended to add a definition of "GA—General Assistance." Section 1101.70 is rescinded. Section 1121.2 (relating to definitions) is amended to add definitions of "CMS," "CMS multisource drug," "EAC," "generic drug," "pricing service" and "WAC," to remove the definition of "Department's pricing service," "HCFA" and "HCFA multisource drug" and to make conforming amendments to the definitions of "AWP," "BaseLine price" and "Federal upper limit." Section 1121.11 (relating to types of services covered) is amended to provide coverage for OTC medications for GA recipients eligible for the pharmacy benefit when the Department has identified the OTC medication as the preferred drug in a therapeutic class. Section 1121.24 (relating to scope of benefits for GA recipients) is amended to revise the scope of benefits for GA recipients consistent with the amendment to § 1121.11. Section 1121.53 (relating to limitations on payment) is amended to replace the reference to "HCFA" and to replace the term "reimbursement formula" with the term "payment formula." Section 1121.56 is amended to revise the methodology for calculating the EACs for brand name and generic drugs and to make conforming amendments. Section 1150.62 is amended to conform to current Federal requirements.

Affected Individuals and Organizations

Pharmacies and other providers that dispense prescription drugs to MA recipients will be affected by this final-omitted rulemaking, which revises the drug cost payment methodology for brand name and generic drugs. GA recipients eligible for the MA Program pharmacy benefit will be affected by this change, which provides additional coverage for OTC medications under certain conditions.

Accomplishments and Benefits

This final-omitted rulemaking aligns the Department's pharmacy payment rates within those of other private third-party payors in this Commonwealth as well as comparable or contiguous State Medicaid programs, thereby enabling the MA Program to take advantage of all available pharmacy pricing opportunities and potential savings while maintaining MA recipient access to medically necessary drugs. The final-omitted rulemaking also expands coverage for GA recipients by allowing payment for certain OTC medications, which has the dual benefit of enabling the Department to realize additional efficiencies while affording GA recipients access to previously noncovered drugs. Finally, the payment level and notice provisions conform the Department's regulations to Federal requirements.

Fiscal Impact

The revised payment methodology for brand name and generic drugs will result in reduced payments to pharmacies enrolled in the MA Program. The Commonwealth will realize $35.256 million ($16.213 million in State funds) in savings in Fiscal Year 2005-2006. The coverage of certain OTC medications for GA recipients will have no net fiscal impact. The revised payment level and notice provisions will have no fiscal impact.

Paperwork Requirements

No new or additional paperwork requirements result from the adoption of this final-omitted rulemaking.

Public Process

The Department published an advance public notice at 35 Pa.B. 3268 announcing its intent to revise the payment methodology for both brand name drugs and generic drugs. The Department invited interested persons to comment on the proposed changes. Only 24 commentators, including 4 trade associations and 4 members of the House of Representatives, responded to the Department's invitation to comment.

Before publishing the public notice, the Department presented a copy of the proposed rulemaking package to implement the revised EAC for both brand name and generic drugs as well as the State MAC pricing methodology for multisource drugs at the Medical Assistance Advisory Committee (MAAC) meeting on December 9, 2004. In addition, the Department discussed the revised payment methodology for both brand name and multisource drugs at the MAAC meeting on February 24, 2005, and shared an advance copy of the public notice announcing the proposed revision to the pharmacy payment methodology for brand name and multisource drugs at the May 26, 2005, MAAC meeting. The Department received no comments from the MAAC.

The Department considered all comments received in response to the advance public notice and has delayed implementation of the revised State MAC methodology to allow additional opportunity for public comment. The Department also revised the calculation of the EAC for brand name drugs from that proposed in the public notice.

Discussion of Comments

Following is a summary of the comments received within the public comment period following publication of the public notice and the Department's response to the comments.

Comment

Several commentators objected to the changes in the payment methodology because they claimed the Department has not conducted the study of the cost of dispensing medications to MA recipients required by Act 53. Several of these commentators claimed that because no study has been conducted, the Department does not know whether the revised payment rates allow for a "fair and reasonable profit," which they contend is required by Act 53. Another commentator acknowledged that the Department had conducted the study but advocated for an updated study before any changes are made to the payment methodology. Without alluding to the previous study, a different commentator also recommended that the Department conduct a study.

Response

As previously discussed, together with the Department of Aging, the Department did commission a study as directed by the General Assembly in Act 53, which was conducted by PwC. The PwC study was the second study that the Department contracted to conduct, after the author of the first study informed the Department of Aging that the "study's limitations are such that the findings cannot, should not, be used as the basis for any aspect of pharmacy reimbursement" and that the "report and results should not be released, or used in any fashion, other than design and methodological lessons."

The Department disagrees that Act 53, or any other provision of State or Federal law, requires that pharmacy payment rates allow for a "fair and reasonable profit." Rather, Act 53 required only that the study include consideration of reasonable profits. It did not impose an independent obligation to set payment rates at a level that would afford providers the opportunity to profit from publicly funded programs. A Federal appellate court has similarly concluded that the Department's payment rates do not have to account for costs, much less profit. The Department also disagrees that another study is necessary, in light of the OIG reports previously discussed, which show that the Department's current payment rates are higher than the cost of both brand name and generic drugs.

Comment

A few commentators expressed concern that the changes in the pharmacy pricing methodology for brand name and generic drugs might result in a decrease in the number of pharmacies available to provide quality services to MA recipients, but only one commentator stated that it would be unwilling to serve MA recipients if the payment rates are changed.

Response

As previously discussed, the revised pharmacy payment methodology brings the MA FFS pharmacy payment rates in line with the payments rates of the HealthChoices MCOs, private third-party payors and other state Medicaid programs. Moreover, the studies previously discussed support the conclusion that pharmacies obtain prescription drugs at costs well below the Department's current payment rates. At the same time, experience shows that MA recipients continued to enjoy access to pharmacy services when the Department revised its payment rates in 1995 and when the HealthChoices MCOs further reduced their payment rates in 1998. Because the revised payment rates compare favorably to the payment rates offered by private payors in this Commonwealth as well as comparable public payors throughout the country, and in light of the past experience when payment rates were decreased, the Department is confident that its revised pharmacy payment rates will maintain access to quality pharmacy services for MA recipients at the same level as that of the general public.

Comment

Several commentators noted that dispensing drugs to MA recipients can be more expensive than dispensing to the general public because of the distinctly different challenges inherent to a provider in the MA Program, specifically that MA recipients often tend to have more complicated illnesses, linguistic and literacy problems and require more cognitive services from the pharmacist.

Response

The Department recognizes that many MA recipients, due to issues of poverty, community and family resources and complex health issues, may require additional provider resources. These needs affect pharmacies in this Commonwealth and other states. As previously discussed, the revised payment rates are consistent not only with those of private third-party payors in this Commonwealth but also with comparable state Medicaid programs. At the same time, the Department's dispensing fee remains higher than those of private third-party payors and the HealthChoices MCOs.

In recognition of the complexity of the health issues that many MA recipients face and to assist them to better manage those issues and to enhance access to services, in March 2005, the Department expanded the Family Care Network, a primary care case management program, to include adults. This program, known as ACCESS Plus,

not only provides a medical home to MA recipients who previously did not have one, but also offers a voluntary disease management program for MA recipients who have asthma, diabetes, chronic obstructive pulmonary disease, coronary artery disease or congestive heart failure. The ACCESS Plus case managers and disease managers are available to act as partners with the pharmacists in managing the health status of MA recipients.

Comment

Several commentators complained that while pharmacy operating costs, including overhead and actual drug costs, are increasing, the Department is proposing to pay pharmacies less. Two commentators expressed the opinion that the Department's dispensing fee is too low, with one of these commentators recommending that the dispensing fee should increase if the payment rates for drug costs are decreased.

Response

The Department has an obligation to be a prudent purchaser of health care services. As previously discussed, the Department continues to rank among the highest payors of drugs. The revised payment methodology aligns the Department's pharmacy payment rates with those of private payors in this Commonwealth, as well as state Medicaid programs, and more accurately reflects the price that providers pay for drugs. The Department has maintained the dispensing fee at $4, which is higher than those of private payors and comparable to those of other State Medicaid programs.

Comment

Several commentators objected to the revised payment rates because they claimed that the Department changed the method for calculating the AWP in January 2005, which also resulted in lower payments to pharmacies.

Response

Since January 2005, the Department bases its calculation of the EAC on the lowest AWP listed for the drug in all of the Nationally recognized pricing services, rather than limiting its calculation to the AWP listed in one pricing service. As these prices are the prices reported by the wholesalers to the pricing services and made available to the Department, it is prudent, appropriate and consistent with its regulations for the Department to use them. Although basing the drug cost determination on the lowest AWP reported in the National pricing services might have resulted in decreased payments to pharmacies for some drugs, the Department is obligated to administer the MA program efficiently and economically. The Department would be remiss in this obligation if it did not avail itself of the base AWP price reported by wholesalers to any of the pricing services. For the same reasons, the Department cannot ignore that even after using the AWP data available in all Nationally recognized pricing services to establish the EAC, its current payment rates are considerably more generous than those of other third-party payors and other State Medicaid programs and considerably higher than the prices providers pay for the drugs.

Comment

Several commentators, including three legislators, raised concerns regarding the use of the public notice process to revise the pharmacy payment methodology rather than following the standard regulatory process. Two commentators complained that the public notice did not explain in sufficient detail the revised method for determining the State MAC for multisource drugs.

Response

Rather than implementing the payment methodology for both brand name and generic drugs by publication of public notice, the Department is proceeding with this final-omitted rulemaking under an expedited process, as directed by the General Assembly in Act 42. The Department believes that the public notice published at 35 Pa.B. 3268 complies with both State and Federal law requirements. In addition, both commentators who complained about the insufficient detail had actual notice of the proposed State MAC revision through participation at the MAAC meetings at which the Department presented and discussed the proposed amendment. Nonetheless, the Department has delayed implementation of the revised method for determining the State MAC to allow for additional public comment in response to a public notice published at 35 Pa.B. 4264 (July 30, 2005).

Comment

Some commentators complained that the administrative requirements in the MA Program are greater than in private third-party plans, such as the use of multiple forms, the timeframe for payment and stringent audits and investigations. Others raised concerns as to the effect of the revised payment rates in light of the recent additional or proposed administrative efficiencies and cost-saving measures instituted by the Department. These measures include PA requirements for additional drugs, the proposal to establish a PDL, the proposal to limit the number of authorized prescriptions per month and the proposal to increase recipient copayments. At the same time, one commentator acknowledged the legitimate cost savings to be realized through PA of high-use drugs, one commentator recommended a PDL, two commentators supported limits on the number of monthly authorized prescriptions and one commentator recommended increased recipient copayments as well as increased use of generic drugs.

Response

Regarding the general concern over the number of Department forms and bulletins, with the implementation of the PROMISe claims processing system in March 2004, all pharmacy claims are billed on-line at the point of sale. Unlike most other MA providers, pharmacies receive immediate confirmation of the approval of the claim or notification of the information needed to complete the adjudication of the claim. The Department has also moved to the use of a Internet-based program, which affords all providers, including pharmacies, online access to information and provider billing guides, thereby further minimizing paperwork requirements.

Regarding the complaints about the "minimum six-week payment cycle" for adjudicated claims, this process applies to most MA providers and complies with timely payment requirements imposed by Federal law. In fact, this requirement is mitigated for pharmacies since the Department adjudicates pharmacy claims at the point of sale, thus decreasing the time between submission and adjudication of claims.

Although the Department is aware of the concerns that providers, including pharmacies, have expressed regarding the number of audits and investigations the Department pursues, the Department has a responsibility under both State and Federal law to investigate any complaint or concern that is either reported to or uncovered by the Department to ensure that services are provided appropriately and in compliance with multiple Federal requirements. The Department has worked and will continue to

work with other State agencies, for example, the Department of Aging, to coordinate reviews to avoid unnecessary or duplicative activities. Regardless of the success of those efforts, however, the Commonwealth's responsibility to assure that public moneys are expended only as permitted by State and Federal law cannot preclude the Department from revising its pharmacy payment rates to align them with those of other private and public payors and to reflect the prices paid by pharmacies.

As previously noted, the Department's efforts to maximize efficiencies in the pharmacy program have not focused exclusively on payment rates. In its ongoing effort to enhance the efficiency and economy of the program while maintaining recipient access to quality pharmacy services, the Department has recently made several other changes to the pharmacy program in the FFS delivery system. These changes can also not be offered as a legitimate reason to prevent revision of the Department's pharmacy payment rates. Many of these changes reflect the processes currently in place in most other private and many other public pharmacy programs.

For example, in implementing the changes to PA requirements, the Department has only followed the lead of other third-party pharmacy plans, both in requiring PA of more drugs and in providing automatic PA based on a systems review of claims history, without additional work on the part of the prescriber or pharmacy. Therefore, the Department has made every effort to minimize the burden on pharmacies while conforming its policies and procedures to current industry standards.

Similarly in proceeding with establishing a PDL, the Department will be implementing a common pharmacy benefit management tool used by most third-party payors, including the MCOs under contract to the Department. By establishing a PDL, the Department will not only afford MA recipients the benefit of its assessment of the most cost-effective and efficacious drugs in a therapeutic class and at the same time enhance revenue to the program through increased manufacturers' drug rebates, but will also ensure consistency between the Department's FFS and managed care delivery systems, by implementing one PDL for both. This should eliminate the pharmacists' legitimate complaints about the inconsistency among MCOs' formularies and the resulting confusion caused by the differing array of requirements imposed by those formularies. In short, a Department-wide PDL will decrease rather than increase administrative burdens on pharmacies.

Finally, in response to the concerns that both commentators and others in the community raised regarding the impact of the proposed monthly prescription limits for adult MA recipients, the Department will not be implementing that proposal. The Department has also modified the recipient copayment increases from its original proposal, with the goal of encouraging the use of generic drugs. Under the new requirements for both adult MA recipients and GA recipients, the copayment for brand name drugs will increase to $3 from $1 and $2, respectively. For multisource drugs, the copayment will remain at $1 for adult MA recipients and decrease from $2 to $1 for adult GA recipients. The Department expects that the modified copayments will benefit not only recipients but pharmacies as well.

Comment

Two commentators recommended that the Department could save money by carving out pharmacy from the managed care programs in order to maximize drug rebates, rather than revising the FFS payment rates.

Response

The Department has analyzed the relative advantages and disadvantages of removing the management of the pharmacy benefit from the MCOs and determined that the disadvantages outweigh the advantages. The pharmacy payment rates established by the MCOs offset the higher level of rebates the Department would receive from drug manufacturers if it administered the pharmacy program Statewide. Nonetheless, the Department will continue to assess the cost-effectiveness of removing the drug benefit from the MCOs in the future.

Regulatory Review Act

Under section 454 of the code, this final-omitted rulemaking is not subject to review under the Regulatory Review Act.

Order

The Department finds that:

(1) Notice of proposed rulemaking is omitted in accordance with section 204(1)(iv) of the CDL and 1 Pa.Code § 7.4(1)(iv) because the regulation relates to Commonwealth grants and benefits.

(b) Adoption of this rulemaking in the manner provided by this order is necessary and appropriate for the administration and enforcement of the code.

Order

The Department, acting under the code, orders that:

(a) The regulations of the Department, 55 Pa. Code Chapters 1101, 1121 and 1150, are amended by amending §§ 1101.21, 1121.2, 1121.11, 1121.24, 1121.53, 1121.56 and 1150.62 and by deleting §§ 1101.70 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Secretary of the Department shall submit this order and Annex A to the Office of General Counsel for approval as to legality and form as required by law.

(c) The Secretary of the Department shall certify and deposit this order and Annex A with the Legislative Reference Bureau as required by law.

(d) This order shall take effect on August 10, 2005.

ESTELLE B. RICHMAN,
Secretary

Fiscal Note: 14-497. No fiscal impact; (8) recommends adoption. The changes associated with this rulemaking will generate a savings to the General Fund of $16.213 million in Fiscal Year 2005-2006 and $15.066 million in Fiscal Year 2006-2007.

Annex A
TITLE 55. PUBLIC WELFARE
PART III. MEDICAL ASSISTANCE MANUAL
CHAPTER 1101. GENERAL PROVISIONS
DEFINITIONS

§ 1101.21. Definitions.

The following words and terms, when used in this part, have the following meanings, unless the content clearly indicates otherwise:

* * * * *

GA—General Assistance—MA funded solely by State funds as authorized under Article IV of the Public Welfare Code (62 P. S. §§ 401—488).

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FEES AND PAYMENTS

§ 1101.70. (Reserved).

CHAPTER 1121. PHARMACEUTICAL SERVICES GENERAL PROVISIONS

§ 1121.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the content clearly indicates otherwise:

AWP—The average wholesale price listed for a drug in one or more available Nationally recognized pricing services.

BaseLine price—That price for multisource drugs determined by available Nationally recognized pricing services as the recalculated mean average for a multisource drug product using only the prices within one standard deviation of the original mean average.

Brand name—A registered trade name commonly used to identify a drug.

CMS—The Centers for Medicare and Medicaid Services.

CMS multisource drug—A multisource drug identified by CMS for which FFP is limited under 42 CFR 447.331—447.333 (relating to drugs: aggregate upper limits of payment; upper limits for multiple source drugs; state plan requirements, findings and assurances).

Compounded prescription—A prescription that is prepared in the pharmacy by combining two or more ingredients and involves the weighing of at least one solid ingredient which shall be a compensable item or a legend drug in a therapeutic amount.

DESI drug—A drug product for which Federal Financial Participation FFP is not available under 42 CFR 441.25 (relating to less than effective drugs).

EAC—Estimated Acquisition Cost—As defined in 42 CFR 447.301 (relating to definitions).

Experimental drug—A drug or product currently being investigated under licensure by the FDA to determine its safety and effectiveness.

FDA—Food and Drug Administration.

FFP—Federal financial participation.

Federal upper limit—The per unit amount set for a multisource drug which is established by CMS under 42 CFR 447.332.

Generic drug—A drug that is "A-rated" by the FDA as therapeutically equivalent to the counterpart brand name drug.

Legend drug—A drug or product that under Federal law or State law can be dispensed only upon the order of a physician.

Licensed prescriber—A person currently licensed under the law of a state to order medication.

Multisource drug—A drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

Nonlegend drug—A drug or product that can be purchased without a prescription.

OBRA '90—The Omnibus Budget Reconciliation Act of 1990 (Pub. L. No. 101-508, 104 Stat. 1388).

Pricing service—A third-party source that compiles and provides drug-specific information needed to maintain the drug reference file under this chapter.

State MAC—The maximum allowable cost established for a multisource drug.

Usual and customary charge—The pharmacy's lowest net charge an MA recipient would pay for a prescription as a non-Medicaid patient at the time of dispensing for the same quantity and strength of a particular drug or product, including applicable discounts, such as special rates to nursing home residents, senior citizens, or other discounts extended to a particular group of patients. This lowest net price does not apply to special in-store rates or discounts extended to charitable organizations, religious groups, store employees and their families, nonprofit organizations, members of the medical profession or other similar non-Medicaid groups.

WAC—Wholesale Acquisition Cost—The manufacturer's list price for a drug to wholesalers or direct purchasers in the United States as listed in one or more available Nationally recognized pricing services.

COVERED AND NONCOVERED SERVICES

§ 1121.11. Types of services covered.

(a) The MA Program covers legend drugs except as otherwise specified in this chapter if the medical necessity has been established and the drug has been prescribed or ordered by a licensed prescriber within the scope of the prescriber's practice.

(b) The MA Program covers the nonlegend drugs specified in § 1121.53(d) (relating to limitations on payment), except that for GA recipients, coverage of nonlegend drugs is limited to insulin and drugs that the Department has identified as the preferred drug in a therapeutic class.

(c) Payment is subject to the conditions and limitations of this chapter and Chapter 1101 (relating to general provisions).

SCOPE OF BENEFITS

§ 1121.24. Scope of benefits for GA recipients.

GA recipients, age 21 to 65, are eligible for medically necessary basic health care benefits as described in Chapter 1101 (relating to general provisions) and this chapter. See §§ 1101.31(e) and 1121.11 (relating to scope; types of services covered).

PAYMENT FOR PHARMACEUTICAL SERVICES

§ 1121.53. Limitations on payment.

(a) The Department will not pay a provider an amount that exceeds the provider's usual and customary charge to the general public.

(b) The Department establishes a State MAC which sets a limit on the drug cost component of the payment formula for selected multisource drugs. The State MAC will include a combination of CMS multisource drugs and the Department's MAC drugs and does not apply if the following exist:

* * * * *

§ 1121.56. Drug cost determination.

(a) The Department will base its drug cost for compensable legend and nonlegend drugs on the lower of:

(1) The EAC established by the Department.

(i) For brand name drugs, the EAC is established by the Department as one of the following:

(A) The lowest WAC listed for the drug in available Nationally recognized pricing services, plus 7%.

(B) If WAC data are not available from a Nationally recognized pricing service, the lowest AWP listed for the drug in available Nationally recognized pricing services, minus 14%.

(C) If both WAC and AWP cost data are available for the drug from a Nationally recognized pricing service, the lower of the two amounts.

(ii) For generic drugs, the EAC is established by the Department as one of the following:

(A) The lowest WAC listed for the drug in available Nationally recognized pricing services, plus 66%.

(B) If WAC data are not available from a Nationally recognized pricing service, the lowest AWP listed for the drug in available Nationally recognized pricing services, minus 25%.

(C) If both WAC and AWP cost data are available for the drug from a Nationally recognized pricing service, the lower of the two amounts.

(2) The State MAC established by the Department.

(b) The Department will update the EAC for individual drugs on a monthly basis as it appears in available Nationally recognized pricing services.

(c) CMS establishes lists that identify and set Federal upper limits for CMS multisource drugs and provides the listing of these drugs and revisions to the list to the Department through Medicaid manual transmittals on a periodic basis.

(d) The Department will determine the State MAC by one of the following methods:

(1) For multisource drugs not classified as a CMS multisource drug, the Department will set the State MAC at the baseline price for the multisource drug entity as determined and provided by available Nationally recognized pricing services.

(2) For drugs classified as CMS multisource drugs, the Department will set the State MAC at the Federal upper limit established for that drug.

(3) For disposable insulin syringes, the Department will set the State MAC at the amount listed in the MA Program Fee Schedule.

(e) The Department will update the State MAC as follows:

(1) The Department will apply the Federal upper limits for CMS multisource drugs to be effective on the date established by CMS and will distribute the update to each pharmacy enrolled in the MA Program when it is available.

(2) The Department will apply the recomputed BaseLine price for multisource drugs not classified as CMS multisource drugs every 6 months, and will distribute the update to each pharmacy enrolled in the MA Program.

(f) With the exception of the CMS multisource drugs, the Department will make further additions to the list of State MAC drugs after consultation with the Medical Assistance Advisory Committee as to whether the application of a State MAC is cost effective to the Department for a particular multisource drug. The Department will add the CMS multisource drugs to the State MAC list effective as of the effective date established by CMS.

(g) With the exception of disposable insulin syringes, the State MAC does not apply if the conditions are met as described in § 1121.53(b)(1) and (2) (relating to limitations on payment).

(h) The most common package size for the purposes of determining the product cost is one of the following:

(1) For capsules, tablets and liquids available in breakable package sizes:

(i) The listed package size if only one package size is listed.

(ii) The 100 or pint package size if more than one package size is listed.

(iii) The next smaller package size from the 100 or pint size, excluding a drug company's unit-dose package size, if more than one package size is listed other than the 100 or pint package size.

(iv) The package size closest to the 100 or pint package size, excluding a drug company's unit-dose package size, if the next smaller package is the unit-dose package size.

(2) The listed package size for all dosage forms available in nonbreakable packages and for all nonlegend drug products.

CHAPTER 1150. MA PROGRAM PAYMENT POLICIES
PAYMENT FOR SERVICES

§ 1150.62. Payment levels and notice of rate setting changes.

(a) The Department will establish maximum payment rates for MA covered services. The established maximum payment rates will not exceed the Medicare upper limit.

(b) The Department will issue public notice of changes in Statewide methods and standards for setting payment rates as required by Federal law.

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