Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

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Independent Regulatory Review Commission

October 16, 2025

IRRC Number: 3388

(1) Agency: Department of Human Services

(2) Agency Number: 14

Identification Number: 544

(3) PA Code Cite: 55 Pa. Code Chapters 1101, 1121, 1141, 1142 and 1144

(4) Short Title: Covered Outpatient Drugs

(5) Agency Contacts (List Telephone Number and Email Address):

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(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
- ☐ Certification by the Governor
- ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The purpose of this final-form rulemaking is to amend the current regulations in Title 55 of the Pennsylvania Code, Chapter 1121, by updating the payment methodology for pharmaceutical services to reflect the payment methodology for covered outpatient drugs approved on July 30, 2018, by the Centers for Medicare & Medicaid Services (CMS) to comply with the Final Rule "Medicaid Program; Covered Outpatient Drugs; Final Rule," published at 81 FR 5170 (February 1, 2016) (amending 42 CFR Part 447). The Department of Human Services (Department) is also making technical corrections to the regulations in Title 55 of the Pennsylvania Code, Chapters 1101, 1121, 1141, 1142, and 1144 to recognize the prescriptive and dispensing authority of certified nurse practitioners and midwives and to specify the payment methodology for pharmaceutical services dispensed by a prescribing provider. Finally, this rulemaking amends Chapter 1121 to reflect advances in information technology that increase administrative and operational efficiencies consistent with industry standards including recognizing electronic prescribing, updating the list of non-compensable services and items, and updating the dispensed day supply limits and limits on refills. For the non-compensable list, the Department is further clarifying that payment will not be made for drugs, services or other items not compensable under the Commonwealth's state plan.

(8) State the statutory authority for the regulation. Include specific statutory citation.

The Department, under the authority of sections 201(2) and 403.1(a)(4) of the Human Services Code (62 P.S. §§ 201(2), 403.1(a)(4)), amended the regulations set forth in Annex A.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The changes to the payment methodology are mandated by Federal law. On February 1, 2016, CMS issued the Covered Outpatient Drug Final Rule, 81 FR 5170. Under the Final Rule, the Department is required to use "actual acquisition cost" (AAC), instead of "estimated acquisition cost" (EAC), as the benchmark for drug ingredient cost, which CMS determined is a "better price indicator" than EAC. See 81 FR 5170, 5174. Under the prior version of 42 CFR 447.502, EAC was defined as the "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 drug most frequently purchased by providers." The Final Rule revises 42 CFR 447.502 and establishes AAC as the basis by which states should determine the pharmacy providers' actual price paid to acquire the drugs for dispensing. The Final Rule also requires the Department to pay a "professional dispensing fee," rather than a "reasonable dispensing fee," that reflects the pharmacist's professional services and cost to dispense the drug product to a Medicaid Fee-for-Service (FFS) recipient. A professional dispensing fee is determined by state or national survey of pharmacy providers or other reliable data. The reasonable dispensing fee is an estimate of the cost for pharmacies to dispense a drug.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

This regulation is needed to ensure that Pennsylvania regulations are consistent with Federal regulations (42 CFR §§ 447.500 – 447.522), the Commonwealth's approved state plan, and to ensure that the Department may claim Federal matching funds (Federal financial participation) for all pharmacy services paid by the Department for MA Program FFS recipients. Outpatient pharmacy providers enrolled in the MA Program, of which there are approximately 3,155, that dispense covered outpatient drugs to FFS recipients will benefit from an increase in payments annually. This regulation is also needed to promote understanding and application of MA regulations governing the scope of benefits and payment for pharmaceutical services. Approximately 3 million people across Pennsylvania are covered by Medicaid and benefit from copay exemptions, removal of cough and cold medications, approval of certain drugs to treat obesity, and increased dispensed day supply limits.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

There are no provisions that are more stringent than Federal standards.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

All state Medicaid agencies are required to comply with the Federal regulations and use AAC as the basis for drug payment to pharmacies plus a professional dispensing fee approved by CMS. This regulation affects payment for drugs dispensed by pharmacies to Pennsylvania MA FFS recipients and therefore does not affect Pennsylvania's ability to compete with other states.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

This regulation will not affect any other regulation of the Department or other state agencies.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

A pharmacy stakeholder meeting was held on July 26, 2016, to allow provider input into the professional dispensing fee survey process. The proposed payment methodology was shared at the March 23, 2017, Medical Assistance Advisory Committee (MAAC) meeting and a description of the plan was posted on the Department's website for public comment. The Department also published a public notice announcing the proposed changes to the payment methodology and provided a comment period. See 47 Pa. B. 1921 (April 1, 2017). The Department published an update to the previous public notice announcing an additional increase in the professional dispensing fee. See 48 Pa.B. 7589 (December 8, 2018). During the COVID-19 public health emergency, the Department increased the dispensed day supply limit and added coverage of cough and cold medications for adults, as announced at the May 28, 2020 MAAC meeting and in MA Provider Bulletin 01-20-07 "Pharmacy Services for Medical Assistance Beneficiaries Related to the COVID-19 Public Health Emergency" issued May 27, 2020. CMS has approved the related amendment to the State Plan.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

The North American Industry Classification System size standard, as indicated in 13 CFR 121.201, for pharmacy and drug retailers is $37.5 million in annual receipts reported on the small business's Internal Revenue Service tax return form. Of the 3,155 MA enrolled outpatient pharmacy providers, the Department had paid Fee-for Service (FFS) claims for 1,246 providers in State Fiscal Year (SFY) 2023-2024. The Department reviewed the paid FFS claims data and used data interpolation to estimate the annual receipts for those providers. For the SFY 2023-2024, 1,220 outpatient pharmacy providers had less than $37.5 million in annual receipts, which would meet the definition of "small business" found in 13 CFR 121.201. This data provides an estimate based off of FFS paid claims and the Department's interpolation and does not factor in providers enrolled in the MA program that did not have FFS claims in SFY 2023-2024. In addition, the Department does not have access to information on the total revenue generated by each outpatient pharmacy provider that is reported on its Internal Revenue Service tax return form. As such, based on the FFS claims data only, the majority of pharmacies receiving FFS payments meet the definition of a small business.

Pharmacies enrolled in the MA Program that provide services to FFS recipients will be affected by the regulations for the payment methodology for covered outpatient drugs. Under the revised payment methodology, the MA Program would pay 6.6 percent more than the prior payment methodology. All MA enrolled pharmacies, including any that qualify as small businesses, will benefit from the net increase in payment. The changes to coverage, including additional copayment exemptions, increases in the dispensed day supply limit, and addition of cough and cold medications and certain drugs to treat obesity will positively affect MA recipients who utilize the covered outpatient drug benefit.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

The final-form regulations require the Department to make payment to outpatient pharmacies enrolled in the MA Program, who dispense drugs to MA FFS recipients, using a revised payment methodology. There are approximately 3,155 pharmacy service locations enrolled in the MA Program representing 1,246 distinct legal entities.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

There are no anticipated financial, economic or social adverse impacts on small businesses, businesses and labor communities and other public and private organizations. The financial impact on pharmacies is positive as the overall payment for dispensing an outpatient drug has increased. There have been no access-to-care issues for MA FFS recipients, who continue to enjoy access to all pharmacies enrolled in the MA Program. The payment methodology in the regulation applies only to FFS and does not impact payments to pharmacies participating with the Department's managed care plans. Individuals receiving MA covered services benefit from additional copay exemptions, the ability to obtain more than a 34-day supply of medications at a time, and coverage of cough and cold medications for adults and certain

drugs to treat obesity. The other changes in the package have no financial impact on small businesses, businesses and labor communities and other public and private organizations.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The purpose of the amendments is to be consistent with the requirements of the Final Rule and the Commonwealth's approved state plan. There has been no adverse impact on access. The net cost increase to the Department, required by the change in federal law, will benefit the outpatient pharmacy providers enrolled in the MA Program. The other changes in the package will benefit individuals receiving MA covered services as they reflect additional copay exemptions or are for clarification of the current benefit. There is no cost or adverse effect on recipients.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Department analyzed the impact of the revised payment methodology to providers by applying the changes to the pharmacy claims paid in calendar year 2015. This year was used because it was the most recent year in which providers were not paid using the revised payment methodology. Applying the changes, the total amount paid by the Department to pharmacies per year increases from $124,514,000 (actual 2015 cost) to $132,731,924 (what would have been paid using the revised methodology), a 6.6 percent increase. The other changes to coverage, including additional copayment exemptions, increasing the dispensed day supply limit, and addition of cough and cold medications and certain drugs to treat obesity will have a neutral effect on pharmacy providers, but will positively affect MA recipients that utilize the covered outpatient drug benefit. There are no new legal, accounting or consulting procedures required.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There is no cost impact to local governments associated with this change. In addition, no new legal, accounting or consulting procedures are required.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

Applying the payment methodology changes to the pharmacy claims paid in calendar year 2015, increases the total paid amount to outpatient pharmacies from $124,514,000 to $132,731,924, a 6.6 percent increase for FFS paid claims. This results in an increased cost to the state of $634,036 beginning Fiscal Year ending 2025, as reflected in the table in (#23).

The additional drugs included in copayment exemptions, increased dispensed day supply limit, and coverage of cough and cold medications have already been implemented in the MA Program and have had minimal financial impact in FFS and no impact on the MA MCO capitation rates. The total MA enrollment in February 2024 was 3,216,875, of whom 2,996,300 received covered outpatient drug benefits from the MA MCOs. The MCOs are paid a per member per month capitated payment. This comprehensive risk-based model allows for the MCOs to assume the financial risk for furnishing the full range of health services covered under the MA Program to plan enrollees. The Department's actuary confirmed that adding certain drugs to treat obesity to coverage will not increase the MCO capitation rates. Likewise, there are no measurable increases in costs anticipated for the FFS delivery system.

There are no new legal, accounting or consulting procedures required.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The final-form regulation does not require any legal, accounting or consulting procedures. The final-form regulation does not require any additional reporting, recordkeeping or other paperwork.

(22a) Are forms required for implementation of the regulation?

There are no forms required for implementation of the regulation.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

There are no forms required for implementation of the regulation.

Gloria K. Gilligan 03/07/2025

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year 24-25	FY +1 Year 25-26	FY +2 Year 26-27	FY +3 Year 27-28	FY +4 Year 28-29	FY +5 Year 29-30
SAVINGS:	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Regulated Community	$0	$0	$0	$0	$0	$0
Local Government	$0	$0	$0	$0	$0	$0
State Government	$0	$0	$0	$0	$0	$0
Total Savings	$0	$0	$0	$0	$0	$0
COSTS:	$634,036	$634,036	$634,036	$634,036	$634,036	$634,036
Regulated Community	$0	$0	$0	$0	$0	$0
Local Government	$0	$0	$0	$0	$0	$0
State Government	$634,036	$634,036	$634,036	$634,036	$634,036	$634,036
Total Costs	$634,036	$634,036	$634,036	$634,036	$634,036	$634,036
REVENUE LOSSES:	$0	$0	$0	$0	$0	$0
Regulated Community	$0	$0	$0	$0	$0	$0
Local Government	$0	$0	$0	$0	$0	$0
State Government	$0	$0	$0	$0	$0	$0
Total Revenue Losses	$0	$0	$0	$0	$0	$0

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY -3 21-22	FY -2 22-23	FY -1 23-24	Current FY 24-25
MA Fee-for-Service	$644,059,000	$589,137,000	$697,354,000	$648,977,000

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.

The regulation does not have an adverse impact on small businesses. Based upon a review of the Department's paid claims data for SFY 2023-2024, 1,220 outpatient pharmacy providers received less than $37.5 million in Department funds, which would meet the definition of "small business" found in 13 CFR 121.201. The Department does not have access to information on the total revenue generated by each pharmacy that is reported on its Internal Revenue Service tax return form. (See the Department's answer to Question 15 for more details.) As such, based on the FFS claims data only, the majority of pharmacies receiving FFS payments meet the definition of a small business.

(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the regulation, including the type of professional skills necessary for preparation of the report or record.

There are no projected reporting, recordkeeping and other administrative costs required for compliance with the regulation.

(c) A statement of probable effect on impacted small businesses.

The final-form rulemaking affects all businesses equally, including any pharmacies that would be considered small businesses. MA-enrolled pharmacies that qualify as small businesses will benefit from the net increase in payment.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation.

There are no less intrusive or less costly alternative methods of achieving the purpose of the regulation. MA enrolled pharmacies that qualify as small businesses will benefit from the net increase in payment.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

There are no provisions specifically developed for minorities, elderly, small businesses, or farmers.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

In the final rule, CMS advised states that they could establish their AAC reimbursement based on several different pricing benchmarks. Potential benchmarks include developing an AAC model of payment that is derived from a state survey of retail pharmacy providers; using published compendia prices, such as wholesale acquisition cost (WAC); using average manufacturer price-based pricing; or using a national survey, such as the National Average Drug Acquisition Cost (NADAC). The

Department analyzed the various benchmarks to establish payment for ingredient cost at AAC and determined that a reimbursement methodology, that includes the lower of the National Average Drug Acquisition Cost (NADAC) and the usual and customary charge to the general public, would be consistent with efficiency, economy, and quality of care while assuring sufficient recipient access in accordance with 42 U.S.C. § 1396a(a)(30)(A), and compliance with ingredient cost payment at AAC pursuant to the Federal Final Rule.

The Department considered using a national survey, regional or neighboring state surveys, or a state-specific survey for establishing the dispensing fee. The Department chose to use a state-specific dispensing fee survey, administered by Mercer Government Human Services Consulting (Mercer), to ensure that the results reflected Pennsylvania-specific pharmacy providers' costs to dispense a drug product to a MA FFS recipient.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

(a) The establishment of less stringent compliance or reporting requirements for small businesses;

The final-form rulemaking affects all businesses equally, including any pharmacies that would be considered small businesses. Because this rulemaking reflects the payment methodology for covered outpatient drugs required for compliance with CMS' Final Rule, the Department cannot establish less stringent compliance or reporting requirements for small businesses.

(b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

Because this rulemaking reflects the payment methodology for covered outpatient drugs required for compliance with CMS' Final Rule, the Department cannot establish less stringent compliance or reporting requirements for small businesses. Further, there are no projected reporting, recordkeeping and other administrative costs required for compliance with the regulation.

(c) The consolidation or simplification of compliance or reporting requirements for small businesses;

Because this rulemaking reflects the payment methodology for covered outpatient drugs required for compliance with CMS' Final Rule, the Department cannot consolidate or simplify compliance or reporting requirements for small businesses. Further, there are no projected reporting, recordkeeping and other administrative costs required for compliance with the regulation.

(d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and

Because this rulemaking reflects the payment methodology for covered outpatient drugs required for compliance with CMS' Final Rule, the Department cannot provide separate operational standards for small businesses.

(e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Because this rulemaking reflects the payment methodology for covered outpatient drugs required for compliance with CMS' Final Rule, the Department cannot exempt small businesses.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

The Department chose to use a state-specific dispensing fee survey to ensure that it adopted a professional dispensing fee that reflects Pennsylvania-specific pharmacy providers' costs to dispense a drug product to a MA FFS recipient. The survey was conducted by Mercer, using a survey that was designed following a review of dispensing fee surveys conducted at the national and state level. All 3,280 pharmacies enrolled in the MA Program at the time were included in the study population. The final total usable response rate was 51.5% of pharmacies enrolled in the MA Program. Respondents self-reported all the data, and a representative of each pharmacy certified the data as accurate. Mercer prepared an analysis of the survey results, which revealed that 81.6% of costs were accounted for by prescription department payroll, 8.9% by prescription department other costs, 6.1% by facility-related costs, and 3.5% by other non-facility administrative (overhead) expenses. The analysis is available at: http://listserv.dhs.pa.gov/Scripts/WA.exe?A2=MAAC-MEETING-MINUTES;4f181273.17&S=.The professional dispensing fee, as defined in the Final Rule at 42 CFR 447.502, was calculated by dividing the total costs by the number of prescriptions dispensed. The survey results reflected $7.00 as the cost of professional dispensing for pharmacies dispensing prescriptions to FFS recipients. After discussion with CMS, the Department recalculated the dispensing fee by including some costs that had been excluded from the calculation, as well as taking into consideration the professional dispensing fees of states bordering Pennsylvania. The Department increased the professional dispensing fee to $10.00. On July 30, 2018, CMS approved the State Plan Amendment with the $10.00 professional dispensing fee and the change was implemented in accordance with the Federal requirement.

(29) Include a schedule for review of the regulation including:

A. The length of the public comment period: 30 days

B. The date or dates on which any public meetings or hearings will be held:	No public meeting or hearings on the final-form regulation.
C. The expected date of delivery of the final-form regulation:	October 2025
D. The expected effective date of the final-form regulation:	Upon notice or publication in the *Pennsylvania Bulletin*.
E. The expected date by which compliance with the final-form regulation will be required:	Upon notice or publication in the *Pennsylvania Bulletin*.
F. The expected date by which required permits, licenses or other approvals must be obtained:	Not applicable

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Department will review the impact of the regulatory amendment on an ongoing basis and monitor its program to ensure recipients have sufficient, continued access to care following the implementation of the changes to the covered outpatient drug reimbursement methodologies.

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Independent Regulatory
Review Commission

October 16, 2025

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FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General By:_____ (Deputy Attorney General) _____ Date of Approval ☐ Check if applicable Copy not approved. Objections attached.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by: DEPARTMENT OF HUMAN SERVICES (Agency) LEGAL COUNSEL: _____ DOCUMENT/FISCAL NOTE NO. 14-544 DATE OF ADOPTION:_____ BY:_____ TITLE: SECRETARY OF HUMAN SERVICES (Executive Officer, Chairman or Secretary)	Copy below is hereby approved as to form and legality. Executive or Independent Agencies. BY:_____ 10/9/2025 Date of Approval (Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title) ☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL-FORM RULEMAKING

DEPARTMENT OF HUMAN SERVICES

OFFICE OF MEDICAL ASSISTANCE PROGRAMS

[55 Pa. Code Chapter 1101 (General Provisions)]
[55 Pa. Code Chapter 1121 (Pharmaceutical Services)]
[55 Pa. Code Chapter 1141 (Physicians' Services)]
[55 Pa. Code Chapter 1142 (Midwives' Services)]
[55 Pa. Code Chapter 1144 (Certified Registered Nurse Practitioner Services)]

Covered Outpatient Drugs

Statutory Authority

Notice is hereby given that the Department of Human Services (Department), under the authority of sections 201(2) and 403.1(a)(4) of the Human Services Code (62 P.S. §§ 201(2) and 403.1(a)(4)), is amending the regulations as set forth in Annex A. Notice of the proposed rulemaking was published in the *Pennsylvania Bulletin* at 53 Pa.B. 7544 on December 2, 2023.

Purpose of Regulation

The purpose of this final-form rulemaking is to amend Chapter 1121 (relating to pharmaceutical services), by updating the payment methodology for pharmaceutical services to reflect the payment methodology approved by the Centers for Medicare & Medicaid Services (CMS) to comply with the Final Rule "Medicaid Program; Covered Outpatient Drugs; Final Rule," (Final Rule) published at 81 FR 5170 (February 1, 2016) (amending 42 CFR Part 447 (relating to payments for services)). The Department is also making technical corrections. These technical corrections amend the regulations in Chapter 1101 (relating to general provisions) to add diabetic supplies, opioid overdose agents and immunizations to the list of services excluded from copayments. This final-form rulemaking also amends Chapters 1121, 1141, 1142 and 1144 to recognize the prescriptive and dispensing authority of certified nurse practitioners (CRNP) and midwives and to specify the payment methodology for pharmaceutical services delivered by a prescribing provider. Finally, this final-form rulemaking amends Chapter 1121 to reflect advances in information technology that increase administrative and operational efficiencies consistent with industry standards including recognizing electronic prescribing, updating the list of noncompensable services, and updating the dispensed day supply limits and limits on refills.

Background

Medicaid is a cooperative Federal-state program by which the Federal government provides funds to states to enable those states, "as far as practicable," to make medical assistance, including Medicaid, available to indigent, elderly and disabled individuals. See 42 U.S.C. §1396. Under Title XIX of the Social Security Act (the Medicaid provisions) (42 U.S.C. §§1396—1396w-7), a state is required to submit a State plan to the United States Department of Health and Human Services for approval. See 42 U.S.C. §1396-1; 42 CFR 430.10 (relating to the State plan). In this Commonwealth, the Department administers the Medical Assistance (MA) Program, which covers Medicaid and State-funded medical services.

As part of the MA Program and the State plan, the Department makes payments to outpatient pharmacies (for example, community pharmacies) that are enrolled as MA providers. The Department makes payments to the enrolled pharmacies for drugs provided to recipients who are enrolled in the MA Fee-for-Service (FFS) Program. The Department receives Federal reimbursement for these eligible drugs, which are also known as "covered outpatient drugs." Covered outpatient drugs are drugs which may be dispensed only upon a prescription, that are approved by the Food and Drug Administration (FDA) and are sold in an outpatient setting. See 42 CFR 447.502 (relating to definitions) regarding the definition of "covered outpatient drug." Prices for these drugs are not set by the pharmacy provider, as might be the case in a typical retail arrangement. Instead, the Department determines what it will pay enrolled pharmacies for each type of drug using two primary factors: the amount that the pharmacist must pay the drug manufacturer to obtain the drug, and the cost of the pharmacist to provide professional pharmacy services (such as filling a prescription and advising the customer of medication interactions).

Federal law establishes state requirements for how states must determine the payments using those two primary factors, among other things. The Department must follow those Federal requirements to be eligible for reimbursement under the Department's approved state plan. As discussed in the following paragraphs, the Federal government changed the requirements for states' payment methodologies. To maintain Federal funding for covered outpatient drugs, the Department is revising the regulations so that the payments made to pharmacy providers meet all the requirements and limitations set forth in Federal law. In the final-form rulemaking, the Department is further clarifying under section 1121.54(1) (relating to noncompensable services and items) that payment will not be made for drugs, services or other items not compensable under the Commonwealth's state plan.

The Final Rule published by CMS revised the requirements for states' payment methodologies to pharmacies for covered outpatient drugs. See 81 FR 5170 (February 1, 2016). As a result of the Final Rule, the Department amended its State Plan, revising the pharmacy provider payment methodology for pharmaceutical services in the MA Program's FFS delivery system. The Department is amending these regulations to comply with the Federal requirements.

Change to Drug Cost Determination (Ingredient Cost)

Under the Final Rule, the Department is required to use "actual acquisition cost" (AAC), instead of "estimated acquisition cost" (EAC), as the benchmark for drug ingredient cost, which CMS determined is a "better price indicator" than EAC. See 81 FR 5170, 5174 (February 1, 2016). Under the prior version of 42 CFR 447.502, EAC was defined as the "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 drug most frequently purchased by providers." The Final Rule revises 42 CFR 447.502 and establishes AAC as the basis by which

states should determine the pharmacy providers' actual price paid to acquire the drugs for dispensing.

The Final Rule defines the term "actual acquisition cost" (AAC) as "the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers." See 42 CFR 447.502. The Final Rule does not mandate that states use a specific formula or methodology to establish AAC. Instead, states have the flexibility to establish AAC based on several different benchmarks. Potential benchmarks include developing an AAC model of payment that is derived from a state survey of retail pharmacy providers; using published compendia prices, such as wholesale acquisition cost (WAC); using average manufacturer price-based pricing; or using a national survey, such as the National Average Drug Acquisition Cost (NADAC).

The NADAC, published by CMS, represents the National average invoice price from wholesalers and manufacturers. CMS informed states that they may use the NADAC pricing benchmark to establish their AAC model of payment. See State Health Official (SHO) Letter # 16-001, Affordable Care Act # 37 (February 11, 2016).

The Department considered the various benchmarks to establish payment for ingredient cost at AAC. The Department determined that NADAC would be consistent with efficiency and economy and will continue to assure quality of care and sufficient recipient access in accordance with section 1902(a)(30)(A) of the Social Security Act (42 U.S.C. §1396a(a)(30)(A)).

CMS advised states in a webinar on "State Pharmacy Reimbursement Requirements," presented on April 28, 2016, that the purpose in establishing the NADAC was to create and publish a national pricing benchmark that State Medicaid programs could use when determining their payment to pharmacy providers. CMS contracted with Myers and Stauffer LC to conduct

surveys of retail community pharmacy prices and to develop the NADAC pricing benchmark. The survey process included both independent and chain retail community pharmacies.

In the preamble to the Final Rule, CMS recognized that there may be instances when a survey price, such as NADAC, is not available for a specific drug product. See 81 FR 5170, 5175 (February 1, 2016). During the April 28, 2016 webinar, CMS reminded states that adopt the NADAC that they must also determine an alternative benchmark equivalent to NADAC for payment for drugs that do not have a NADAC available. CMS did not mandate that states use a specific formula or methodology to determine an alternative benchmark equivalent to NADAC.

The Department's previous pricing methodology used wholesale acquisition cost (WAC) as a benchmark and the Department already had access to the WAC pricing through subscription to a nationally recognized pricing service. Therefore, the Department decided to continue to use WAC as the benchmark for drugs that do not have a NADAC. States that adopt a benchmark using WAC as the alternative methodology used when a NADAC price is not available, must provide data that demonstrates that the payment methodology is based on AAC. See 81 FR 5170, 5176 (February 1, 2016).

In the discussion of the use of compendia prices listed in nationally recognized pricing services, such as WAC, to implement the AAC, CMS noted that "the published prices may not reflect the actual prices paid by retail pharmacies" and therefore, the Commonwealth was expected to make adjustments to these benchmarks to "reflect discounts and other price concessions that are commonly obtained by retail pharmacies." See SHO Letter # 16-001, Affordable Care Act # 37 (February 11, 2016). Mercer Government Human Services Consulting (Mercer) identified that approximately 83% of drugs and 75% of claims paid by FFS in the MA Program during calendar year 2015 have a NADAC price; 25% of claims did not have a

NADAC available. Mercer compared NADAC to WAC for calendar year 2015 and determined that WAC minus 3.3% and WAC minus 50.5% were equivalent to NADAC values for brand name drugs and generic drugs, respectively, for payment for drugs without a published NADAC. The Department will announce any change to WAC rates that equates to NADAC by publication in the *Pennsylvania Bulletin* and notice on the Department's web site.

As previously described, payment for the ingredient cost of brand covered outpatient drugs will be based on NADAC, or an equivalent to NADAC, when a NADAC is not available. For generic drugs, the payment has additional constraints set forth in law. Therefore, payment for generic covered outpatient drugs will be based on NADAC, or an equivalent to NADAC when a NADAC is not available; the Federal Upper Limit (FUL) published by CMS; or the Department's state maximum allowable cost (State MAC) in accordance with 42 U.S.C. § 1396r-8(e).

The Department is continuing the use of a State MAC rate for generic covered outpatient drugs. The Department is also continuing to include the FUL in the lower of payment methodology for generic drugs to remain consistent with the requirement that payment for multiple source drugs must not exceed the aggregate upper limits of payment. See 42 CFR 447.512 (relating to drugs: aggregate upper limits of payment). This payment methodology for brand and generic covered outpatient drugs also applies to compounded drugs.

Payment for covered outpatient drugs is additionally currently limited by, and will continue to be limited by, the 340B Drug Pricing Program. The 340B Drug Pricing Program, managed by the Health Resources and Services Administration (HRSA), allows certain health care providers ("covered entities") to obtain discounted prices on drugs from drug manufacturers. State Medicaid programs make payment to covered entities for drugs dispensed to Medicaid

recipients but may not claim Federal Drug Rebates on 340B purchased drugs. HRSA calculates a 340B ceiling price for each drug, which represents the maximum price a manufacturer can charge a covered entity for the drug. To prevent Medicaid overpayment for drugs that are purchased through the 340B Drug Program, payment for the ingredient cost for brand and generic covered outpatient drugs is based on the methodology described previously but may not exceed the 340B ceiling price as described in section 340B(a)(1) of the Public Health Service Act (42 U.S.C. § 256b(a)(1)). See SHO # 116-001, Affordable Care Act # 37 (February 11, 2016).

CMS approved the State Plan Amendment, which included the ingredient cost pricing methodology described in this final-form rulemaking, with an approval date of July 30, 2018.

Change to Professional Dispensing Fee

The CMS Final Rule also requires the Department to pay a "professional dispensing fee," rather than a "reasonable dispensing fee," that reflects the pharmacist's professional services and cost to dispense the drug product to a Medicaid FFS recipient. The reasonable dispensing fee is an estimate of the cost for pharmacies to dispense a drug. A professional dispensing fee is determined by a state or National survey of pharmacy providers or other reliable data, and is defined as:

> [T]he professional fee which: (1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed; (2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's

> coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, recipient counseling, physically providing the completed prescription to the Medicaid recipient, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and (3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

See 42 CFR 447.502; see also Final Rule, 81 FR 5170 (February 1, 2016). CMS did not mandate in the Final Rule that states must use a specific formula or methodology to determine the professional dispensing fee. Rather, CMS explained that states have the flexibility to set their professional dispensing fee by using methods such as a national survey, regional or neighboring state surveys, or a state-specific survey. See Covered Outpatient Drug Final Rule with Comment (CMS-2345-FC) Frequently Asked Questions (July 6, 2016).

The Department chose to use a State-specific dispensing fee survey to ensure a professional dispensing fee that reflects Pennsylvania-specific pharmacy providers' costs to dispense a drug product to an MA Program FFS recipient. The survey was conducted by Mercer, using a survey that was designed following a review of dispensing fee surveys conducted at the national and state level.

All 3,280 pharmacies enrolled in the MA Program at the time were included in the study population. The final total usable response rate was 51.5% of pharmacies enrolled in the MA Program. Respondents self-reported all the data, and a representative of each pharmacy certified the data as accurate. The data revealed that 81.6% of costs were accounted for by prescription

department payroll, 8.9% by prescription department other costs, 6.1% by facility-related costs, and 3.5% by other non-facility administrative (overhead) expenses.

The professional dispensing fee, as defined in the Final Rule at 42 CFR 447.502, was calculated by dividing the total costs by the number of prescriptions dispensed. The survey results reflected $7 as the cost of professional dispensing for pharmacies dispensing prescriptions to FFS recipients. After discussion with CMS, the Department recalculated the dispensing fee by including some costs that were excluded from the calculation, as well as taking into consideration the professional dispensing fees of states bordering this Commonwealth. The Department increased the professional dispensing fee to $10. On July 30, 2018, CMS approved the State Plan Amendment with the $10 professional dispensing fee and the change was implemented in accordance with the Federal requirement.

The Department is proposing an amendment to § 1121.55 (relating to method of payment) to reflect the professional dispensing fee.

Summary of Revised Payment Methodology for Pharmacy Providers

In summary, the Department will use the professional dispensing fee and the drug cost determinations, as previously described, to determine payments to pharmacies for covered outpatient drugs. The Department will continue to include "usual and customary" in its method of payment. See 42 CFR 447.512. Accordingly, payment for brand drugs will be based on the lower of:

1. NADAC, or an equivalent to NADAC when a NADAC is not available, plus a $10 professional dispensing fee.
2. The pharmacy provider's usual and customary charge to the general public.

See 42 CFR 447.512; see also 55 Pa. Code § 1121.2 (relating to definitions). Payment for generic drugs will be based on the lower of:

1. NADAC, or an equivalent to NADAC when a NADAC is not available; the FUL published by CMS; or the Department's state maximum allowable cost (State MAC), plus a $10 professional dispensing fee.
2. The pharmacy provider's usual and customary charge to the general public.

See 42 CFR 447.512; see also 55 Pa. Code § 1121.2. The Department amended § 1121.55 by deleting § 1121.56 and adding § 1121.56a (relating to drug cost determination) to reflect this revised payment methodology.

Technical Amendments

The Department also made several technical changes to Chapters 1101, 1121, 1141, 1141, 1141, 1142 and 1144 to promote understanding and application of MA regulations governing the scope of benefits and payment for pharmaceutical services, and to align with the Department's current payment policies. As noted previously, the Department revised section 1121.54(1) (relating to noncompensable services and items) to prohibit payment for drugs, services or other items not compensable under the Commonwealth's state plan.

Affected Individuals and Organizations

Pharmacies enrolled in the MA Program that provide services to FFS recipients will be affected by this final-form rulemaking through the implementation of the payment methodology for covered outpatient drugs. There are currently 3,155 pharmacy service locations enrolled in the MA Program, representing 1,246 distinct legal entities. Overall pharmacy payment in FFS is estimated to increase by 6.6% based upon the current payment methodology. There is no

anticipated access to care issues for MA Program recipients receiving pharmaceutical services in FFS. This change does not impact payments to pharmacies participating with MA managed care organizations. MA Program FFS recipients will not be affected by these changes.

The technical amendments are intended to promote understanding and application of MA regulations governing the scope of benefits and payment for pharmaceutical services, including the prohibition of payment for noncompensable services or items.

Accomplishments and Benefits

The amendments to these regulations are needed to make the payment methodology described in regulation consistent with the payment methodology mandated by the Final Rule. Compliance with the revised Federal regulation from the Final Rule and consistency with the Commonwealth's approved state plan will ensure receipt of Federal matching funds (Federal financial participation) for all pharmacy services paid by the Department for MA Program FFS recipients. Outpatient pharmacy providers enrolled in the MA Program that dispense covered outpatient drugs to FFS recipients will benefit from a 6.6% increase in payments annually.

The Department issued a public notice that announced changes to the FFS payment methodology for outpatient drugs in the MA Program. See 47 Pa.B. 1921 (April 1, 2017). The Department subsequently submitted a State Plan Amendment to CMS. On July 30, 2018, CMS approved the State Plan Amendment, which included the payment methodology described in this final-form rulemaking.

Upon publication of the final-form regulation in the *Pennsylvania Bulletin,* the Department will also be issuing a public notice and submitting a State Plan Amendment to CMS to update the list of drugs that are exempt from cost sharing.

Fiscal Impact

Under the revised payment methodology, FFS payment to outpatient pharmacies will increase by 6.6%.

Paperwork Requirements

There are no legal, accounting or consulting procedures or additional reporting, recordkeeping or other paperwork required to comply with this final-form rulemaking.

Effective Date

This final-form rulemaking will take effect upon publication in the *Pennsylvania Bulletin*.

Public Comment

Written comments, suggestions and objections regarding the proposed rulemaking were requested within a 30-day period following publication in the *Pennsylvania Bulletin*. The Department received two letters from legislative members and comments from the Independent Regulatory Review Commission (IRRC). The Department did not receive any comments from the public or stakeholders.

The following is a summary of the comments received within the public comment period and the Department's responses to those comments.

General Comments – coverage and access

Representative Frankel expressed broad support of the coverage and access provisions under the proposed rulemaking, including the coverage of agents for obesity and supplies for contraception and removing the co-pay from opioid overdose agents. The Pennsylvania Black Maternal Health Caucus asserted that the proposed rulemaking makes much-needed changes to pharmacy coverage under the MA Program.

Response:

The Department acknowledges the comments and thanks the commentators for the support.

Section 1121.53. Limitations on Payment - supply

Both legislative letters encouraged the Department to review § 1121.53(c) and to allow more than the 90-day supply of contraceptives and provide for a 12-month supply of contraception in a single prescription fill. IRRC also requested the Department review and consider this suggestion.

Response:

The Department thanks the members for these comments. The Department agrees with the concern regarding missed days of contraceptives and is committed to supporting recipients with access to these medications. The Department, however, is not limiting systemic contraceptives to a 90-day supply. Under the final-form rulemaking, the Department further clarified this language under § 1121.53(c). Under the final-form rulemaking, the exception for systemic contraceptives enables the MA Program to allow prescriptions for contraceptives to be filled or refilled up to one year, in accordance with 49 Pa. Code § 27.18(h) j).

Section 1121.53(c). Limitations on Payment - implementation

IRRC requested that the Department explain how the supply limit will be implemented in § 1121.53(c) as well as improve the clarity of the contraceptives payment provision so that it is easily understood by the regulated community.

Response:

The Department has revised the language and has further updated § 1121.53(c) to provide clarity. The claims processing system will pay for up to 12 months of systemic contraceptives at a time per individual.

Section 1121.54(10). Noncompensable Services and Items

IRRC asked the Department to explain if there is a difference between drugs that may be prescribed specifically for "sex reassignment procedures" and drugs prescribed for "gender dysphoria."

Response:

Clinically, there is no difference between the drugs used for sex reassignment procedures or for gender dysphoria. However, as revised, paragraph (10) does not permit payment for any drugs prescribed in conjunction with noncompensable procedures.

Section 1121.54(20). Noncompensable Services and Items

Representative Frankel also commented on fertility agents being listed as a noncompensable service or item and expressed concern that there are times when fertility agents should be covered, such as when experiencing iatrogenic infertility.

Response:

The Department recognizes that infertility is a complicated and complex issue; however, the Department declines to make this suggested change. To date, this Commonwealth's MA Program has never covered "agents used to promote fertility". The addition to the list of noncompensable services is consistent with the Department's CMS-approved State Plan. Further, the majority of Medicaid programs do not cover fertility treatments. The Department will continue to review federal policy changes that may impact changes to coverage, as well as coverage by other state Medicaid programs.

Contact Person

The contact person is Lacey Walker, Department of Human Services, Office of Medical Assistance Programs, Bureau of Policy, Analysis and Planning, P.O. Box 2675, Harrisburg, PA 17120, RA-PWMAProgComments@pa.gov.

Persons with a disability who require an auxiliary aid or service may use the Pennsylvania Hamilton Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

Regulatory Review Act

Under section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)), on October 16, 2025, the Department submitted a copy of this regulation to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health Committee and the Senate Health and Human Services Committee. In compliance with the Regulatory Review Act, the Department also provided the Committees and the IRRC with copies of all public comments received, as well as other documentation.

In preparing the final-form regulation, the Department reviewed and considered all comments received from the Committees, the IRRC and the public.

In accordance with § 5.1(j.1) and (j.2) of the Regulatory Review Act, this regulation was [*deemed*] approved by the Committees on _____. The IRRC met on _____and approved the regulation.

In addition to submitting the final-form rulemaking, the Department has provided the IRRC and the Committees with a copy of the Regulatory Analysis Form prepared by the Department. A copy of this material is available to the public upon request.

Findings

The Department finds:

(1) The public notice of intention to amend the administrative regulation by this Order has been given pursuant to §§ 201 and 202 of the Commonwealth Documents Law (45 P.S. §§ 1201-1202) and the regulations at 1 Pa. Code §§ 7.1-7.2.

(2) That the adoption of this regulation in the manner provided by this Order is necessary and appropriate for the administration and enforcement of the Human Services Code.

Order

The Department, acting pursuant to the authority of sections 201(2) and 403.1(a)(4) of the Human Services Code (code) (62 P.S. §§ 201(2) and 403.1(a)(4)), orders:

(a) The regulations of the Department are amended to read as set forth in Annex A of this Order.

(b) The Secretary of the Department shall submit this final-form rulemaking and Annex A to the Offices of General Counsel and Attorney General for approval as to legality and form as required by law.

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

(d) This final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

Annex A

TITLE 55. HUMAN SERVICES

PART III. MEDICAL ASSISTANCE MANUAL

CHAPTER 1101. GENERAL PROVISIONS

FEES AND PAYMENTS

§ 1101.63. Payment in full.

* * * * *

(b) *Copayments for MA services.*

(1) Recipients receiving services under the MA Program are responsible to pay the provider the applicable copayment amounts set forth in this subsection.

(2) The following services are excluded from the copayment requirement for all categories of recipients:

(i) Services furnished to individuals under 18 years of age.

* * * * *

(xxv) More than one of a series of a specific allergy test provided in a 24-hour period.

(xxvi) Diabetic supplies.

(xxvii) Drugs, including immunizations, that are dispensed by a LICENSED prescriber AS DEFINED IN § 1121.2 (RELATING TO DEFINITONS).

(xxviii) Specific drugs identified by the Department in the following categories:

(A) Antihypertensive agents.

(B) Antidiabetic agents.

(C) Anticonvulsants.

(D) Cardiovascular preparations.

(E) Antipsychotic agents, except those that are also schedule C-IV antianxiety agents.

(F) Antineoplastic agents.

(G) Antiglaucoma drugs.

(H) Antiparkinson drugs.

(I) Drugs with only an approved indication for the treatment of acquired immunodeficiency syndrome (AIDS).

(J) Opioid overdose agents.

(K) Immunizations.

(3) [The following services are excluded from the copayment requirement for categories of recipients except GA recipients age 21 to 65:

(i) Drugs, including immunizations, dispensed by a physician.

(ii) Specific drugs identified by the Department in the following categories:

(A) Antihypertensive agents.

(B) Antidiabetic agents.

(C) Anticonvulsants.

(D) Cardiovascular preparations.

(E) Antipsychotic agents, except those that are also schedule C-IV antianxiety agents.

(F) Antineoplastic agents.

(G) Antiglaucoma drugs.

(H) Antiparkinson drugs.

(I) Drugs whose only approved indication is the treatment of acquired immunodeficiency syndrome (AIDS)] [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 context clearly indicates otherwise:

[*AWP*—The average wholesale price for a drug as found in the Department's pricing service publication.]

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

* * * * *

[*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.

FUL—Federal Upper Limit—The per unit amount set for a multisource drug which is established by CMS under [42 CFR 447.332] 42 CFR 447.514 (relating to upper limits for multiple source drugs).

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.

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.

NADAC—National Average Drug Acquisition Cost—CMS-published drug prices derived from a monthly Nationwide survey of invoice prices for covered outpatient drugs purchased by retail community pharmacies from wholesalers and manufacturers.

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.

Professional dispensing fee—As defined ~~at~~ IN 42 CFR 447.502 (relating to definitions).

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

U&C—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, including generic drug discount and savings programs. 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.

* * * * *

(b) The MA Program covers [the] nonlegend drugs as 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].

* * * * *

PROVIDER PARTICIPATION

§ 1121.42. Ongoing responsibilities of providers.

In addition to the ongoing responsibilities established in Chapter 1101 (relating to general provisions) pharmacies shall, as a condition of participation, comply with the following requirements:

(1) Permit authorized State and Federal officials or their authorized agents to conduct onsite reviews for the purpose of verification of information furnished as a basis for payment under the MA Program and for establishing the pharmacy's usual and customary charge to the general public as defined in [Chapter 1101] this chapter. During the course of the review, the reviewers shall be allowed access to the dispensing area. The provider shall allow reviewers access to records and documents necessary to determine whether payment for services is or was due under the Program and whether services that have been and are being provided comply with Federal

and State law. The reviewer shall be allowed to photocopy[,] or duplicate these records and documents. These records include:

(i) MA prescriptions on file.

(ii) Non-MA prescriptions without the reviewer having access to patient identification.

(iii) Pharmaceutical purchase invoices.

(iv) The pricing system used by the [store, including but not limited to, pricing rolodex, patient profile and pricing codes] pharmacy.

(v) [Price lists attached to prescription containers] [Reserved].

(2) Conform to accepted standards of practice and quality of service when dispensing prescriptions to MA recipients. It shall be considered contrary to accepted standards of practice for a pharmacy to differentiate between MA recipients and the general public, as defined in Chapter 1101.

PAYMENT FOR PHARMACEUTICAL SERVICES

§ 1121.51. General payment policy.

Payment is made for covered pharmaceutical services provided by participating pharmacies, subject to the conditions and limitations in this section and §§ 1121.52—[1121.56] 1121.56a and Chapter 1101 (relating to general provisions). Payment will not be made for a compensable pharmaceutical service if payment is available from another public agency or another insurance or health program. This does not apply to MA recipients whose drugs have been prescribed through the [County Mental Health/Mental Retardation Programs] County Mental Health/Developmental Services Programs operated under the [Mental Health and Mental Retardation Act] Mental Health and Intellectual Disability Act of 1966 (50 P.S. §§ 4101—

4704). In this instance only, providers may bill the MA Program for services as specified in this chapter.

§ 1121.52. Payment conditions for various services.

(a) MA prescriptions, including those for recipients in skilled nursing facilities, intermediate care facilities or intermediate care facilities for [the mentally retarded] individuals with intellectual disabilities, which [have been] are either written, electronic or verbally ordered by a licensed prescriber shall contain on the prescription [form]:

(1) The name and address of the patient.

* * * * *

(8) The [professional license number] National Provider Identifier (NPI) of the licensed prescriber.

(b) [The following service requires prior authorization as specified in § 1101.67 (relating to prior authorization): Each original prescription for single entity and multiple vitamins when prescribed for prenatal use. The Department will automatically issue a prior authorization for prescriptions indicating a diagnosis of pregnancy for single entity and multiple vitamins] [Reserved].

(b.1) Compensable pharmaceutical services that require prior authorization shall be authorized by publication of notice in the *Pennsylvania Bulletin* and listed on the Department's web site. Providers must follow the procedures as set forth in § 1101.67 (relating to prior authorization), to ensure appropriate and timely processing of prior authorization requests for compensable pharmaceutical services that require prior authorization.

(c) For payment to be made for filling altered prescriptions, the pharmacy shall certify in writing on the prescription that the change was made by the licensed prescriber. Changes in the

nature or brand of a medication, the strength of a medication, directions or quantity dispensed are acceptable only if the consent of the LICENSED prescriber was obtained before dispensing. The written explanation of the pharmacy on the prescription must state that this was done and give the reasons for the change.

§ 1121.53. Limitations on payment.

* * * * *

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

(1) The licensed prescriber certifies that a specific brand is medically necessary by doing all of the following:

(i) Writes on the prescription form "Brand Necessary" or "Brand Medically Necessary" in the LICENSED prescriber's own handwriting or by an electronic alternative means as clarified in § 1121.52a (relating to clarification of the term "written"—statement of policy).

(ii) Receives prior authorization from the Department to use the brand name product.

(2) [In the case of a telephone prescription, the licensed prescriber sends a properly completed prescription, as described in paragraph (1), to the pharmacist within 15 days of the date of service] [Reserved].

(c) Payment for prescriptions, WITH THE EXCEPTION OF SYSTEMIC CONTRACEPTIVES, is limited to [quantities consistent with the medical needs of the patient not to exceed a 34-day supply or 100 units] no more than a 90-day supply or 100 units,

whichever is greater~~, except that payment~~. PAYMENT for systemic contraceptives ~~may exceed the 90-day supply limit as specified by the Department~~ IS LIMITED TO NO MORE THAN A 1-YEAR SUPPLY. Prescriptions may be refilled [as long as the total authorization does not exceed a 6 months' or five refill supply, whichever comes first, from the time of original filling of the prescription] in accordance with 49 Pa. Code § 27.18(h)—(j) (relating to standards of practice). Refills shall be authorized by the licensed prescriber at the time the prescription is ordered, and the quantity dispensed on the refills may exceed the quantity prescribed on the initial prescription only if noted at the time the licensed prescriber orders the initial prescription.

(d) Payment for prescribed nonlegend drugs shall be limited to drugs [and dosage forms listed in the following categories:

(1) Analgesics except long acting products.

(i) Acetaminophen and acetaminophen combinations in the form of tablets, capsules, suppositories, liquids and drops.

(ii) Aspirin and aspirin combinations in the form of tablets, capsules and suppositories.

(iii) Salicylates in the form of tablets, capsules and liquids.

(iv) Ibuprofen in its available dosage forms.

(2) Antacids.

(3) Antidiarrheals.

(i) Kaolin-pectin combinations.

(ii) Loperamide in its available dosage forms.

(4) Antiflatulents.

(i) Simethicone.

(ii) Simethicone combined with antacid.

(5) Antinauseants.

(i) Concentrated balanced solutions of sugar and orthophosphoric acid.

(ii) Cyclizine lactate.

(iii) Dimenhydrinate.

(iv) Meclizine hydrochloride.

(6) Bronchodilators.

(7) Cough—cold preparations, not including mouthwashes, lozenges, troches, throat sprays or rubs, only when prescribed for MA recipients under 21 years of age.

(8) Contraceptives.

(9) Hematinics, not including long-acting products.

(i) Ferrous fumarate.

(ii) Ferrous gluconate.

(iii) Ferrous sulfate.

(10) Insulin and disposable insulin syringes.

(11) Laxatives and stool softeners.

(12) Nasal preparations.

(i) Oxymetazoline.

(ii) Phenylephrine.

(iii) Xylometazoline.

(iv) Naphazoline.

(13) Ophthalmic preparations.

(i) Ocular lubricants containing polyvinyl alcohol or cellulose derivatives.

(ii) Phenylephrine in all ophthalmic forms.

(iii) Sodium chloride in strengths of 2% or greater in ophthalmic forms.

(14) Topical products containing one or more of the following active ingredients.

(i) Anesthetics.

(A) Benzocaine.

(B) Cyclomethycaine.

(C) Dibucaine.

(D) Lidocaine.

(E) Pramoxine.

(F) Tetracaine.

(ii) Antibacterials.

(A) Bacitracin.

(B) Neomycin.

(C) Polymyxin.

(D) Povidone-iodine.

(E) Tetracycline.

(iii) Dermatological baths.

(A) Colloidal oatmeal and combinations.

(B) Soya protein complex and combinations.

(iv) Fungicidals.

(A) Iodochlorhydroxyquin (clioquinol).

(B) Miconazole nitrate.

(C) Salicylanilide.

(D) Salicylic acid.

(E) Sodium caprylate.

(F) Sodium proprionate.

(G) Triacetin (glyceryl triacetate).

(H) Tolnaftate.

(I) Undecylenic acid, esters and salts.

(v) Rectal preparations.

(A) Bismuth subgallate.

(B) Yeast.

(C) Zinc oxide.

(vi) Tar preparations, not including soaps and cleansing agents.

(vii) Wet dressings.

(A) Aluminum acetate.

(B) Aluminum sulfate.

(C) Calcium sulfate.

(D) Zinc sulfate.

(15) Vitamins and minerals.

(i) Single entity and multiple vitamins with or without fluoride for children under 3 years of age.

(ii) Single entity and multiple vitamins when prescribed for prenatal use.

(iii) Nicotinic acid and its amides.

(iv) Calcium salts.

(16) Diagnostic agents.

(17) Quinine] <u>listed on the Department's web site</u>.

(e) [Payment for single entity and multiple vitamins is limited to the following:

(1) Those prescribed, with or without fluorides, for children under 3 years of age.

(2) Those prescribed for prenatal use] [Reserved].

(f) Payment to a pharmacy for prescriptions dispensed to a recipient in either a skilled nursing facility, an intermediate care facility or an intermediate care facility for [the mentally retarded] individuals with intellectual disabilities shall be limited to one dispensing fee for each drug dispensed within a 30-day period.

§ 1121.54. Noncompensable services and items.

Payment will not be made to a pharmacy for the following services and items:

(1) [Drugs and other items prescribed for obesity, appetite control or other similar or related habit altering tendencies. Drugs which have been cleared for use in the treatment of hyperkinesis in children and primary and secondary narcolepsy due to structural damage of the brain are compensable if the physician indicates the diagnosis on the original prescription] ~~[Reserved]~~ DRUGS, SERVICES OR OTHER ITEMS NOT COMPENSABLE UNDER THE MEDICAID STATE PLAN.

(2) Nonlegend drugs in the form of troches, lozenges, throat tablets, cough drops, chewing gum, mouthwashes and similar items.

(3) Pharmaceutical services provided to a hospitalized person.

(4) Drugs and devices classified as experimental by the FDA or whose use is classified as experimental by the FDA.

(5) Drugs and devices not approved by the FDA or whose use is not approved by the FDA.

(6) Placebos.

(7) [Legend and nonlegend soaps, cleansing agents,] Nonlegend dentifrices, mouthwashes, douche solutions, [diluents, ear wax removal agents,] deodorants, liniments[, antiseptics, irrigants] and other personal care and medicine chest items.

(8) Compounded prescriptions when one of the following applies:

(i) Compensable items are used in less than therapeutic quantities.

(ii) Noncompensable items are compounded.

(9) Nonlegend drugs not listed as compensable pharmaceutical services on the Department's web site as specified in § 1121.53(d) (relating to limitations on payment).

(10) Drugs prescribed in conjunction with [sex reassignment procedures or other] noncompensable procedures.

(11) The following items when prescribed for recipients in a skilled nursing facility, an intermediate care facility or an intermediate care facility for [the mentally retarded] individuals with intellectual disabilities:

(i) Intravenous solutions.

(ii) Noncompensable drugs and items as specified in this section.

(iii) The following nonlegend drugs:

(A) Analgesics.

(B) Antacids.

(C) [Antacids with simethicone] [Reserved].

(D) Cough-cold preparations.

(E) Contraceptives.

(F) Laxative and stool softeners.

(G) Ophthalmic preparations.

(H) Diagnostic agents.

(iv) Legend laxatives.

(12) Items prescribed or ordered by a prescriber who has been barred or suspended from participation in the MA Program. The [Department will periodically send pharmacies a list of the names of suspended, terminated or reinstated practitioners and the dates of the various actions] list of providers precluded from participation in the MA Program will be posted on the ~~Department~~ DEPARTMENT'S web site. Pharmacies are responsible for checking this list before filling prescriptions.

(13) Prescriptions or orders filled by a pharmacy other than the one to which a recipient has been restricted under § 1101.91 (relating to recipient misutilization and abuse). [The Department will issue special medical services eligibility cards to restricted recipients indicating the name of the pharmacy to which the recipient is restricted.] Pharmacies are responsible for checking the [recipient's medical services eligibility card] Eligibility Verification System (EVS) to determine if the recipient is restricted to a specific provider before filling the prescription.

(14) DESI drugs and identical, similar or related products or combinations of these products.

(15) A pharmaceutical service for which payment is available from another public agency or another insurance or health program except for those drugs prescribed through the [county mental health/mental retardation] County Mental Health/Developmental Services programs as specified in § 1121.51 (relating to general payment policy).

(16) FDA approved pharmaceutical products whose indicated use is not to treat or manage a medical condition, illness or disorder.

(17) Legend and nonlegend pharmaceutical products distributed by a company that has not entered into a National rebate agreement with the Federal government as provided under [section

4401 of OBRA '90] section 1927 of the Social Security Act (42 U.S.C. § 1396r-8), except for those specific drug products authorized by the Federal government as essential to the health of an MA recipient. The Department will issue [a special list comprised] and post on the ~~Department~~ DEPARTMENT'S web site revisions to the list of those companies that [signed rebate agreements with the Federal government and those products authorized as essential to the health of an MA recipient. Pharmacies are responsible for checking the list before filling the prescription] participate in the Federal Drug Rebate Program.

(18) [Legend and non-legend cough and cold preparations, except when prescribed for MA recipients under 21 years of age] [Reserved].

(19) Erectile dysfunction drugs unless used for an FDA approved indication other than for the treatment of sexual or erectile dysfunction.

(20) Agents when used to promote fertility.

(21) Agents used for cosmetic purposes or hair growth.

§ 1121.55. Method of payment.

(a) The Department will pay a pharmacy for a compensable legend and nonlegend drug (after deducting the applicable copayment amount, as described in § 1101.63(b) (relating to payment in full)), the [lowest] lower of the following amounts:

(1) The [EAC for the] drug cost for brand name and generic drugs, including the ingredients of compounded drugs, as determined by § 1121.56a (relating to drug cost determination), multiplied by the number of units dispensed, plus a [$2] $10 professional dispensing fee.

(2) [The State MAC for the drug, multiplied by the number of units dispensed, plus a $2 dispensing fee] [Reserved].

(3) The provider's usual and customary charge to the general public.

(4) For MA recipients with a pharmacy benefit resource which is a primary third party payer to MA, the [lower of the following amounts:

(i) The EAC for the drug, multiplied by the number of units dispensed, plus a $0.50 dispensing fee.

(ii) The State MAC, multiplied by the number of units dispensed, plus a $0.50 dispensing fee] drug cost as determined by § 1121.56a, multiplied by the number of units dispensed, plus a $0.50 dispensing fee.

(b) [The Department will pay a pharmacy for a compensable compounded prescription at the lower of the cost of all ingredients plus a $3 dispensing fee or the provider's usual and customary charge to the general public. For MA recipients with a pharmacy benefit resource which is a primary third party payer to MA, the dispensing fee shall be $0.50] [Reserved].

(c) The provider shall bill the Department at its usual and customary charge to the general public.

§ 1121.56. [Drug cost determination] [Reserved].

[(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 3.2%.

(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.

(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 at least 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, the Department will set the State MAC at the lower of the following:

(i) The upper payment limit established by the CMS.

(ii) Provided that the generic product is available at the price established by the Department from at least two wholesalers:

(A) If the generic product is available from more than one manufacturer, the base price of 150% of the lowest acquisition cost for the generic product, unless 150% of the lowest

acquisition cost is not at least 120% of the second lowest acquisition cost, in which case the base price will be set at 120% of the second lowest acquisition cost.

(B) If the generic product is available from only one manufacturer, the base price is 120% of the acquisition cost for the generic product.

(2) 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:

(1) If the State MAC for a multisource drug is set at the Federal upper payment limit established by CMS, the Department will apply the Federal upper limits for CMS multisource drugs to be effective on the date established by CMS and will describe the update to each pharmacy enrolled in the MA Program when it is available.

(2) The Department will apply the price for all other State MAC multisource drugs every 3 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 for all nonlegend drug products.

(3) The smallest package size for all dosage forms available in nonbreakable packages.]

§ 1121.56a. Drug cost determination.

(a) The Department will base its drug cost for compensable legend and nonlegend drugs for enrolled pharmacies as follows:

(1) For brand name drugs:

(i) The NADAC.

(ii) If no NADAC is available, a WAC rate that equates to NADAC values published by CMS under subsection (c).

(2) For generic drugs, the lowest of:

(i) The NADAC.

(ii) If no NADAC is available, a WAC rate that equates to NADAC values published by CMS under subsection (c).

(iii) The FUL established by CMS.

(iv) The State MAC established by the Department.

(b) The ingredient cost of a 340B purchased drug shall be based on the methodology set forth in subsection (a), except that payment for the drug cost shall not exceed the 340B ceiling price, as described in section 340B(a)(1) of the Public Health Service Act (42 U.S.C. § 256b(a)(1)).

(c) The Department will update the CMS-published NADAC in the Department's claims adjudication system at least monthly.

(d) WAC rates adjusted to equate to NADAC values will be updated periodically, announced by publication of notice in the *Pennsylvania Bulletin* and made available on the Department's web site.

(e) The Department will determine the brand and generic WAC rates that equate to NADAC values by dividing the NADAC unit prices by the WAC unit prices, minus one, expressed as a percentage.

(f) ~~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.~~ THE DEPARTMENT WILL UTILIZE THE CMS-DETERMINED FUL FOR MULTISOURCE DRUGS IN THE PAYMENT METHODOLOGY.

(g) The Department will establish State MAC rates when there are two or more manufacturers of generic alternatives to the brand name product to enable the Department to realize discounts from the brand price.

(h) State MAC rates will be updated quarterly and as needed to account for marketplace price changes and drug shortages.

(i) The State MAC rates will be established by the Department as follows:

(1) *Tier 1*: Greater of 150% of the lowest-cost generic and 120% of the second lowest-cost generic for unit costs ranging from $0 to $5.

(2) *Tier 2*: Greater of 130% of the lowest-cost generic and 110% of the second lowest-cost generic for unit costs ranging from $5.01 to $20.

(3) *Tier 3*: Greater of 120% of the lowest-cost generic and 110% of the second lowest-cost generic for unit costs greater than $20.01.

(j) The State MAC does not apply if the conditions are met as described in § 1121.53(b)(1) (relating to limitations on payment).

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

(1) For brand name drugs:

(i) The provider's usual and customary charge.

(ii) The WAC + 3.2%.

(2) For generic drugs:

(i) The provider's usual and customary charge,

(ii) The WAC + 0%,

(iii) The FUL.

(iv) The State MAC.

(l) The Department will update the WAC for individual drugs at least on a monthly basis as it appears in a Nationally recognized pricing service.

CHAPTER 1141. PHYSICIANS' SERVICES

PAYMENT FOR PHYSICIANS' SERVICES

§ 1141.60. Payment for medications administered or dispensed [or ordered] in the course of [an office] a visit.

[Physicians may be reimbursed for the actual cost of medications] (a) Payment is made to physicians for covered brand name and generic drugs as determined by § 1121.56a(k) (relating to drug cost determination), multiplied by the number of units administered or dispensed to an eligible recipient in the course of an office or home visit [providing the physician is certified for dispensing by the Office of Medical Assistance, Bureau of Provider Relations]. Payment for these services is subject to the conditions and limitations in Chapter 1121 (relating to pharmaceutical services). There is no [reimbursement] payment made to a physician for medical supplies or equipment dispensed in the course of an office or home visit. Payment for medical supplies and equipment is made only to pharmacies and medical suppliers participating in the Medical Assistance program.

[*Exception:*] (b) Physicians may bill the Department for Rho(d) Immune Globulin, intrauterine devices, eyeglasses and for immunizing biologicals and antigens and drugs not provided by the Department of Health.

CHAPTER 1142. MIDWIVES' SERVICES

PAYMENT FOR MIDWIVES' SERVICES

§ 1142.56. Payment for medications administered or dispensed in the course of a visit.

Payment is made to a midwife for covered brand name and generic drugs as determined by § 1121.56a(k) (relating to drug cost determination), multiplied by the number of units administered or dispensed to an eligible recipient in the course of an office or home visit.

Payment for these services is subject to the conditions and limitations in Chapter 1121 (relating to pharmaceutical services).

CHAPTER 1144. CERTIFIED REGISTERED NURSE PRACTITIONER SERVICES

PAYMENT FOR CERTIFIED REGISTERED NURSE PRACTITIONER SERVICES

§ 1144.54. Payment for medications administered or dispensed in the course of a visit.

Payment is made to a CRNP for covered brand name and generic drugs as determined by § 1121.56a(k) (relating to drug cost determination), multiplied by the number of units administered or dispensed to an eligible recipient in the course of an office or home visit. Payment for these services is subject to the conditions and limitations in Chapter 1121 (relating to pharmaceutical services).

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HUMAN SERVICES

October 16, 2025

Mr. David Sumner, Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, Pennsylvania 17101

Dear Executive Director Sumner,

Enclosed is a final-form rulemaking that amends the Department of Human Services' (Department) payment methodology for providers who are enrolled in the Medical Assistance (MA) Program and who dispense covered outpatient drugs to MA beneficiaries in the Fee-for-Service (FFS) delivery system. Notice of the proposed rulemaking was published in the *Pennsylvania Bulletin* at 53 Pa.B. 7544 on December 2, 2023.

The purpose of this final-form rulemaking is to amend the current regulations in 55 Pa. Code Chapter 1121 by updating the payment methodology for covered outpatient drugs to reflect the payment methodology approved by the Centers for Medicare & Medicaid Services (CMS). The CMS Final Rule requires states to establish a payment methodology for Medicaid FFS payment that uses actual acquisition cost rather than estimated acquisition cost to pay for pharmacy ingredient costs and to pay a professional dispensing fee, rather than a "reasonable dispensing fee." The Department is also making technical corrections.

This final-form rulemaking is being submitted for review pursuant to the Regulatory Review Act. The Department of Human Services will provide the Commission with any assistance required to facilitate a thorough review of this proposal.

Sincerely,

Valerie A. Arkoosh, MD, MPH
Secretary

Enclosure

From: Lindberg, Dylan P.
To: Curley, Maeve; Fricke, Erika L.
Subject: RE: DHS Final-form Regulation #14-544 (Covered Outpatient Drugs) Resubmission
Date: Thursday, October 16, 2025 10:23:35 AM
Attachments: image001.jpg

Confirmed. Thanks!

From: Curley, Maeve <macurley@pa.gov>
Sent: Thursday, October 16, 2025 10:22 AM
To: Fricke, Erika L. <EFricke@pahouse.net>; Lindberg, Dylan P. <DLindberg@pahouse.net>
Subject: RE: DHS Final-form Regulation #14-544 (Covered Outpatient Drugs) Resubmission
Importance: High

Good morning Dylan,

I received an OOO reply from Erika – are you able to confirm receipt of this package? Thank you.

Best,
Maeve

From: Curley, Maeve
Sent: Thursday, October 16, 2025 8:53 AM
To: Fricke, Erika L. <efricke@pahouse.net>
Subject: DHS Final-form Regulation #14-544 (Covered Outpatient Drugs) Resubmission
Importance: High

Good morning,

DHS is re-submitting Reg. No. 14-544, Covered Outpatient Drugs (final-form) to the House Health Committee.

Please provide written (email) confirmation that this rulemaking was received by the Committee chair's office.

Best,
Maeve

Maeve Curley
Pronouns: She/Her
Regulatory Coordinator
PA Department of Human Services | Office of Policy Development
macurley@pa.gov
https://www.dhs.pa.gov

From: Michael Siget
To: Curley, Maeve
Subject: RE: [EXTERNAL]: DHS Final-form Regulation #14-544 (Covered Outpatient Drugs) Resubmission
Date: Thursday, October 16, 2025 9:08:00 AM
Attachments: image001.jpg

Received. Thank you.

From: Curley, Maeve <macurley@pa.gov>
Sent: Thursday, October 16, 2025 8:53 AM
To: Michael Siget <Msiget@pahousegop.com>
Subject: [EXTERNAL]: DHS Final-form Regulation #14-544 (Covered Outpatient Drugs) Resubmission
Importance: High

Good morning,

DHS is re-submitting Reg. No. 14-544, Covered Outpatient Drugs (final-form) to the House Health Committee.

Please provide written (email) confirmation that this rulemaking was received by the Committee chair's office.

Best,
Maeve

Maeve Curley
Pronouns: She/Her
Regulatory Coordinator
PA Department of Human Services | Office of Policy Development
macurley@pa.gov
https://www.dhs.pa.gov

From: Freeman, Clarissa
To: Curley, Maeve
Subject: RE: DHS Final-form Regulation #14-544 (Covered Outpatient Drugs) Resubmission
Date: Thursday, October 16, 2025 10:19:50 AM

Good morning,

Received.

Thank you,

Clarissa L. Freeman
Deputy Chief Counsel | Senate Democratic Caucus
Executive Director-Health and Human Services Committee
Office of the Democratic Leader
Room 535 MCB
Harrisburg, PA 17120-3043
717-783-1220

From: Curley, Maeve <macurley@pa.gov>
Sent: Thursday, October 16, 2025 8:53 AM
To: Freeman, Clarissa <clarissa.freeman@pasenate.com>
Subject: DHS Final-form Regulation #14-544 (Covered Outpatient Drugs) Resubmission
Importance: High

¦ EXTERNAL EMAIL ¦

Good morning,

DHS is re-submitting Reg. No. 14-544, Covered Outpatient Drugs (final-form) to the Senate Health and Human Services Committee.

Please provide written (email) confirmation that this rulemaking was received by the Committee chair's office.

Best,
Maeve

Maeve Curley
Pronouns: She/Her
Regulatory Coordinator
PA Department of Human Services | Office of Policy Development
macurley@pa.gov
https://www.dhs.pa.gov

From:	Freeman, Clarissa
To:	Curley, Maeve
Subject:	RE: DHS Final-form Regulation #14-544 (Covered Outpatient Drugs) Resubmission
Date:	Thursday, October 16, 2025 10:19:50 AM

Good morning,

Received.

Thank you,

Clarissa L. Freeman
Deputy Chief Counsel | Senate Democratic Caucus
Executive Director-Health and Human Services Committee
Office of the Democratic Leader
Room 535 MCB
Harrisburg, PA 17120-3043
717-783-1220

From: Curley, Maeve <macurley@pa.gov>
Sent: Thursday, October 16, 2025 8:53 AM
To: Freeman, Clarissa <clarissa.freeman@pasenate.com>
Subject: DHS Final-form Regulation #14-544 (Covered Outpatient Drugs) Resubmission
Importance: High

Good morning,

DHS is re-submitting Reg. No. 14-544, Covered Outpatient Drugs (final-form) to the Senate Health and Human Services Committee.

Please provide written (email) confirmation that this rulemaking was received by the Committee chair's office.

Best,
Maeve

Maeve Curley
Pronouns: She/Her
Regulatory Coordinator
PA Department of Human Services | Office of Policy Development
macurley@pa.gov
https://www.dhs.pa.gov