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

November 9, 2023

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 proposed regulation 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 current 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, update the list of non-compensable services, and update the dispensed day supply limits and limits on refills.

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

The Department proposes to amend the regulation set forth in Annex A 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)).

(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) and to ensure that the Department can 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 3411, 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. MA recipients benefit from copay exemptions, removal of cough and cold medications and drugs to treat obesity from benefit exclusions 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 their 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 promulgating agency 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 for 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 issued 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 issued 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 an amendment to the State Plan to allow for continuation of both changes following the expiration of the COVID-19 Public Health Emergency.

(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?

Pharmacies enrolled in the MA Program that provide services to FFS recipients will be affected by the proposed 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. The Department does not have access to MA enrolled pharmacies' full annual receipt information and, therefore, is unable to estimate the number of pharmacy providers that are small businesses. MA enrolled pharmacies that qualify as small businesses will benefit from the net increase in payment. The proposed changes, including additional copayment exemptions, increasing the dispensed day supply limit, and addition of cough and cold medications and drugs to treat obesity to coverage 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 proposed 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 3411 pharmacy service locations enrolled in the MA Program representing 1,302 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 proposed 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, ability to obtain more than a 34-day supply of medications at a time, and coverage of cough and cold medications for adults and drugs to treat obesity. The other proposed 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 proposed amendments is to be consistent with the requirements of the Final Rule. 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 proposed 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 to 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 what the impact of the revised payment methodology would be 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 proposed changes, including additional copayment exemptions, increasing the dispensed day supply limit, and addition of cough and cold medications and drugs to treat obesity to coverage 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 proposed 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 2023 was 3,682,781, of whom 3,413,525 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 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 proposed regulation does not require any legal, accounting or consulting procedures. The proposed 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.**

Not applicable.

Gloria K. Gilligan 05/26/2023

(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 22-23	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
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:	$0	$0	$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	$0	$0	$634,036	$634,036	$634,036	$634,036
Total Costs	$0	$0	$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 19-20	FY -2 20-21	FY -1 21-22	Current FY 22-23
MA Fee-for-Service	$344,107,000	$808,350,000	$644,059,000	$746,852,000

(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.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

The regulation does not have an adverse impact on small businesses.

(a) Small businesses who receive payment for pharmacy services that are funded in part by Federal matching funds to MA FFS recipients are subject to the regulation. The Department does not have access to MA enrolled pharmacies' full annual receipt information and, therefore, is unable to estimate the number of pharmacy providers that are small businesses.
(b) There are no 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.
(c) The regulation does not have an adverse impact on small businesses. MA enrolled pharmacies that qualify as small businesses will benefit from the net increase in payment.
(d) There are no less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

(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' cost 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;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

There is no anticipated adverse impact on small business.

(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 reflected Pennsylvania-specific pharmacy providers' cost 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 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.dpw.state.pa.us/Scripts/wa.exe?A3=ind17&L=MAAC-MEETING-MINUTES&E=base64&P=3288271&B=--_004_5822099a405848cc8cdb9d039c6e317fENCTCEXCH008PALCL_&T=application%2Fpdf;%20name=%22PA%20PDFS%202016%20Final.pdf%22&N=PA%20PDFS%202016%20Final.pdf&attachment=q&XSS=3The 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: 03/23/2017, 05/28/2020

C. The expected date of delivery of the final-form regulation: August 2024

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.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED

Independent Regulatory
Review Commission

November 9, 2023

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

By: Amy M. Elliott
Digitally signed by Amy M. Elliott
DN: cn=Amy M. Elliott, o=Pennsylvania Office of Attorney General, ou=Chief Deputy Attorney General, email=aelliott@attorneygeneral.gov, c=US
Date: 2023.11.06 07:48:38 -05'00'

(Deputy Attorney General)

11/6/2023
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: Dennis Glantz Hatcher

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:

September 7, 2023
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 PROPOSED 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) intends to amend the regulation set forth in Annex A 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)).

Purpose of Regulation

The purpose of this proposed regulation 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 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). The Department is also making technical corrections. These technical corrections amend the current regulations in Title 55 of the Pennsylvania Code, Chapter 1101 to add diabetic supplies, opioid overdose agents and immunizations to the list of services excluded from copayments. This proposed rulemaking also amends Chapters 1121, 1141, 1142, and 1144 to recognize the prescriptive and dispensing authority of certified nurse practitioners (CRNPs) 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, update the list of noncompensable services, and update 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.A. § 1396. Under Title XIX of the Social Security Act (the Medicaid provisions), a state is required to submit a State plan to the United States Department of Health and Human Services ("HHS") for approval. See 42 U.S.C.A. § 1396-1; 42 CFR 430.10. In Pennsylvania, the Department administers the Medical Assistance (MA) Program, which covers Medicaid and state-funded medical services.

As part of the MA Program and its State plan, the Department makes payments to outpatient pharmacies (*e.g.,* community pharmacies) that are enrolled as MA providers. The Department makes payments to the enrolled pharmacies for drugs provided to beneficiaries 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 FDA, and are sold in an outpatient setting. See 42 CFR 447.502 (definition of "covered outpatient drug"). Prices for these drugs are not set by the pharmacy or pharmacist, 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 in order 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 must revise its regulation so that the payments it makes to pharmacy providers meet all of the requirements and limitations set forth in federal law.

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 Fee-for-Service delivery system. The Department now proposes these amendments 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 had 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 (the Act) (42 U.S.C.A. § 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 via 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 proposed payment methodology is based on actual acquisition cost (AAC). *See* 81 FR 5170, 5176 (February 1, 2016).

In its 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 state 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 equate to NADAC by publication in the *Pennsylvania Bulletin* and notice on the Department's website.

As described above, 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.A. § 1396r–8(e).

The Department is continuing its 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. 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 above 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.A. § 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 proposed regulation, 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 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. 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 that it adopted a professional dispensing fee that reflected Pennsylvania-specific pharmacy providers' cost to dispense a drug product to a 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 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 $7.00 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 State Plan Amendment with the $10.00 professional dispensing fee and the change was implemented in accordance with the Federal requirement.

The Department is proposing an amendment to Section 1121.55 of the Department's regulations, 55 Pa. Code § 1121.55, 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 described above, 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 provider's usual and customary charge to the general public.

See 42 CFR 447.512; *see also* 55 Pa. Code § 1121.2. 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 Federal Upper Limit (FUL) published by CMS; or the Department's state maximum allowable cost (State MAC), plus a $10 professional dispensing fee.
2. The provider's usual and customary charge to the general public.

See 42 CFR 447.512; *see also* 55 Pa. Code § 1121.2. The Department is proposing an amendment to § 1121.55, and proposes to reserve §1121.56 and add § 1121.56a to reflect this revised payment methodology.

Technical Amendments

As noted in the Requirements section below, the Department also proposes several technical changes to Chapters 1101, 1121, 1141, 1142, and 1144 to promote understanding and application of Medical Assistance (MA) regulations governing the scope of benefits and payment for pharmaceutical services, and to align with the Department's current payment policies. These technical amendments are discussed in §§ 1101.63, 1121.52, 1121.53(c)-(d), 1121.54, 1141.60. 1142.56, 1144.54.

1. *§ 1121.52. Payment conditions for various services.* The addition of "electronic" is proposed to recognize electronic prescriptions, consistent with Act 96 of 2018 (P. L. 662, No. 96) (49 Pa. Code § 27.1).

2. *§ 1121.53(c). Limitations on payment.* The Department proposes changes to the limitation on prescriptions from a quantity of 34-day supply or 100 units, whichever is greater to a quantity of 90-day supply or 100 units, whichever is greater. The exception to the 90-day supply limit is systemic contraceptives. Department coverage was approved by CMS and commenced March 1, 2020, for all MA recipients. The proposed amendment facilitates access to drugs for MA recipients, including those who may have difficulty getting to a pharmacy. The Department proposes the removal of the limits on refills to 6 months or five refill supply, whichever comes first. The proposed amendment allows for prescriptions to be refilled in accordance with 49 Pa. Code § 27.18(h)-(j).

3. *§ 1121.53(d). Limitations on payment.* The Department also proposes the removal of the list of covered prescribed nonlegend drugs and dosage forms. Many of the drugs or dosages listed are obsolete. Advances in information technology have made the process of listing specific drug categories and drugs in regulations outdated, administratively inefficient, and inconsistent with current

pharmacy standards. Rather than updating a list through the regulatory process which could be quickly outdated, the Department publishes the Medical Assistance Pharmacy Program FFS Drug Reference File on the Department's website for public access. *See* DHS Pharmacy Services Covered Drugs Search Tool. Retrieved from https://www.humanservices.state.pa.us/CoveredDrugs/CoveredDrugs/Index

4. *§ 1121.54. Noncompensable services and items*. The Department proposes the removal of prescribed legend and nonlegend cough and cold preparations for recipients 21 or older consistent with Department coverage approved by CMS and which commenced March 1, 2020. The Department also proposes removing drugs prescribed in conjunction with sex reassignment procedures consistent with the removal from the State Plan of the noncoverage of these drugs. The Department also proposes to remove drugs to treat obesity. State Medicaid agencies have the option to cover drugs to treat obesity that meet the Medicaid requirements for coverage and the Department started covering these drugs on January 1, 2023.

5. *§ 1141.60. Payment for medications dispensed or ordered in the course of an office visit.* The Final Rule published by CMS revised the requirements for states' payment methodologies only to pharmacy providers for covered outpatient drugs. *See* 81 FR 5170 (February 1, 2016). The proposed amendment includes a reference to § 1121.56a(k), outlining the payment methodology for drugs dispensed by prescribing practitioners, including physicians, CRNPs, and midwives. This information was not previously included in regulation.

6. *§ 1142.56. Payment for medications administered or dispensed in the course of a visit.* The proposed amendment would recognize prescriptive and dispensing authority of midwives in accordance with 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs).

7. *§ 1144.54. Payment for medications administered or dispensed in the course of a visit*. The proposed amendment would recognize the prescriptive and dispensing authority of CRNPs in accordance with 49 Pa. Code § 21.284 (relating to prescribing and dispensing parameters).

Requirements

The following is a summary of the major provisions of this proposed rulemaking.

§ 1101.63. Payment in full.

The Department reviewed the list of services and drugs excluded from the copayment requirement for consistency with current Department operations. The proposed amendment to this section adds opioid overdose agents supporting the administration's commitment to improve

access to care and use all available resources and funding to address the opioid epidemic. The proposed amendment also adds immunizations to the list of pharmaceutical services exempt from copayment to ensure access to preventative care. Lastly, the proposed amendment adds non-drug diabetic supplies to the list of covered services exempt from copayment to ensure access to all supportive needs for the treatment of diabetes.

In addition, the proposed amendment removes reference to general assistance (GA) recipients as the Department combined several adult benefit packages into one Adult Benefit Package, which includes recipients who were part of the GA program. With the consolidation, GA recipients have the same pharmacy benefits as all other MA recipients.

§ 1121.2. Definitions.

This section is amended by:

- Deleting the definition of AWP (average wholesale price) as this benchmark is not used in the revised payment methodology.
- Deleting the definition of EAC because this term is obsolete under the Federal Final Rule. NADAC, or if no NADAC is available, a WAC rate adjusted to equate to NADAC values, will be used to determine ingredient cost.
- Correcting the reference to the Federal regulation in the definition of Federal upper limit, as 42 CFR 447.332 no longer exists.
- Amending the definition of "legend drug" to replace the term "physician" with the term "licensed prescriber." This proposed amendment reflects the current recognition that licensed physicians, midwives, CRNPs, dentists, and physician assistants have prescriptive authority.
- Adding a definition of "NADAC – National Average Drug Acquisition Cost," as this benchmark is a component of the payment methodology for ingredient cost. The NADAC, published by CMS, represents the national average invoice price from wholesalers and manufacturers. *See* Medicaid, Pharmacy Pricing; retrieved from https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html States that adopt NADAC are required to specify an alternative methodology that will be used when a NADAC price is not available for a covered outpatient drug. 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 proposed payment methodology is based on AAC. *See* 81 FR 5170, 5176 (February 1, 2016); SHO Letter # 16-001, Affordable Care Act # 37 (February 11, 2016).
- Adding a definition of "Professional dispensing fee" consistent with Federal regulation. *See* 42 CFR 447.502.
- Amending the definition of "usual and customary charge" to include the initials "U&C".

COVERED AND NONCOVERED SERVICES

§ 1121.11. Types of services covered.

In subsection (b), the word "the" in front of the word nonlegend is proposed to be deleted and the word "as" is proposed to be added in front of the word "specified" to improve readability. In addition, the proposed amendment removes reference to general assistance (GA) recipients, as the Department combined several adult benefit packages into one Adult Benefit Package. There is no longer a need to reference the GA recipients, as recipients have the same pharmacy benefit as all other MA recipients.

PROVIDER PARTICIPATION

§ 1121.42. Ongoing responsibilities of providers.

Proposed amendments include deleting the reference in paragraph (1) to Chapter 1101 for the definition of U&C and adding "this chapter" to clarify the location of the definition of U&C for pharmacy providers; removing the comma between "photocopy" and "or duplicate" to be grammatically correct; deleting the outdated and obsolete phrases in (iv) "store, including but not limited to, pricing rolodex, patient profile and pricing codes" and replacing with the term "pharmacy"; deleting all of (v) to be consistent with current pharmacy practice standards.

PAYMENT FOR PHARMACEUTICAL SERVICES

§ 1121.51. General payment policy.

Proposed amendments include the following changes in terminology to be consistent with Medicaid terminology and changes to certain titles: deleting "County Mental Health/Mental Retardation Programs" and adding "County Mental Health/Developmental Services Program. The proposed rulemaking also deletes "Mental Health and Mental Retardation Act" and adds "Mental Health and Intellectual Disabilities Act." In the Federal Final Rule 9070-F, *Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction*, CMS sought to standardize the language between the Medicare and Medicaid programs, including by replacing the term "mental retardation" with "intellectual disability."

§ 1121.52. Payment conditions for various services.

In Subsection (a), the phrase "the mentally retarded" is proposed to be amended to "individuals with intellectual disabilities." Also, the addition of "electronic" is proposed to recognize electronic prescriptions, consistent with Act 96 of 2018 (P.L. 662, No. 96) and the word "form" is proposed to be deleted in recognition that a prescription may now be a written, electronic, or oral order in accordance with 49 Pa. Code § 27.1 (relating to definitions).

In paragraph (a)(8), language is proposed to include the National Provider Identifier (NPI) on the prescription, which is required by 42 U.S.C.A. § 1396a(a)(kk)(7), instead of the professional license number. The Department is proposing to delete the language in subsection (b) which is outdated and obsolete; coverage of single entity and multiple vitamins is not limited to prenatal use. In subsection (b.1), the Department proposes to add language addressing requirements related to prior authorization of pharmaceutical services, consistent with current procedure.

§ 1121.53. Limitations on payment.

This section is amended by adding a reference to the FUL in Subsection (b) as both the FUL and the State MAC are limits on the drug cost component for selected multisource drugs. The FUL and the State MAC are separate and distinct components of the drug cost component of payment for generic drugs. The FUL is published by CMS; the State MAC is established by the Department. A multisource drug may have both a FUL and a State MAC. For this reason, the Department is also deleting the reference that the State MAC includes a combination of the CMS multisource drugs and the State MAC drugs.

Subparagraph (b)(1)(i) proposes to add language recognizing electronic prescribing. Subparagraph (b)(2) is proposed to be deleted as unnecessary, because the State Board of Pharmacy defines the standards of practice related to oral prescriptions in their regulations. *See* 49 Pa. Code § 27.18(n)-(o) (relating to standards of practice).

Subsection (c) is amended by changing the limitation on prescriptions of a quantity of 34-day supply or 100 units, whichever is greater, to a 90-day supply or 100 units, whichever is greater, except that payment for systemic contraceptives can exceed the 90-day supply limit as specified by the Department. This change is consistent with the State Plan, approved by CMS, effective March 1, 2020, which originally ensured access to prescriptions for all MA recipients during the COVID-19 pandemic, and now continues. The proposed amendment provides more convenient access to MA recipients with transportation issues and is consistent with current dispensing limits permitted by the MA managed care organizations and private insurers. The exception for systemic contraceptives enables the Department to pay for more than 90 day-supplies in one dispensing in accordance with 49 Pa. Code § 27.18 (h)-(j). The limits on refills of 6 months or five refill supply, whichever comes first, from the time of original filling of the prescription is replaced with prescriptions may be refilled "in accordance with 49 Pa. Code § 27.18 (h)-(j) (related to standards of practice)" to ensure consistency with all regulatory provisions. The amendment to the limits on refills are also consistent with the State Board of Pharmacy's regulations which allow for prescriptions to be refilled up to 12 months. The word "licensed" is proposed to be added to describe and be consistent with the term licensed prescriber.

Subsection (d) is proposed to be amended by adding language indicating that payment for nonlegend drugs is limited to drugs listed on the Department's website. The categories of nonlegend drugs listed in Subsection (d)(1) through (17) are proposed to be deleted. While there is no change to the Department's policy for coverage of nonlegend drugs, some of the categories and many of the drugs listed are obsolete. Advances in information technology have made the

process of listing the categories and nonlegend drugs in regulations outdated, administratively inefficient, and inconsistent with current industry standards. Rather than updating a list through the regulatory promulgation process which would provide no detail about the covered drug and which could be quickly outdated, the Department posts the Medical Assistance Pharmacy Program FFS Drug Reference File on the Department's website. The Drug Reference File contains all covered outpatient drugs, including covered nonlegend drugs included in the CMS Drug Product Data File. The CMS File lists the active drugs that have been reported by participating drug manufacturers as of the most recent rebate reporting period under the Medicaid Drug rebate Program (MDRP). Any interested party can access the File. The phrase "and dosage forms" is proposed to be deleted as the file on the website provides detailed data about the drug product that was previously unavailable under the list in subsection (d)(1) through (17).

The language in Subsection (e) is proposed to be deleted and reserved as vitamins are not limited to children under three years of age and for prenatal use. Proposed Subsection (f) proposes to replace the phrase "the mentally retarded" with "individuals with intellectual disabilities."

§ 1121.54. Noncompensable services and items.

Paragraph (1) is proposed to be removed entirely to permit coverage of drugs prescribed for obesity. Obesity is a chronic, progressive, relapsing, and treatable multi-factorial disease that results in adverse metabolic, biomechanical, and psychosocial health consequences. Advances in drug therapies to treat obesity has given the medical community treatment options.

Paragraph (7) reference to "legend and nonlegend soaps, cleansing agents," and the reference to "diluents, ear wax removal agents" are proposed to be deleted as the scope of pharmaceutical services includes these products.

Paragraph (9) is proposed to be amended to include "as compensable pharmaceutical services on the Department's website as specified in § 1121.53(d)" to be consistent with the proposed change to that Subsection.

Paragraph (10) is proposed to be amended to remove "sex reassignment procedures or other" because the Department currently covers drugs prescribed for gender dysphoria without regard to sex reassignment procedures.

Paragraph (11) proposes to delete the phrase "the mentally retarded" and add "individuals with intellectual disabilities"; and delete the reference to "Antacids with simethicone" in clause (11)(iii)(C) as it is duplicative of clause (11)(iii)(B) Antacids.

Paragraph (12) is proposed to be amended by adding a statement that the list of providers precluded from participation is posted on the Department website and deleting the statement that the Department will send copies of the list to pharmacies, as this information is more readily accessible and well-maintained on the website.

Paragraph (13) is proposed to be amended by deleting the outdated reference to "special medical services eligibility cards" for recipients restricted (lock-in) to specific pharmacies, and by adding language referencing the Eligibility Verification System (EVS) to verify a recipient restriction, which is how providers verify eligibility and identify if a beneficiary is restricted to a provider.

Paragraph (15) updates the reference to the "county mental health/mental retardation" programs with the "County Mental Health/Developmental Services" programs.

Under paragraph (17), the Department proposes to update the reference to the federal law for accuracy. The reference to the Department issuing a special list of drug companies is edited to reflect the current procedure of issuing periodic updates to the list of drug companies that participate in the Federal Drug Rebate Program by a remittance advice which is also posted on the Department website. The pharmacy's responsibility to check the list before filling the prescription is proposed to be deleted as unnecessary. When a pharmacist enters a claim for a prescribed drug, the pharmacist is notified on-line at the point-of-sale if the prescribed drug is not a compensable pharmaceutical service.

Paragraph (18) is proposed to be deleted.

Paragraph (20) adds to the list of noncompensable services "agents used to promote fertility." Subsection (21) adds to the list of noncompensable services "agents used for cosmetic purposes or hair growth." The addition of Subsection (20) and (21) are consistent with provisions in the Department's CMS-approved State Plan.

§ 1121.55. Method of payment.

The Department proposes to replace "lowest" with "lower" in subsection (a) for grammar and clarity. Subsection (a)(1) is amended by deleting the obsolete term EAC and replacing it with a reference to the drug cost determination in Section 1121.56a for brand name, generic, and compounded drugs. The subsection is also amended by replacing the term "dispensing fee," with "professional dispensing fee" and specifying a $10 professional dispensing fee. Subsection (a)(2) is amended by deleting the payment methodology, which is now being delineated in Section 1121.56a. The language previously in subsection (a)(3) is now included in amended Subsection (a)(2). The language previously in subsection (a)(4) is now included in Subsection (a)(3) and is amended by deleting the reference to EAC and State MAC. Subsection (b) is being deleted and the subsection reserved, as the specific dispensing fee for compounded prescriptions no longer applies and is being replaced by the professional dispensing fee.

§ 1121.56. Drug cost determination.

Because of the extensive changes necessary to Section 1121.56 to reflect the payment methodology approved by the CMS to comply with the Final Rule, the Department proposes to reserve the entire section. The new payment methodology is proposed to be set forth in a new section 1121.56a.

§ 1121.56a. Drug cost determination.

Proposed subsection (a)(1) provides that the payment to enrolled licensed pharmacies for ingredient cost of brand name drugs is the NADAC established by CMS. If no NADAC is available, then a WAC rate adjusted to equate to NADAC values will be used.

Proposed subsection (a)(2) provides that the payment to enrolled licensed pharmacies for ingredient cost of generic drugs is the lower of the following: NADAC, or if no NADAC is available, a WAC rate adjusted to equate to NADAC values, the CMS published FUL, or the State MAC established by the Department.

Proposed subsection (b) provides that the payment for 340B purchased drugs is based on the payment methodology in Subsection (a), except that payment cannot exceed the 340B ceiling price.

Proposed subsection (c) provides how the Department will update its reference to NADAC and the frequency of updates to NADAC. The language previously in § 1121.56(c) of the regulation is included in proposed § 1121.56a(f).

Proposed subsection (d) provides for periodic updates to the WAC rates that equate to NADAC, and that updates will be announced by publication of notice in the *Pennsylvania Bulletin*, and made available on the Department's website. The methodology for determining State MAC rates, previously in § 1121.56(d)(1), is included in proposed § 1121.56a(i). The language proposed to be deleted in § 1121.56(d)(2) and § 1121.56(g) related to disposable insulin syringes, is not being added to § 1121.56a because the disposable insulin syringes are not drugs and Chapter 1121 applies to drugs. Disposal insulin syringes are medical supplies and subject to Chapter 1123.

Proposed subsection (e) provides the methodology to determine the WAC rates that equate to NADAC values.

Proposed subsection (f), which is based on § 1121.56(c), explains the FUL. The Department proposes to delete the reference to how and when CMS provides the list of drugs with an FUL due to the possibility of changes in the manner in which CMS communicates with the States.

Proposed subsection (g), which is based on § 1121.56(f), describes when the Department will establish a State MAC and does not retain the § 1121.56(f) reference to consultation with the Medical Assistance Advisory Committee (MAAC) as to whether the application of a State MAC is cost effective to the Department for a particular multisource drug. The Department had consulted with the Pharmacy Subcommittee of the MAAC, but this Subcommittee no longer exists. The Subcommittees of the MAAC are now organized to reflect service delivery systems rather than provider types.

Proposed subsection (h) describes the frequency of updates to the State MAC. The language previously in § 1121.56(h), which contains the obsolete method for determining

product cost based on package size, is not retained here. The product cost is based on the 11-digit NDC, which is a more accurate metric for determining product cost.

Proposed subsection (i), which is based on § 1121.56(d)(1), describes the method to establish the State MAC rates.

Proposed subsection(j) provides that the State MAC does not apply if the conditions are met under § 1121.53(b) (relating to limitations on payment).

Proposed subsection (k) provides for the determination of ingredient cost for licensed prescribers, previously in Section 1121.56(a). The determination of ingredient cost for payment to enrolled dispensing prescribers is not subject to the requirements in the Covered Outpatient Drug Final Rule. The proposed language describing the determination of ingredient cost has been simplified to reflect pricing based upon the availability of pricing information from nationally recognized pricing services. The Department's pricing service, First Databank, stopped publishing AWP as a pricing benchmark. As a result, a comparison of "lowest of" AWP and WAC prices listed in all the nationally recognized pricing services became ineffectual with WAC defaulting as the prevailing price. The Department continues to rely on a nationally recognized pricing service to identify WAC when determining ingredient cost for payment to dispensing prescribers and determined that it was impractical to continue to require its claims processing contractor to continue subscribing to all nationally recognized pricing services.

Proposed subsection (l), which is based on § 1121.56(b), continues to provide for WAC to be updated at least monthly.

PAYMENT FOR PHYSICIANS' SERVICES

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

The proposed amendments to this section include changing the title by replacing the term "dispensed or ordered" with "administered or dispensed," and removing "office" to allow for payment in the course of an office or home visit. The proposed amendments to the language includes replacing "Physicians may be reimbursed for the actual cost of medications" with "Payment is made to physicians for covered brand name and generic drugs as determined by § 1121.56a(k), multiplied by the number of units" in that sentence. The proposed amendment also clarifies that the conditions and limitations in Chapter 1121 apply to pharmaceutical services administered or dispensed by a physician. The Department proposes to replace the term "reimbursement" with "payment made" to improve clarity and consistency regarding the payment for medications.

PAYMENT FOR MIDWIVES' SERVICES

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

The Department proposes to add this section to recognize the prescribing and dispensing authority of midwives. The proposed amendment also clarifies that the conditions and

limitations in Chapter 1121 apply to pharmaceutical services administered or dispensed by a midwife.

PAYMENT FOR CERTIFIED REGISTERED NURSE PRACTITIONER SERVICES

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

The Department proposed to add this section to recognize the prescribing and dispensing authority of CRNPs. The proposed amendment also clarifies that the conditions and limitations in Chapter 1121 apply to pharmaceutical services administered or dispensed by a CRNP.

Affected Individuals and Organizations

Pharmacies enrolled in the MA Program that provide services to FFS recipients will be affected by the proposed regulations for the payment methodology for covered outpatient drugs. There are currently 3,572 pharmacy service locations enrolled in the MA Program, representing 1,307 distinct legal entities. Overall pharmacy payment in FFS is estimated to increase by 6.6 percent 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 promote understanding and application of MA regulations governing the scope of benefits and payment for pharmaceutical services.

Accomplishments and Benefits

The amendments to the 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 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 percent 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 proposed regulation.

Fiscal Impact

Under the revised payment methodology, FFS payment to outpatient pharmacies is estimated to increase by 6.6 percent.

Contact Persons

via U.S. Mail:

Lacey Gates
Department of Human Services
Office of Medical Assistance Programs
Bureau of Policy, Analysis and Planning
P.O. Box 2675
Harrisburg, PA 17120

via email to: RA-PWMAProgComments@pa.gov
Please reference regulation #14-549 in subject line.

Persons with a disability who require an auxiliary aid or service may use the AT&T Relay Service at:
1-800-654-5984 (TDD users) or
1-800-654-5988 (voice users)

Paperwork Requirements

There are no legal, accounting or consulting procedures or additional reporting, recordkeeping or other paperwork required to comply with the proposed regulation.

Effective Date

This regulation is effective upon notice or publication as final in the *Pennsylvania Bulletin*.

Public Hearings

The Department is not proposing to conduct public hearings on regulations mandated by the Final Rule. In lieu of public hearings, the Department provided stakeholders an opportunity for review and public comment. A pharmacy stakeholder meeting was held on July 26, 2016, to allow for provider input into the professional dispensing fee survey process. The proposed payment methodology was shared at the March 23, 2017, MAAC meeting and a description of the plan was posted on the Department's website for public comment. The Department also issued 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 issued an update to the previous public notice announcing an additional increase in the professional dispensing fee. See 48 Pa.B. 7589 (December 8, 2018).

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed rulemaking to the Department at the following address: Department of Human Services, Office of Medical Assistance Programs, c/o Deputy Secretary's Office, Attention: Lacey Gates, Room 515, Health and Welfare Building, Harrisburg, PA 17120, within 30 calendar days after the date of publication of this proposed rulemaking in the *Pennsylvania Bulletin.* Reference Regulation No. 14-544 when submitting comments.

Persons with a disability who require an auxiliary aid or service may submit comments by using the AT&T Relay Service at 1-800-654-5984 (TDD users) or 1-800-654-5988 (voice users).

Regulatory Review Act

Under Section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on November 9, 2023, the Department submitted a copy of this proposed rulemaking 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 addition to submitting the proposed rulemaking, the Department has provided the IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department. A copy of this form is available to the public upon request.

Under Section 5(g) of the Regulatory Review Act, if the IRRC has any comments, recommendations, or objections to any portion of the proposed regulation, it may notify the Department and the Committees within 30 days after the close of the public comment period. Such notification shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review by the Department, the General Assembly and the Governor, of any comments, recommendations or objections raised, prior to final publication of the regulation.

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.

(ii) Services and items furnished to pregnant women, which include services during the postpartum period.

* * * * *

(xxiv) Screenings provided under the EPSDT Program.

(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 prescriber.

(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 whose only approved indication is 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.]

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

[*EAC – Estimated Acquisition Cost* – As defined in 42 CFR 447.301 (relating to definitions).]

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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.**

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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 42 CFR 447.502 (relating to definitions).**

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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

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§ 1121.11. Types of services covered

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(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]**.

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PROVIDER PARTICIPATION

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§ 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).**

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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**a** 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 Disabilities 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]**:

* * * * *

(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 are authorized by publication of notice in the *Pennsylvania Bulletin* and are listed on the Department's website. 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.

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§ 1121.53. Limitations on payment.

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(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 prescriber's own handwriting **or by an electronic alternative means as clarified in § 1121.52a (relating to clarification of the term "written")**.

(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 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 for systemic contraceptives can exceed the 90-day supply limit as specified by the Department**. 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) (related 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 **listed on the Department's website. [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.]

[(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.**

(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 website 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 is posted on the Department website**. 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]** **42 U.S.C.A. § 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]** **and post on the Department website revisions to the** list **[comprised]** 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:]** **drug cost as determined by § 1121.56a, multiplied by the number of units dispensed, plus a $0.50 dispensing fee.**

[(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.

(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 licensed 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 set forth in § 1121.56a(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.

(iii) The FUL established by CMS.

(iv) The State MAC established by the Department.

(b) The ingredient cost of a 340B purchased drug is based on the methodology set forth in § 1121.56a(a), except that payment for the drug cost shall not exceed the 340B ceiling price, as described in 340B(a)(1) of the Public Health Service Act (42 U.S.C.A. § 256b).

(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 website.

(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.

(g) The Department establishes 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 are updated quarterly and as needed to account for marketplace price changes and drug shortages.

(i) The State MAC rates are 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 non-legend drugs for enrolled licensed prescribers on the lower of:

(1) For brand name drugs:

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

(ii) WAC + 3.2%.

(2) For generic drugs:

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

(ii) WAC + 0%,

(iii)FUL.

(iv)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

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PAYMENT FOR PHYSICIANS' SERVICES

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

[Physicians may be reimbursed for the actual cost of medications] <u>Payment is made to physicians for covered brand name and generic drugs as determined by § 1121.56a(k), multiplied by the number of units</u> 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]**. **<u>Payment for these services is subject to the conditions and limitations in Chapter 1121 (relating to pharmaceutical services).</u>** There is no **[reimbursement] <u>payment made</u>** 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: 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

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PAYMENT FOR MIDWIVES' SERVICES

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<u>§ 1142.56. Payment for medications administered or dispensed in the course of a visit.</u>

<u>Payment is made to a midwife for covered brand name and generic drugs as determined by § 1121.56a(k), multiplied by the number of units administered or dispensed</u>

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).

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CHAPTER 1144. CERTIFIED REGISTERED NURSE PRACTITIONER SERVICES

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PAYMENT FOR CERTIFIED REGISTERED NURSE PRACTITIONER SERVICES

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§ 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), 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

November 9, 2023

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

Dear Executive Director Sumner:

Enclosed is a proposed regulation that amends the Department of Human Services' 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.

The purpose of this proposed regulation 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. These technical corrections amend: the current regulations under Chapter 1101 to add diabetic supplies, opioid overdose agents and immunizations to the list of services excluded from copayments; Chapters 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 covered outpatient drugs dispensed by a prescribing provider; and Chapter 1121 to recognize electronic prescribing, to update the list of noncompensable services and to update the dispensed day supply limits.

This proposed regulation 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:	Bulletin
To:	Dietrich, Dawn
Cc:	Serafin, Kenneth; Madden, Victoria; Whare, Jennifer (GC); Curley, Maeve; Patchen, Sherri; Kranz, Hannah; Adeline E. Gaydosh
Subject:	[External] Re: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Date:	Thursday, November 9, 2023 9:24:28 AM

Good morning, Dawn,

Thank you for sending this proposed rulemaking. Per our conversation, please advise if a December 2nd publication date will work.

Thank you,
Adeline

Adeline Gaydosh | Legal Assistant
agaydosh@palrb.us | 717.783.3984
Legislative Reference Bureau
Pennsylvania Code & Bulletin Office
647 Main Capitol Building
Harrisburg, PA 17120

From: Dietrich, Dawn <dadietrich@pa.gov>
Sent: Thursday, November 9, 2023 8:42 AM
To: Bulletin <bulletin@palrb.us>
Cc: Serafin, Kenneth <kserafin@pa.gov>; Madden, Victoria <vmadden@pa.gov>; Whare, Jennifer (GC) <jwhare@pa.gov>; Curley, Maeve <macurley@pa.gov>; Patchen, Sherri <shpatchen@pa.gov>; Kranz, Hannah <hkranz@pa.gov>
Subject: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)

Good morning.

DHS is submitting Reg. No. 14-544, Covered Outpatient Drugs (Proposed Rulemaking). This regulation was submitted to both the Senate Health and Human Services Committee and the House Health Committee this morning.

Please provide written (email) confirmation that this rulemaking was received by your office.

Thank you,

Dawn

Dawn Dietrich | Legal Office Administrator 3
Department of Human Services | Governor's Office of General Counsel
625 Forster Street, 3rd Floor West | Harrisburg, PA 17120
Phone: 717.787.6398 | Fax: 717.772.0717
www.dhs.pa.gov

RECEIVED

Independent Regulatory Review Commission

November 9, 2023

From:	Fricke, Erika L.
To:	Dietrich, Dawn
Cc:	Frankel, Dan
Subject:	RE: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Date:	Thursday, November 9, 2023 8:37:30 AM

Received.

From: Dietrich, Dawn <dadietrich@pa.gov>
Sent: Thursday, November 9, 2023 8:31 AM
To: Fricke, Erika L. <EFricke@pahouse.net>
Cc: Serafin, Kenneth <kserafin@pa.gov>; Madden, Victoria <vmadden@pa.gov>; Whare, Jennifer (GC) <jwhare@pa.gov>; Curley, Maeve <macurley@pa.gov>; Patchen, Sherri <shpatchen@pa.gov>; Kranz, Hannah <hkranz@pa.gov>
Subject: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Importance: High

Good morning.

DHS is submitting Reg. No. 14-544, Covered Outpatient Drugs (Proposed Rulemaking) to the Senate Health and Human Services Committee and the House Health Committee.

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

Thank you,

Dawn

Dawn Dietrich | Legal Office Administrator 3
Department of Human Services | Governor's Office of General Counsel
625 Forster Street, 3rd Floor West | Harrisburg, PA 17120
Phone: 717.787.6398 | Fax: 717.772.0717
www.dhs.pa.gov

From: Michael Siget
To: Dietrich, Dawn
Subject: RE: [EXTERNAL]: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Date: Thursday, November 9, 2023 8:33:27 AM

Received by Chair Rapp's office. Thank you.

RECEIVED
Independent Regulatory Review Commission
November 9, 2023

From: Dietrich, Dawn <dadietrich@pa.gov>
Sent: Thursday, November 9, 2023 8:31 AM
To: Michael Siget <Msiget@pahousegop.com>
Cc: Serafin, Kenneth <kserafin@pa.gov>; Madden, Victoria <vmadden@pa.gov>; Whare, Jennifer (GC) <jwhare@pa.gov>; Curley, Maeve <macurley@pa.gov>; Patchen, Sherri <shpatchen@pa.gov>; Kranz, Hannah <hkranz@pa.gov>
Subject: [EXTERNAL]: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Importance: High

Good morning.

DHS is submitting Reg. No. 14-544, Covered Outpatient Drugs (Proposed Rulemaking) to the Senate Health and Human Services Committee and the House Health Committee.

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

Thank you,

Dawn

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625 Forster Street, 3rd Floor West | Harrisburg, PA 17120
Phone: 717.787.6398 | Fax: 717.772.0717
www.dhs.pa.gov

From:	Bradbury, Joan
To:	Dietrich, Dawn
Cc:	Whare, Jennifer (GC); Curley, Maeve; Kranz, Hannah
Subject:	Re: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Date:	Thursday, November 9, 2023 10:09:20 AM

Received.

Joan Bradbury
Executive Director
Senate HHS Committee
Get Outlook for iOS

From: Dietrich, Dawn <dadietrich@pa.gov>
Sent: Thursday, November 9, 2023 9:34 AM
To: Bradbury, Joan <jbradbury@pasen.gov>
Cc: Whare, Jennifer (GC) <jwhare@pa.gov>; Curley, Maeve <macurley@pa.gov>; Kranz, Hannah <hkranz@pa.gov>
Subject: FW: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)

Good morning, Joan.

Are you able to send a confirmation email that this regulation has been received? IRRC will close early today, so we need to get our confirmations to them ASAP.

Thank you,

Dawn

From: Dietrich, Dawn
Sent: Thursday, November 9, 2023 8:31 AM
To: jbradbury@pasen.gov
Cc: Serafin, Kenneth <kserafin@pa.gov>; Madden, Victoria <vmadden@pa.gov>; Whare, Jennifer (GC) <jwhare@pa.gov>; Curley, Maeve <macurley@pa.gov>; Patchen, Sherri <shpatchen@pa.gov>; Kranz, Hannah <hkranz@pa.gov>
Subject: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Importance: High

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Thank you,

Dawn

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Department of Human Services | Governor's Office of General Counsel
625 Forster Street, 3rd Floor West | Harrisburg, PA 17120
Phone: 717.787.6398 | Fax: 717.772.0717
www.dhs.pa.gov

From: Freeman, Clarissa
To: Dietrich, Dawn
Cc: Whare, Jennifer (GC); Curley, Maeve; Kranz, Hannah
Subject: RE: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Date: Thursday, November 9, 2023 10:30:41 AM

Received.

Clarissa L. Freeman, Esq.
Legal 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: Dietrich, Dawn <dadietrich@pa.gov>
Sent: Thursday, November 9, 2023 9:32 AM
To: Freeman, Clarissa <Clarissa.Freeman@pasenate.com>
Cc: Whare, Jennifer (GC) <jwhare@pa.gov>; Curley, Maeve <macurley@pa.gov>; Kranz, Hannah <hkranz@pa.gov>
Subject: FW: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Importance: High

■ EXTERNAL EMAIL ■

Good morning, Clarissa.

Are you able to send a confirmation email that this regulation has been received? IRRC will close early today, so we need to get our confirmations to them ASAP.

Thank you,

Dawn

From: Dietrich, Dawn
Sent: Thursday, November 9, 2023 8:31 AM
To: Freeman, Clarissa <Clarissa.Freeman@pasenate.com>
Cc: Serafin, Kenneth <kserafin@pa.gov>; Madden, Victoria <vmadden@pa.gov>; Whare, Jennifer (GC) <jwhare@pa.gov>; Curley, Maeve <macurley@pa.gov>; Patchen, Sherri <shpatchen@pa.gov>; Kranz, Hannah <hkranz@pa.gov>
Subject: Reg. No. 14-544 - Covered Outpatient Drugs (Proposed Rulemaking)
Importance: High

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Dawn

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