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Covered Outpatient Drugs Ruling Position Statement

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Recommendation

The Centers for Medicare & Medicaid Services (CMS) Covered Outpatient Drugs (COD) rule requires state Medicaid agencies to reimburse pharmacy providers for covered outpatient drug products based on actual acquisition cost (AAC) and that a professional dispensing fee (PDF) be paid to reflect pharmacist's professional services and costs.[1] **We are recommending that a professional dispensing fee of $12.00 be incorporated into the new reimbursement formula submitted in the state plan amendment (SPA) for the state of Illinois to CMS.** The proposed SPA for Illinois reflects the study findings by The MPI Group[2], factors in Illinois Medicaid specific requirements, aligns appropriately with other state's SPA PDFs, and most importantly, addresses the critical role that pharmacists have to ensure prescriptions are appropriately dispensed. Additionally, **we recommend that CMS provide technical guidelines to states on how the PDF should be calculated, so that it is fair and equitable to both the state AND pharmacy providers**.

Introduction

CMS released the COD final rule on January 21, 2016. The rule was developed to provide guidance on pivotal areas of Medicaid Fee for Service (FFS) drug reimbursement and address the new components of the Medicaid Drug Rebate Program as a result of the Affordable Care Act. The intent of the ruling is to aid states and the federal government in managing increasing drug costs by creating an equitable reimbursement system for Medicaid programs and pharmacies[3]; CMS estimates that the implementation of the FUL formula will cut $2.7 billion to states and federal governments over 5 years.[1] The focus of this position statement is to describe the potential impact of the ruling on pharmacy providers including possible changes in reimbursements and to respectfully provide an evidence based monetary recommendation for the PDF to Illinois Medicaid.

Implementation timeline

State Medicaid agencies are required to revise their state plan and submit a SPA to CMS by June 30, 2017 with an effective date no later than April 1, 2017. To our knowledge, as of yet, Illinois has not submitted a plan.

General Provisions

Currently, community pharmacies are reimbursed with a structured formula of ingredient cost of the medication plus a dispensing fee. The state's actual acquisition cost (AAC) reimbursement methodology does not cover all costs associated with the prescription on a claim level basis. Furthermore, the aggregate reimbursement is required to be below the Federal Upper Limit, as posted by CMS. As pharmacies pay more for drugs due to drug price increases or inflation, the

risk of inadequate AAC based reimbursement increases. Typically, the ingredient cost is calculated utilizing an estimated acquisition cost (EAC) benchmark such as wholesale acquisition cost (WAC). Concerns have been raised regarding the use of EAC to reimburse ingredient cost. EAC is an estimate which may result in reimbursements by CMS that are "non-reflective" of AAC for some drugs.[4] The Illinois Medicaid reimbursement formula is currently structured to pay a dispensing fee of $5.50 (multiple source drugs) or $2.40 (single source drugs) for non-340B drugs.

The new COD ruling mandates that the pharmacy reimbursement formula use AAC, replacing EAC, when determining the cost of the medication plus a professional dispensing fee (PDF). The addition of the word professional to the dispensing fee is a new component of the ruling. CMS has publicly endorsed the notion that pharmacists should be compensated appropriately for their cognitive services and recognizes that pharmacists play a vital role in the healthcare industry. The PDF should encompass the professional services and costs that are associated with dispensing a prescription. Examples of some of the activities that would be included in the PDF are performing drug utilization review (DUR), checking patient insurance coverage, reviewing preferred drug list and beneficiary counseling (refer to Appendix A). In addition, Illinois Medicaid has specific prescription restrictions that, when encountered, require additional steps for pharmacy providers (refer to Appendix B). Medication therapy management, an important patient care service provided by pharmacists, is not part of the PDF. CMS provides no technical guidance, recommended benchmark or formula on how to set the PDF; as a result, CMS allows each state to determine what is considered fair and equitable.

States are required to consider the new COD formula in totality, the AAC and PDF, when determining the total reimbursement to pharmacy providers. CMS further states that pharmacy provider reimbursement rates should be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access, in accordance with section 1902(a)(30)(A) of the Social Security Act.[1] CMS is allowing states flexibility by not setting specific standards or requiring a uniform methodology for these calculations; however, states must provide any supporting documents for their position in the SPA.

Excluded from the COD AAC requirement are specialty drugs that are not distributed by retail community pharmacies and are primarily distributed through other alternative settings such as mail order pharmacies and physician office administered drugs.

Potential consequence of the ruling

CMS historically sets the precedent in healthcare reimbursement. A potential impact of the ruling is a "ripple effect" where this reimbursement model becomes the standard for how other third party payers will reimburse pharmacy providers. Third party payers may move to adopt the new ruling's reimbursement model of AAC plus a PDF. This reimbursement methodology is potentially problematic for pharmacy providers because there is no true standard on how the PDF should be set from a monetary standpoint while AAC is a fixed reimbursement rate.

SPA from Other States

Wisconsin has proposed a two tier PDF model for reimbursement based on total annual prescription volume for all provider types. The proposed PDF will either be $15.69 when the total annual volume is < 35,000 prescriptions or $10.51 when the total annual volume is ≥ 35, 000 prescriptions. Wisconsin previously utilized national average drug acquisition cost (NADAC) for ingredient cost and will continue to do so.[5]

Delaware has set the PDF rate at $10.00 per prescription and will utilize NADAC in the ingredient cost, and if this pricing is not available, then the formula will use AWP minus 19%.[6]

North Dakota Medicaid has set the PDF rate at $12.46 per prescription and will use "lesser of the AAC methodology".[7]

Analysis of Cost of Dispensing

In response to the COD ruling, there are two potential pathways that can occur in Illinois. The state will either 1) uphold the current reimbursement method, stating that the current formula meets the COD requirements or 2) restructure the payment formula. If the state decides to restructure the payment formula, a reasonable PDF is essential for pharmacy providers. The PDF should account for appropriate compensation in order to continue providing sufficient beneficiary access and maintain sound business practice.

The Coalition for Community Pharmacy Action (CCPA) on behalf of the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) commissioned The MPI Group to perform an independent study to assess monetary requirements to dispense a prescription in the United States.[2] The study encompassed all states and types of payers, which included Medicaid (only Medicaid FFS prescriptions were evaluated). Specifically, the Medicaid cost of dispensing was computed for more than 105 million prescriptions filled by 18,174 pharmacies in the 2013 calendar year. The cost of dispensing model assessed five cost elements (refer to Appendix C), which included 1) prescription department salaries and benefits, 2) other prescription department costs, 3) facilities costs, 4) other store and location costs, and finally, 5) allocated corporate overhead, where applicable. Costs associated with marketing expenses, bad debt, and charitable contributions were subtracted from the cost to fill Medicaid prescriptions since Medicaid does not account for these costs. The study also evaluated average work time needed to dispense a prescription for Medicaid.

The study reported that the national average cost to dispense a Medicaid prescription in 2013 was $10.30 per prescription and $11.47 per pharmacy. The average time to fill one Medicaid prescription was reported to take 9.3 minutes.

The study compared these results to all third party payers, the cost of dispensing is less costly for Medicaid prescriptions (versus overall cost of dispensing per prescription = $10.55 and overall cost of dispensing per pharmacy = $11.54) but required more time to fill (other third party prescription = 9.0 minutes). A cost difference existed between per prescription and per pharmacy. Per prescription takes into consideration prescription volume whereas, per pharmacy treats every pharmacy equally and assumes the costs of dispensing is the same regardless of prescription volume. It should be highlighted that when the authors calculated the dispensing fee for Medicaid the study did not assess the cognitive aspect or DUR activities, such as identifying potential drug interactions and appropriateness of the script that is attached to each prescription and is required prior to dispensing to the patient. Finally, Medicaid Managed Care cost of dispensing was not part of the study and should be evaluated in a future study.

Impact of Inflation

The cost of dispensing a Medicaid prescription reported by the study was $10.30 per prescription and $11.47 per pharmacy in the year 2013. In order to portray the most accurate projection for dispensing Medicaid prescriptions in the year 2017, the impact of inflation must be taken into account. As reported by the US Bureau of Labor Statistics, the 2016 Consumer Price Index (CPI) in the United States is 243.603, with an inflation rate of 2.7%.[8] Utilizing a cumulative rate of inflation for the previous 4 years of 4.6%, the Medicaid cost of dispensing per prescription is $11.00 and Medicaid cost of dispensing per pharmacy is $12.00.

Per prescription inflation calculation for 2017:

$ 10.30 X 4.6% = $10.77

Per pharmacy inflation calculation for 2017:

$11.47 X 4.6% = $12.00

Conclusion

The primary purpose of the Centers for Medicare & Medicaid Services (CMS) Covered Outpatient Drugs (COD) ruling is to decrease overall cost while maintaining equitable reimbursement rates to pharmacy providers. (1) Medication dispensing involves multiple workflow steps, and requires the unique knowledge base of pharmacists to ensure safety to patients. It is reasonable to request a professional dispensing fee so that each prescription is properly compensated for time, cognitive services and for quality of patient care provided.

To reiterate, the proposed SPA for Illinois should reflect the study findings by The MPI Group[2], should factor in Illinois Medicaid specific requirements, should be appropriately aligned with other states' SPA PDFs, and most importantly address the critical role that pharmacists have to ensure prescriptions are appropriately dispensed. We are recommending a professional dispensing fee of $12.00 be incorporated into the new reimbursement formula submitted in the SPA for the state of Illinois to CMS. Additionally, we recommend that CMS provide technical guidelines to states on how the PDF should be calculated, so that it is fair and equitable to both the state AND pharmacy providers.

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Definitions[9]

AAC: Actual acquisition cost is the price that closely reflects actual acquisition costs to pharmacies.
AMP: Average manufacturer price is utilized to calculate drug rebates.
AWP: Average wholesale price is a benchmark used to calculate EAC.
EAC: Estimated acquisition cost is a benchmark used by many state Medicaid programs to set payment for drug ingredient costs.
FUL: Federal upper limit sets a reimbursement limit for certain multiple source drugs.
NADAC: National average drug acquisition cost may be utilized to calculate AAC.
WAC: Wholesale acquisition cost is a benchmark used to calculate EAC.

Appendices

Appendix A[10]

Drug utilization review (DUR), as defined by the Academy of Managed Care Pharmacy, is an authorized, structured, ongoing review of health care provider prescribing, pharmacist dispensing, and patient use of medication. There are three forms of DUR: prospective (before dispensing), concurrent (at the time of prescription dispensing), and retrospective (after the therapy has been completed).

A prospective DUR may include all of the following activities:

1. Prior authorization (PA) programs
2. Drug-drug and drug-disease interactions
3. Drug-disease contraindications
4. Dosing appropriateness
5. Drug dose modification
6. Drug-patient precautions (due to age, allergies, gender, pregnancy, etc.)
7. Medication directions
8. Formulary substitutions (e.g., therapeutic interchange, generic substitution)
9. Inappropriate duration of drug treatment

Appendix B

Illinois Medicaid related programs for prescription processing in outpatient pharmacy setting include:
-Drug Prior Authorization for certain drugs
-Preferred Drug List
-Four Prescription Policy
-Refill exceeds maximum limitation

Appendix C[2]

The study identified five elements related to the cost of dispensing (Cost of Dispensing Model):

1. Prescription Department Payroll (personnel):
   - Compensation
   - Benefits

- Payroll taxes

2. Prescription Department Costs (non-ingredient):
   - Prescription containers, labels, and other pharmacy supplies
   - Professional liability insurance for pharmacists
   - Prescription department licenses, permits, and fees
   - Dues, subscriptions, and continuing education for the prescription department
   - Delivery expenses (only prescription-related)
   - Computer systems, including web services (related only to the prescription department)
   - Pharmacy-specific equipment (e.g., automated dispensing systems) depreciation, rental, and/or lease costs
   - Transaction fees
   - Other prescription-department-specific costs

3. Facilities Costs:
   - Rent
   - Utilities (gas, electric, water, and sewer)
   - Real estate taxes
   - Facility insurance
   - Maintenance and cleaning
   - Depreciation
   - Mortgage interest
   - Other facility costs

4. Other Store/Location Costs:
   - Marketing and advertising
   - Professional services (e.g., accounting, legal, consulting)
   - Telephone and data communications
   - Computer systems and support
   - Other depreciation and amortization
   - Office supplies
   - Other insurance
   - Taxes other than real estate, payroll, or sales taxes
   - Franchise fees, if applicable
   - Bad debts
   - Charitable contributions
   - Other interest
   - Other costs not included elsewhere

5. Corporate Costs Allocated to the Prescription Department:
   This cost element applies only to stores that are part of a group of stores or larger business enterprise for which centralized services are performed at district, regional or central corporate locations.

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