

Medicaid Drug Rebate Program - Challenges Across the Industry

Version 1.0

June 2019



This white paper intends to educate interested parties regarding the general operational aspects of the Medicaid Drug Rebate Program (MDRP), provide a high-level description of the various end-to-end processes involved in the administration of the MDRP, identify challenges related to Medicaid drug rebate invoicing, billing quantity discrepancies, and the reconciliation between state Medicaid agencies and participating pharmaceutical manufacturers, offer recommendations for modifying processes with a focus on improved efficiencies for all parties involved in the administration of Medicaid rebate transactions and communicate key recommendations to the Centers for Medicare & Medicaid Services (CMS) MDRP Operations group with a goal of streamlining the process for all stakeholders.

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1. EXECUTIVE SUMMARY

This white paper intends to offer the pharmaceutical industry an overview of the Medicaid Drug Rebate Program (MDRP) also known as the Omnibus Budget Reconciliation Act (OBRA) enacted in 1990. This paper also intends to introduce the reader to NCPDP Work Group 7, Manufacturer and Associated Trading Partner Transaction Standards.

Long before the MDRP came into existence, NCPDP was involved in and continues to work towards the development of pharmacy standards in the industry. The enactment of the MDRP created a greater need for standards as well as an overall understanding of how claims are processed and how transaction data is exchanged. Prior to the MDRP, pharmaceutical manufacturers had little interest in transaction data and how claims processing worked because of reliance on distributors to move their products.

The enactment of the MDRP brought subject-matter experts from the pharmaceutical manufacturing community together to address the requirements found in the MDRP. Shortly thereafter, the pharmaceutical manufacturing community embraced NCPDP as an organization where consensus could be reached by members of the community, at which time Work Group 7 was established.

The basic purpose of Work Group 7 was and continues to include education, monitoring and maintaining standards for the electronic exchange of data amongst pharmaceutical manufacturers and trading partners to facilitate business processes. Over the years, and as contracting transactions became more complex, Work Group 7 expanded its scope beyond the MDRP.

2. PURPOSE AND SCOPE

The Medicaid Drug Rebate Program Task Group identified the need to provide an overview to stakeholders regarding the MDRP. The MDRP continues to challenge the industry as government regulations become more complex. This white paper intends to provide the following:

- Educate interested parties regarding the general operational aspects of the MDRP.
- Provide a high-level description of the various end-to-end processes involved in the administration of the MDRP.
- Identify challenges related to Medicaid drug rebate invoicing, billing quantity discrepancies, and the reconciliation between state Medicaid agencies and participating pharmaceutical manufacturers.
- Offer recommendations for modifying processes with a focus on improved efficiencies for all parties involved in the administration of Medicaid rebate transactions.
- Communicate key recommendations to the Centers for Medicare & Medicaid Services (CMS) MDRP Operations group with a goal of streamlining the process for all stakeholders.

3. MEDICAID DRUG REBATE PROGRAM

3.1 Background

Historically the U.S. government has been the single largest payer of prescription drugs through its funding of Medicare, Medicaid, Department of Defense, Children’s Health Insurance Program and other smaller federal and state programs.¹ In order to gain access to these government funded programs, U.S. pharmaceutical manufacturers must sign a national rebate agreement with the Secretary of Health and Human Services (HHS) agreeing to pay a rebate amount per unit on all covered outpatient drugs dispensed to Medicaid patients. As of February 2019², there were over 65 million people enrolled in Medicaid which makes it the single largest federal health care program and “represents one-sixth of the national health care economy.”³ The Medicaid program is jointly funded by the federal government (based on each state’s Federal Medical Assistance Percentage “FMAP”) and the state Medicaid agencies who share the cost of drugs dispensed to qualified Medicaid enrollees.⁴ All fifty states and the District of Columbia cover prescription drugs under the MDRP, which was authorized by Section 1927 of the Social Security Act.⁵ The Medicaid and CHIP Payment and Access Commission (MACPAC)⁶ reported total government spending for Medicaid outpatient drugs at about \$64 billion for fiscal year 2017. After collecting about \$35 billion in rebates from participating pharmaceutical companies, MACPAC reported a “net drug spend” amount of \$29 billion.

Since OBRA of 1990, U.S. pharmaceutical manufacturers have been required to pay rebates to state Medicaid programs in order to reduce the price paid by the government for prescription drugs dispensed to enrollees.⁷ Participating pharmaceutical manufacturers must pay rebates to states on covered outpatient drugs which have been dispensed to Medicaid beneficiaries and paid for by Medicaid.⁸ It is important to note that the MDRP applies to drugs dispensed or administered to a Medicaid patient in an outpatient setting. Therefore, drugs administered and reimbursed in a hospital inpatient setting would not be eligible for a Medicaid rebate. Covered outpatient drugs exclude diabetic supplies and vaccines but some states reimburse for over the counter medicines if prescribed by a physician. In addition to signing up to participate in the MDRP, pharmaceutical manufacturers must also sign agreements with Health Resources & Services Administration (HRSA) and the Secretary of Veterans Affairs and offer discounted pricing under the 340B Drug Pricing program and the Federal Supply Schedule.

Since the inception of the MDRP in 1991, drug rebates were only applicable to drugs dispensed to Medicaid enrollees under a state’s Fee for Service (FFS) plan. In other words, the state had to reimburse a provider for a patient’s drug before the rebate would be due. The Patient Protection and Affordable Care Act (PPACA) which was signed into law on March 23, 2010⁹, expanded the program to cover drugs dispensed to Medicaid patients covered by Medicaid Managed Care Organizations (MCOs) and also allowed states the option to expand their Medicaid program to cover more of their residents. Medicaid MCOs are required to report the drugs dispensed to their enrollees no later than 45 days after the end of each calendar quarter.¹⁰ State Medicaid agencies collect the drug encounters from the Medicaid MCOs each quarter so they can invoice participating manufacturers for rebates on these drug claims. Each state

¹ <https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/>

² <https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html>

³ <https://oig.hhs.gov/reports-and-publications/top-challenges/2017/>

⁴ 42 U.S.C. § 1396r-8(b)(1)

⁵ <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>

⁶ <https://www.macpac.gov/publication/march-2019-report-to-congress-on-medicicaid-and-chip/>

⁷ The Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, § 4401; 42 U.S.C. § 1396r-8.

⁸ 42 U.S.C. §§ 1396r-8(a)(1) and 1396r-8(b)(1).

⁹ PPACA, P.L. 111-148 § 2501(c); 42 U.S.C. § 1396b(m)(2) and 42 U.S.C. § 1396r-8(b)(1).

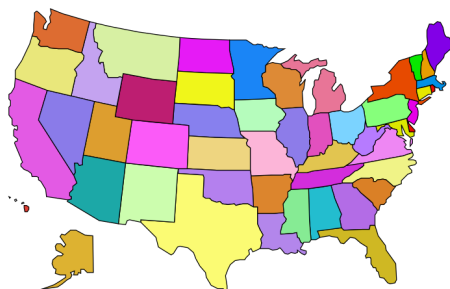
¹⁰ <https://www.medicaid.gov/medicaid/managed-care/guidance/final-rule/index.html>

is also required to report their estimated and actual quarterly Medicaid drug expenses to CMS each quarter. The new law also increased the mandated Medicaid minimum Unit Rebate Amount (URA) which is paid for each drug unit dispensed to a Medicaid patient. Under the mandates in section 2501 of the PPACA of 2010, branded drug rebates are a minimum of 23.1% of Average Manufacturer Price (AMP) and generics are a minimum of 13% of AMP.¹¹ Both branded and now generic drugs are subject to a Consumer Price Index (CPI) penalty which is added to the minimum rebate amount. There are special URA calculations for blood clotting factors, drugs with pediatric indications and branded line extensions.

Participating manufacturers have all reported a large increase in their total Medicaid rebate liabilities – some with payments double or even triple compared to pre-Affordable Care Act (ACA) rebate amounts. This significant increase in Medicaid rebate liability has expanded the manufacturer’s focus on validating the drug claims which are invoiced for a rebate. The majority of Medicaid drug claims are processed without issue but there remain claims which upon review by the manufacturer contain suspected errors. In those cases, the manufacturer does not pay the claims and places them into a dispute status. Due to the large increase in claims invoiced for a Medicaid rebate, the volume of outstanding disputes has increased. Disputes are a matter of concern because they are time consuming to resolve for both the states and manufacturers.¹² The accurate reporting of Medicaid drug claims should be the goal for all stakeholders who dispense and report Medicaid drug claims.

While the federal government holds the contract with the manufacturers, the programs themselves are administered at a state level. Accordingly, each state supplies each of the participating manufacturers with a quarterly invoice, summarized by National Drug Code (NDC), containing the rebate amount which is payable within 38 days from the postmark date of the participating manufacturer’s invoice. These individual invoices from various state Medicaid programs represent billions of dollars of rebates paid by the manufacturers to the states. The rebates are shared by the states and the federal government.

3.2 Overview of Medicaid Drug Rebate Program



There are currently 51 Medicaid programs participating in the MDRP. Each program operates independently under the federal guidance of CMS. In addition, there are approximately 600 pharmaceutical manufacturers currently participating in this program.¹³ Multiple third party rebate vendors facilitate rebate processing and invoicing on behalf of the states.

At the end of each calendar quarter, the Medicaid programs will submit invoices to each of the participating manufacturer labelers for rebates due. The rebates are calculated using the government pricing data reported to CMS by the participating manufacturers and the state utilization data. The

¹¹ PPACA Section 2501 Prescription Drug Rebates, page 306 <https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>

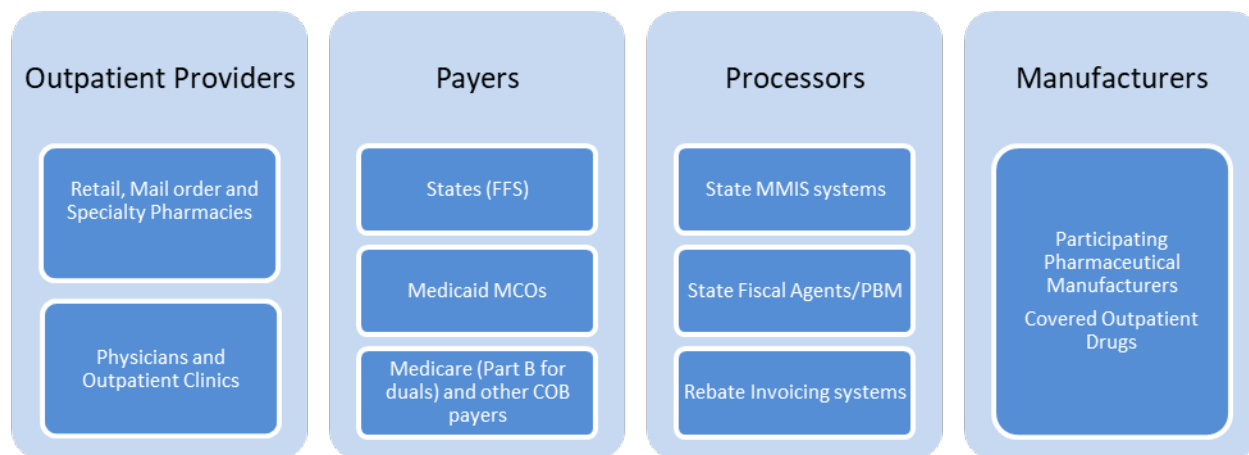
¹² [OIG “Medicaid Drug Rebate Dispute Resolution Could Be Improved” August 2014, OEI-05-11-00580](https://www.oig.dhs.gov/publication/medicaid-drug-rebate-dispute-resolution-could-be-improved-august-2014)

¹³ <https://www.medicare.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>

utilization data is a compilation of all drug claims, point-of-sale pharmacy prescriptions and medical outpatient drug claims, dispensed to Medicaid patients during the prior calendar quarter. The states often submit multiple invoices to each labeler for the different programs (e.g., FFS, Medicaid MCO, Expansion, State Pharmaceutical Assistance Programs (SPAP), Aids Drug Assistance Programs (ADAP)) as well as for supplemental rebates. Some states also invoice for the pharmacy point-of-sale claims and the medical drug claims in separate invoices. The volume of rebate invoices submitted by all 51 state Medicaid programs can be as high as 150-170 for each labeler. The quantity of invoices received by a participating manufacturer each quarter depends on the number of labelers they own, their participation in voluntary rebate programs e.g., SPAPs, supplemental and other ancillary programs and the types of products in their portfolio e.g., pharmacy products, Healthcare Common Procedure Code System (HCPCS) type products, drugs used by ADAP programs, hemophilia drugs, etc. A state that invoices for multiple types of programs could require thousands of invoices to be generated each quarter. Every invoice generated must be validated, processed and paid by the manufacturer. The corresponding payment is then reconciled and posted by the state.

3.3 Medicaid Drug Rebate Program Stakeholders

There are many stakeholders involved in the end-to-end administration of the MDRP. Once a qualified covered outpatient drug is dispensed or administered to a Medicaid patient, data transactions are handed off many times across multiple stakeholders. A large majority of the data exchanged is processed successfully with the complete and accurate details. Occasionally, however, there are transactions which are submitted with incomplete details and/or inaccurate information. While many of the entities across the data flow are negatively impacted by this subset of claims, the states/state rebate processors and the manufacturers are impacted the most. They carry the burden of correcting erroneous transactions in an effort to remain compliant with the MDRP. An OIG report entitled “Medicaid Drug Rebate Dispute Resolution Could Be Improved” dated August 2014,¹⁴ recommended CMS and the states work together to improve the quality of the data received from providers and pharmacies. Any improvement in the data would improve the accuracy of the claims invoiced for rebate and therefore reduce the number of disputed claims.

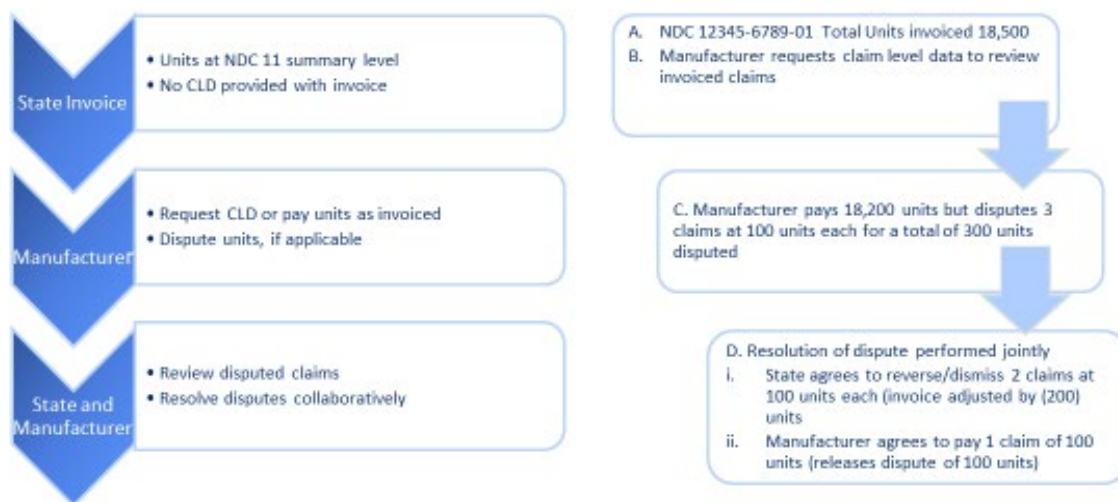


¹⁴ [OIG “Medicaid Drug Rebate Dispute Resolution Could Be Improved” August 2014, OEI-05-11-00580](#)

4. DISPUTING INVOICED CLAIMS

Each calendar quarter, upon receipt of a summarized Medicaid rebate invoice (not including Claim Level Data (CLD)), the participating manufacturer performs high-level validations prior to paying the invoice. A manufacturer can dispute utilization on an original invoice or initiate a dispute on utilization that was previously paid. Currently, there is no time limit on initiating disputes or resolving previously disputed utilization. The OIG report previously referenced states, 24 of the 29 states reviewed reported an estimate of 2% or less of their invoiced rebates were held up in a dispute status. The OIG report also states, “While the percentage of money in dispute appears to be small, it still represents millions of dollars.” The disputes consume a tremendous amount of state and manufacturer resources to reach resolution.

In the same OIG report, many states reported they struggle to prevent disputes because of poor quality claims data from providers and pharmacies. Although no estimates are readily available to quantify exactly how many dollars are tied up in unresolved disputes across the MDRP as a whole, the total disputes will likely grow if current processes are not improved. These problems have been exacerbated with the addition of Medicaid managed care utilization data since the MDRP expansion to include rebates due on Medicaid MCO claims dispensed on or after March 23, 2010.



4.1 Common Reasons for Disputes

4.1.1 Quantity issues due to discrepancies in unit of measure

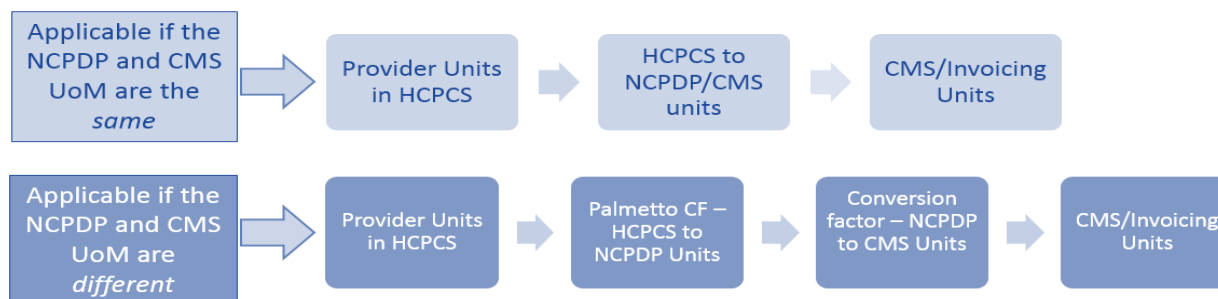
Each calendar quarter a portion of the total Medicaid drug claims submitted by the pharmacy and physician providers are captured by state claim processors in a unit of measure such as NCPDP units of measure or HCPCS units which are not ready for invoicing. In preparation for manufacturer invoicing, the state rebate vendor must convert units received to the applicable CMS unit of measure for inclusion on the summary level MDRP invoices. The most complicated conversions are related to physician administered drugs (medical claims). The provider generally reports the dose administered to the patient in a HCPCS unit of measure. The states must identify the correct conversion factor to apply to the units as reported by the pharmacy or physician provider based on a crosswalk of HCPCS (often called J Codes) to NDC11s based on the specific NDC11 units administered to the Medicaid patient. The HCPCS units must then be converted to the CMS invoicing unit of measure for the applicable NDC11 before the utilization is included on the manufacturer’s summary level rebate invoice. Without an NDC11 on the claim, the state cannot accurately identify which product was administered and therefore cannot collect drug rebates as required.

It should be noted that some products require a conversion factor that increases the number of units invoiced while the others result in a lower number of units after applying the conversion factor. Therefore, the state could inadvertently be under-invoicing or over-invoicing the applicable manufacturer. Below is an example of a product that would increase the units invoiced after a conversion to the HCPCS units is applied.

Manufacturer ABC								
Codes		Product		J Code		CMS Medicaid		Formula
J Code #	NDC11	Product Description	Generic Name	Billing Unit	Units per Pkg	Billing Unit	Units per Pkg	Convert from J code to CMS units
J9123	12345-9876-11	Branded Injectable, 2mg/ml; 50 ml single use vial	Xeninject	10 mg	10	1 ml	50	J code units x 5
J9123	12345-9877-11	Branded Injectable, 2mg/ml; 100 ml single use vial	Xeninject	10 mg	20	1 ml	100	J code units x 5

In the above chart, the provider HCPCS units must be multiplied by five to be consistent with the CMS unit of measure. If the HCPCS units for this illustrative product were not converted, the state would have under-invoiced the manufacturer by four units, thereby foregoing valid rebates due the state. Some manufacturers with common physician administered products will proactively correct the invoiced units and pay the corrected rebate amount. Other manufacturers will dispute the inaccurate units and wait for the state to submit the accurate units before paying. In many cases, states are reluctant to alter the Medicaid MCO medical encounter claims and therefore the disputes remain outstanding for multiple quarters or even years. For some products, a second step is required to convert the claim units to the CMS invoicing unit of measure prior to invoicing.

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These products, often liquids, kits, creams or aerosols, are those which are reported by NCPDP in a unit of measure that is not the same as the one used by CMS.

Unit of Measurement (UOM)

CMS Medicaid Medicaid Drug Rebate 8 Available Options	NCPDP Billing Unit Standard (BUS) Pricing Compendia/Payers 3 Standard Options	CMS Medicare Average Sales Price Reimbursement “No Standard”
AHF – Refers only to Anti-Hemophilic Factor Units (EACH)	EACH – Counted Products (powder filled vials, tablets, suppositories, pills, kits)	IU – International Unit USP – United States Pharmacopeia
CAP – Capsule (EACH)	GM – Gram (products weighted, e.g., ointments)	ML - Milliliter
EA – Each (EACH)	ML – Milliliter (products poured)	MG – Milligram MCG - Microgram
GM – Gram (GM)		EACH
ML – Milliliter (ML)		DOSE Unit(s)
SUP – Suppository (EACH)		Vial
TAB – Tablet (EACH)		CC – Cubic Centimeter
TDP – Transdermal Patch (EACH)		SQ CM – Square Centimeter

Although the focus of this section is on conversions required for outpatient medical claims, it is important to note any pharmacy claim which has a NCPDP unit of measure different from the CMS unit of measure must also be converted by the states prior to invoicing for a Medicaid rebate. Effective January 15, 2019, CMS contracted with Palmetto GBA, LLC to maintain Pricing, Data Analysis and Coding (previously maintained by Noridian Healthcare Solutions). Although the NDC/HCPCS crosswalk¹⁵ is often leveraged by states to convert from HCPCS units to NCPDP units, there is no public source for the conversions required from NCPDP to CMS units. Each state must identify and maintain these conversion factors to ensure they are accurately invoicing for the appropriate number of claim units.

4.1.2 340B Claims Submitted for Medicaid Rebate

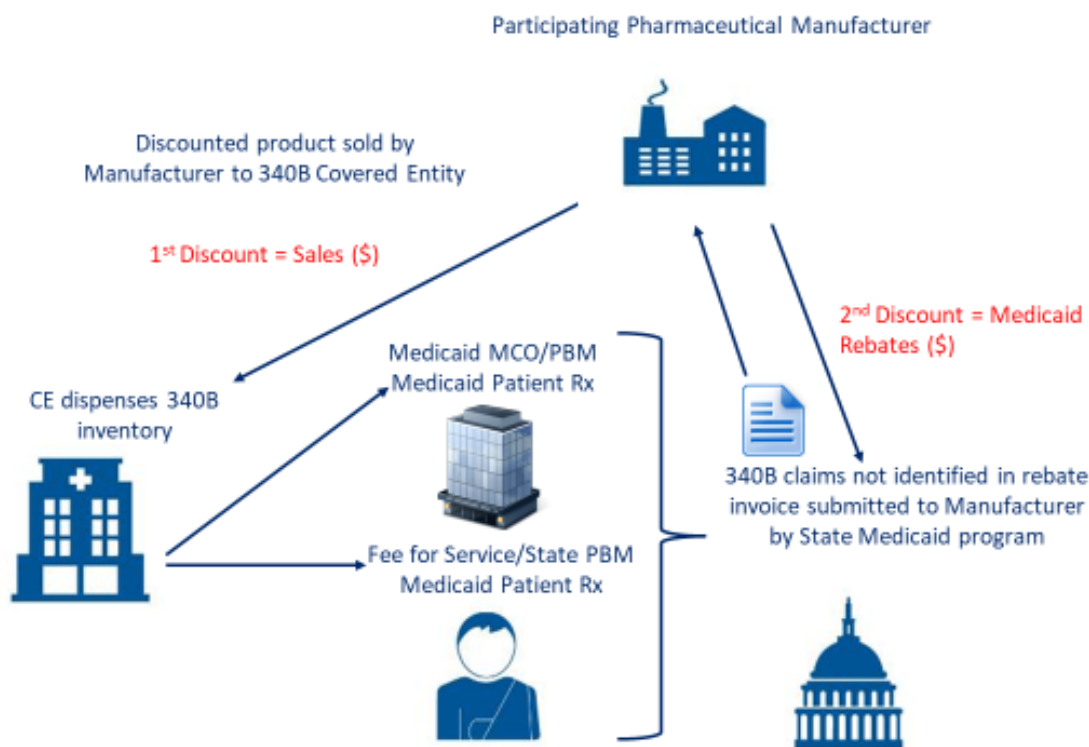
The 340B Drug Pricing Program requires manufacturers participating in the MDRP to also provide drug discounts on covered outpatient drugs to eligible “Covered Entities” as defined in Section 340B (a)(4) of the Public Health Service Act in order for the manufacturer’s drugs to be reimbursed by Medicaid and Medicare Part B. HRSA, the agency that administers the 340B Drug Pricing Program, oversees Covered Entity registration and enrollment and requires Covered Entities to recertify compliance with 340B program requirements on an annual basis.

¹⁵ Palmetto GBA website <https://www.dmepdac.com/>

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In general, a Covered Entity may choose to dispense 340B purchased drugs to their Medicaid patients (carve-in) or they may dispense drugs purchased at the market price instead (carve-out). A state's policy regarding 340B drugs may differ between their Medicaid FFS patients and their Medicaid MCO patients. HRSA permits a Covered Entity to contract with a pharmacy to dispense 340B drugs to a Covered Entity's eligible patients. Covered Entities often have relationships with one or more contract pharmacies to serve their qualified 340B patients. Federal guidance requires these contract pharmacies to carve-out FFS Medicaid unless the Covered Entity, the contract pharmacy, and the state Medicaid agency have an arrangement to prevent duplicate discounts and notify HRSA of the arrangement. Many states do not permit such arrangements for their Medicaid FFS beneficiaries.

The 340B Drug Pricing Program prohibits duplicate discounts. A duplicate discount occurs when a manufacturer sells their drugs to a Covered Entity at a discounted 340B price and pays a state a Medicaid rebate on the same drug.



In order for states to know which claims they should not request Medicaid rebates for in order to prevent duplicate discounts, there are three general ways a Covered Entity designates their entity and/or claims as having been filled with 340B discounted stock:

- If a Covered Entity intends to carve-in FFS patients, they must first register with HRSA by placing their information on the Medicaid Exclusion File. Some states use the Medicaid Exclusion File for FFS and Medicaid managed care although HRSA states the file's intended use is for FFS.
- Some states require a second registration directly with the state Medicaid agency.

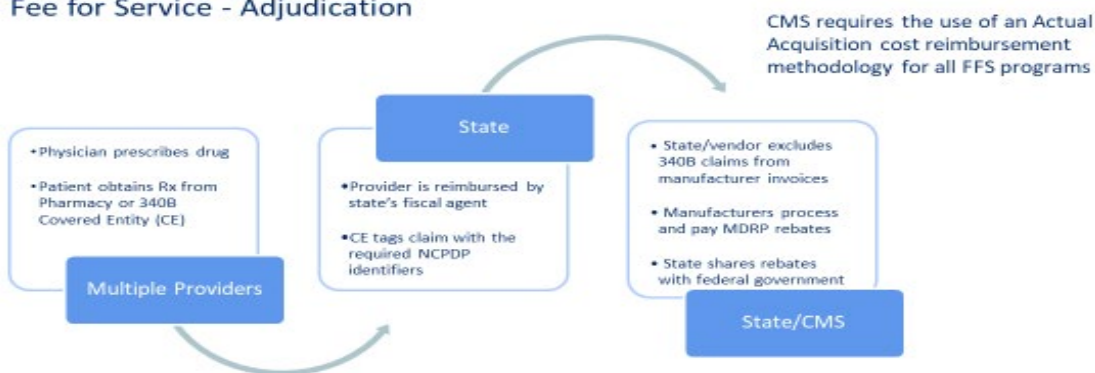
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- Some states require Covered Entities to identify individual claims as 340B at the point-of-sale (using NCPDP identifiers) or retrospectively.

There are various issues that can cause a claim to be invoiced in error which could then be disputed by the manufacturer:

- Covered Entity not providing accurate information to HRSA, the state, or the state’s rebate processor.
- Medicaid MCOs or PBMs not properly receiving or forwarding 340B claim identifiers to the state.
- State or state’s rebate processor failing to adequately scrub out 340B claims prior to invoicing pharmaceutical manufacturers.

Fee for Service - Adjudication



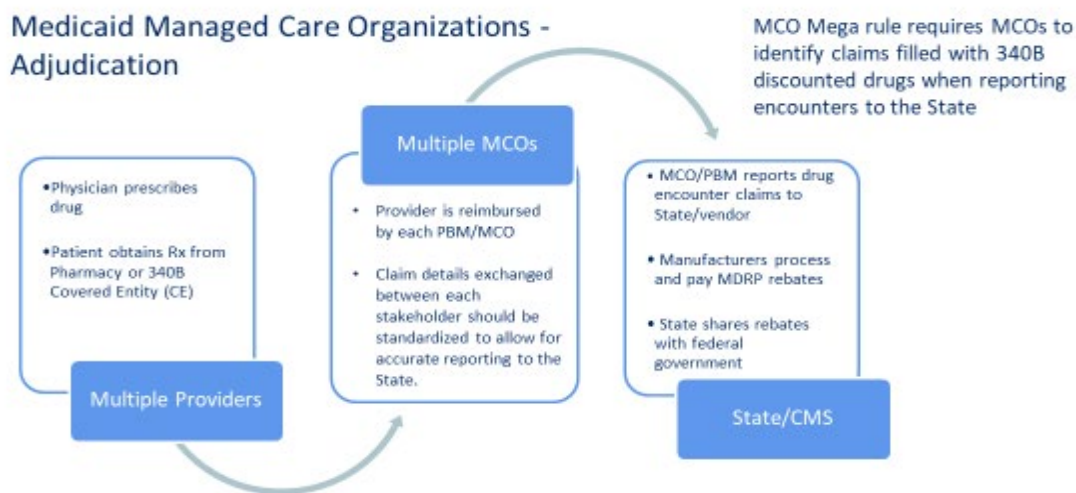
Both manufacturers and HRSA have the authority to audit Covered Entities. A Covered Entity may also perform a self-audit. Some states have mandated that manufacturers work directly with Covered Entities to recover duplicate discounts. In those cases, HRSA may require the Covered Entity to offer repayment to manufacturers for confirmed duplicate discounts.

While Covered Entities must agree to the terms and conditions of the 340B Drug Pricing Program, the federal government, states, Medicaid MCOs, PBMs, manufacturers, and Covered Entities and their contract pharmacies are all stakeholders who must work together to ensure the integrity of the 340B Program. The exchange of CLD, ongoing open communication, proper provider enrollment/registration with HRSA and other supporting documentation is essential in avoiding disputes. Once claims have been placed into dispute, the resolution process can be drawn out for many quarters or even years negatively impacting resources at both the state and the manufacturer level.

CMS–2390–F, “Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability,” published in May of 2016¹⁶ requires the managed care plans to have procedures in place to either exclude or identify

¹⁶ <https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health->

utilization data for drugs subject to discounts under the 340B Drug Pricing Program. In some cases, a state may require Covered Entities to report to them 340B drug claims from Medicaid rebate invoices. The rule required MCO contracts with an effective date of July 1, 2017 or later to comply with the new exclusion or identification requirements.



4.1.3 CLAIMS FOR Terminated Drug

According to the CMS MDRP, a termination date for a specific drug product as referenced by a particular 11-digit NDC is defined as:

- the expiration date of the drug's last lot sold OR
- the date on which the drug was withdrawn from the market¹⁷

The termination date as defined above should be submitted by the manufacturer via the Medicaid Drug Program (MDP) system (formerly the Drug Data Reporting for Medicaid (DDR) system) in a timely manner and indicates a particular drug product (NDC) is unavailable in the marketplace for sale and dispensing and therefore should not be covered after that date. Subject to timely and accurate manufacturer reporting of a termination date in the MDP system, states should not pay claims for terminated drug products if the date of service is after the termination date¹⁸. Therefore, manufacturers should not be

¹⁷ Centers for Medicaid and CHIP Services, Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers, Release No. 91 dated September 12, 2014

¹⁸ Centers for Medicaid and CHIP Services, Medicaid Drug Rebate Program Notice for State Technical Contacts, Guidance Regarding Rebate Obligations For Terminated Manufacturers And Terminated Products, Release No. 168 dated September 12, 2014

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invoiced for claims with dates of service after the termination date. In the event a claim is invoiced, the manufacturer is likely to dispute paying a rebate on the claim.

If the termination date in the MDP system is accurate and was entered timely (e.g., when the last lot of a product is shipped), the dispute can quickly be resolved.

Retrospective reporting of termination dates complicates the resolution of disputed units and leaves the manufacturer liable for payment of rebates on terminated products.

If a manufacturer fails to report an accurate termination date in a timely manner in the MDP system, states have limited ability to identify the drug as terminated and consequently, not payable. As a result, the terminated drug product may be incorrectly paid by the state and identified and included in the quarterly rebate invoicing. Manufacturers should not request credits or dispute the invoiced rebates with the state for a terminated drug product if the claim with a date of service occurred prior to the reporting of the retroactive termination date.

Once a drug product is terminated in the MDP system, the manufacturer is required to continue to pay states for claims that are received with a date of service prior to the termination date using the manufacturer's calculated URA for the last active quarter of the drug.

5. CLAIM LEVEL DATA NECESSARY TO VALIDATE SUMMARY LEVEL INVOICES

As mentioned previously, the quarterly manufacturer Medicaid rebate invoices are summarized at the NDC11 level and sent to manufacturers without the underlying CLD. Although there are a few states who have indicated they are unable to provide complete CLD to manufacturers, many do offer the data. There are various ways a participating manufacturer may obtain CLD for the purpose of validating their summary level invoices:

- Web Portal - Where available a manufacturer may sign-up to access a web portal managed by the state or their third party vendor to pull down CLD for each NDC11 invoiced. In some cases, the portal may support pulling the CLD for an entire labeler.
- Email request – Some states require the manufacturer to submit a request for CLD via email to a state employee or their third party invoicing vendor.
- Data vendor – Manufacturers may contract with a third party data vendor who obtains and standardizes the CLD from states on behalf of manufacturer’s clients for the purpose of validating Medicaid rebate invoices.

Most manufacturers will perform summary level tolerance checks on their invoiced utilization (e.g., units per prescription, reimbursement amount per unit, etc.) However, the most common reasons for dispute cannot be identified without a review of the detailed CLD. Complete sets of CLD can support key validations that may identify common issues such as:

- Unit of measure issues which may be due to incorrect provider units reported, e.g., the provider units were reported using an incorrect HCPCS code, the provider units converted incorrectly or the provider units were not converted at all, etc.
- Claims invoiced by a 340B Drug Pricing Program Covered Entity that may have dispensed a 340B Program discounted drug to the Medicaid enrollee (i.e., a duplicate discount).
- Duplicate claims invoiced within a current quarter, across prior quarters or across multiple programs. This issue is most common in Medicaid MCO claims or can often occur when a state transitions to a new rebate invoicing vendor.
- Medicaid MCO claims improperly invoiced in a rebate quarter that is not consistent with the claim’s date of service¹⁹.
- Claims with a date of service after a product’s termination date.

The validation of CLD can be challenging for manufacturers due to various reasons, such as:

- Missing fields – Some states will not provide key CLD fields necessary to validate the CLD obtained. Examples of fields which are often excluded or scrambled include the claim Rx ID, claim Date of Service and/or the NPI of the dispensing provider. The lack of some or all of these fields makes certain claim validations impossible, for example, the search for potential 340B duplicate claims is not possible without a valid provider NPI.
- No standard format – Currently no standard CLD format exists for use across the 51 Medicaid programs. As a result, a manufacturer will often be required to review CLD in multiple formats making validations even more complicated and time consuming.
- Multiple quarters to be reviewed each cycle – The validation of both original and prior quarter adjustment claims requires the review of multiple quarters of data per product, per program invoiced.

¹⁹ CMS Manufacturer Release 100 “Reporting Managed Care Drug Utilization for Rebate Purposes”
<https://www.medicaid.gov/medicaid/prescription-drugs/program-releases/index.html>

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- Payment time constraints – Medicaid invoices must be paid within 37 calendar days after they are mailed to manufacturers (e.g., the postmark date) to avoid paying interest on the rebates due the state. The large volume of invoices received since the ACA which expanded Medicaid rebates to Medicaid MCO drug encounters, has more than doubled the number of invoices manufacturers must validate and pay each quarter. Reviewing CLD for the large number of invoices received is extremely time consuming. Therefore, many manufacturers will use a “pay and chase” model by paying as invoiced but then reviewing the CLD after peak processing is over and disputing retrospectively in the next quarterly cycle.
- 340B Drug Pricing Program growth – The large increase in the number of 340B program Covered Entities and contract pharmacies since 2010 has expanded the potential for 340B duplicate discounts. The majority of HRSA audits have identified 340B duplicate claims in FFS programs but the audits have not searched for 340B duplicates in the large volume of Medicaid MCO claims.²⁰

The OIG report referenced earlier in this document included a recommendation for CMS to work with the states to educate pharmacy and physician providers on the importance of submitting complete and accurate claims information to the state or to the state’s Medicaid MCOs. The OIG also recommended CMS work with the states to develop a consistent set of claim fields and a standardized layout for states to use when sending CLD to manufacturers.

²⁰ <https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf>

6. HIGH LEVEL RECOMMENDATIONS WHICH WOULD BENEFIT THE OVERALL PROCESSES OF THE MDRP

6.1 Quantity Issues Due to Discrepancies in Unit of Measure

As discussed previously, many products require a unit of measure conversion from the units reported by the provider before they can be included in a manufacturer’s rebate invoice. The conversions required are not easy to find especially for newly marketed products. A report entitled “ASP NDC - HCPCS Crosswalk for Medicare Part B Drugs” is maintained by CMS and updated quarterly.²¹ Although the crosswalk provides information which is important to a provider to accurately report a medical drug claim, the report does not include the conversion factor needed to convert from provider units to the CMS invoicing units. Reference the [NCPDP Billing Unit Standard Fact Sheet](#) for additional information.

October 2018 NDC - HCPCS Crosswalk for Medicare Part B Drugs Effective October 1, 2018 through December 31, 2018

The ASP crosswalks are maintained by the Division of Ambulatory Services to support ASP-based Medicare Part B payments only. The crosswalks are intended to help the public (including entities that submit manufacturer ASP data and providers who bill for drugs) understand which drug products (identified by NDCs) are assigned to which HCPCS billing codes. The crosswalks are not intended to be a comprehensive list of all drugs/NDCs available in the United States. The NDC to HCPCS Crosswalk also includes information on the NDC package size and the number of billable units (as defined by the HCPCS code descriptor). Comments on the file may be sent to sec303aspdata@cms.hhs.gov.

HCPCS CODE	SHORT DESCRIPTOR	LABELER NAME	NDC	DRUG NAME	HCPCS DOSAGE	PKG SIZE	PKG QTY	BILLUNITS	BILLUNITSPKG
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Many states will also reference a report from Palmetto GBA, LLC which includes helpful information and a conversion factor from HCPCS to NCPDP units for many drugs²². However, in some cases an NDC will not be on the report or the information provided may be inaccurate.

NDC	NDC Mod	HCPCS	HCPCS Mod	Relationship Start Date	Relationship End Date	HCPCS Description	NDC Label	Number of Items in NDC Package	NDC Package Measure	NDC Package Type	Route of Administration	Billing Units	HCPCS Amount #1	HCPCS Measure #1	CF	Start Date #1	End Date #1	Prior Start Date #2	Prior End Date #2	Prior Conversion Factor #2	Prior Start Date #3	Prior End Date #3	Prior Conversion Factor #3
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²¹ CMS ASP reporting <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>

²² Palmetto GBA, LLC crosswalk files <https://www.dmepdac.com/palmetto/PDAC.nsf/T/NDC+-HCPCS%20Crosswalk>

Recommendations

NCPDP’s Work Group 7 recommends adding product fields to the MDP system that would be populated and maintained by the manufacturer responsible for the reported NDC with detailed information specific to products which require one or more unit of measure conversions. A report of these newly populated fields could then be accessed by the states in an electronic format to be used to accurately convert the applicable product units. Helpful fields would include:

- Level II HCPCS code assigned to product or the temporary code to be used, if applicable
- Specific NDC11(s) which should be cross walked to the HCPCS code assigned to this product
- HCPCS billing unit of measure and number of doses per package
- CMS billing unit of measure and units per package
- Conversion formula from HCPCS to NCPDP units of measure for invoicing
- Conversion formula from NCPDP to CMS units of measure for invoicing
- Multi-source date (if applicable)
- Effective start dates and end dates for the HCPCS/NDC relationship

An additional recommendation would be focused on manufacturers with products that require a conversion from provider units to CMS units. Manufacturers should be encouraged to proactively communicate details regarding new products or products which are consistently incorrectly converted. An example of helpful details is shown below.

Brand Drug Name (Generic Name)

Dosing is provided for illustrative purposes only.

John Doe

Dose administered = 90mg
Provider HCPCS units = 90 (J1234)
HCPCS conversion = 90/10 = 9 ml
NCPDP conversion = none required
CMS invoiced units = 9

NDC 11	Package Size	HCPCS Code	HCPCS Unit of Measure	Conversion Factors	CMS UPPS	Invoicing Unit of Measure
12345-6789-10	100mg/10ml SUV	J1234	1mg = 1 HCPCS unit	HCPCS units/10 = NCPDP units NCPDP units/1 = CMS units	10	ml

*Attach product insert URL for reference by user.

*Include disclaimer as required by manufacturer’s counsel

6.2 340B Claims Submitted for Medicaid Rebate

The growth in the number of 340B Covered Entities and contract pharmacies, along with the increased number of Medicaid enrollees has exponentially expanded the issues surrounding the identification of claims filled with 340B discounted drugs for the purpose of excluding them from the manufacturer Medicaid rebate invoices.

Recommendations

1. State Medicaid agencies and 340B Covered Entities review the NCPDP [340B Information Exchange Reference Guide](#) to gain a better understanding of the multiple challenges relative to reporting 340B transactions.
2. Ideally, CMS/HRSA would encourage all states to use a consistent methodology to identify 340B claims. In the absence of a common methodology, there are other changes that would benefit many of the stakeholders:
 - a. Develop a 340B Drug Pricing Program subpage on the CMS website under the [Medicaid.gov/Medicaid/Prescription Drugs](#) section with general information about the 340B Drug Pricing Program and links to each State Medicaid program's 340B requirements/ guidance, similar to the Managed Care information on the Medicaid.gov/Medicaid/Managed Care page.
 - b. Ensure states provide guidance relative to reporting both FFS and Medicaid MCO claims, Covered Entity reporting, the use of contract pharmacies and the use of retrospective 340B claim assignment models.
 - c. Mandate Covered Entities report to HRSA the dispensing/participating NPI used to bill Medicaid for all of their sites (parent and child) who have chosen to carve-in Medicaid patients for inclusion in the Medicaid Exclusion File. If an outpatient facility or sub-grantee/sub-contractor bills under a different NPI than the parent site, that information must be appropriately listed for each outpatient facility.
 - d. Encourage Medicaid MCOs to assign unique BIN/PCN numbers to assist Covered Entities and their contract pharmacies in the identification of Medicaid patients for the purpose of accurately reporting the claim as 340B.
 - e. Request stakeholders work collaboratively to avoid 340B duplicate discounts by addressing any applicable reporting errors due to data discrepancies.
3. Proactive review and modification of state 340B Drug Pricing Program reporting guidelines to prepare for the changes in a future version of the NCPDP Telecommunication Standard to be named in HIPAA.

6.3 Terminated Products

States will often reference both a compendium and the MDP system however, on occasion they may differ. The ideal would be to have an exportable universal drug reference file available on a daily or weekly basis which identifies products with new or updated termination dates within the state's defined date range for download by state Medicaid agencies or their vendors. This is similar to the file currently available to the states on a quarterly basis.

Reference the NCPDP white paper, [Dates Associated with Pharmaceutical Products](#), for additional information.

6.4 Use of Standardized Data Could Increase Efficiencies and Reduce Disputes

In the OIG report referenced previously, it was recommended CMS work with the states to standardize the submission of claims data. Manufacturers would benefit from receiving the standardized CLD from the state at the time of the quarterly invoice submission, preferably in an electronic format.

In an effort to address the OIG’s suggestion to standardize claim level data submissions, CMS published a list of “suggested” and “helpful” claim fields and field definitions via a “DRP Hot Topics and Best Practices” document, published in September 2018.²³ Also, included on the Dispute Resolution tab is a link to CMS guidance regarding the HIPAA Privacy rule and the release of the prescription number field in the claim level data.²⁴

Recommendation

Distribute a communication regarding the suggested claim level data fields as a Manufacturer Release and a State Release to raise awareness of the suggested Best Practices.

²³ DRP Hot Topics/Best Practices <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/dispute-resolution/index.html>

²⁴ Status of prescription numbers under the HIPAA Privacy Rule <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/dp-drp/drp-hippa-privacy-rule.pdf> also on the HHS site <https://www.hhs.gov/hipaa/for-professionals/faq/456/does-hipaa-permit-state-medicaid-agencies-to-disclose-information-to-pharmaceutical-manufacturers/index.html>

7. APPENDIX A. GLOSSARY

340B Drug Pricing Program (Section 340B)

Congress enacted Section 340B of the Public Health Service Act (created under Section 602 of the Veterans Health Care Act of 1992). To have their drugs reimbursed by Medicaid and Medicare Part B manufacturers must participate in the 340B program by entering into a pharmaceutical pricing agreement (PPA), with the Health Resources & Services Administration. Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers, called “covered entities,” that serve the nation’s most vulnerable patient populations.

AIDS Drug Assistance Program (ADAP)

A state and territory-administered program authorized under Part B that provides FDA-approved medications to low-income people living with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare.

Ancillary Rebate Programs

Rebate programs outside of federally mandated programs. May be voluntary or mandated by state legislation.

Average Sales Price (ASP)

Manufacturers with Medicaid rebate agreements are required to report ASP data to CMS for reimbursement of Medicare Part B drugs.

Average Manufacturer Price (AMP)

Per the Medicaid Drug Rebate statute and the rebate agreement, the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. AMP is calculated and reported to CMS monthly and quarterly. AMP is used in the calculation of the Unit Rebate Amount (defined below.)

Best Price (BP)

Per the Medicaid Drug Rebate statute and the rebate agreement, the lowest price available per product code regardless of the package size reported to CMS quarterly.

Centers for Medicaid & Medicare Services (CMS)

US Department of Health & Human Services agency responsible for administering Medicare and overseeing aspects of Medicaid.

Covered Outpatient Drug

A drug is considered a Covered Outpatient Drug when the drug may be dispensed only upon prescription and if it meets at least one of the criteria as described in Section 1927(k)(2) of the Social Security Act.

Fee For Service Medicaid (FFS)

Traditional Medicaid program whereby physicians and healthcare providers are reimbursed for each service or product they provide.

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Federal Supply Schedule (FSS)

The Veterans Administration (VA) Federal Supply Schedule program supports the healthcare acquisition requirements for medical equipment/supplies, pharmaceuticals, and services of the VA and other federal government agencies. Pharmaceutical manufacturers calculate FSS on an annual basis.

Health Resources & Services Administration (HRSA)

The primary federal agency for improving health care to people who are geographically isolated, economically or medically vulnerable.

Healthcare Common Procedure Coding System (HCPCS)

A medical code set that identifies health care procedures, equipment, and supplies for claim submission purposes. It has been selected for use in the HIPAA transactions. HCPCS Level I contains numeric CPT codes which are maintained by the AMA. HCPCS Level II contains alphanumeric codes used to identify various items and services that are not included in the CPT medical code set. These are maintained by HCFA, the BCBSA, and the HIAA. HCPCS Level III contains alphanumeric codes that are assigned by Medicaid state agencies to identify additional items and services not included in levels I or II. These are usually called "local codes", and must have "W", "X", "Y", or "Z" in the first position. HCPCS Procedure Modifier Codes can be used with all three levels, with the WA - ZY range used for locally assigned procedure modifiers.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

HIPAA is United States legislation that provides data privacy and security provisions for safeguarding medical information. Also, known as the "Privacy Rule." A major goal is the protection of health information to/from any healthcare provider (Covered Entities) in any electronic form. HHS provided guidance to states specific to the disclosure of claims level data for the purpose of validating Medicaid Drug Rebate Invoices.

<https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/dispute-resolution/index.html>

Labeler

A labeler identifies a pharmaceutical manufacturer with a five-digit number that appears in the beginning of a National Drug Code (NDC) number. Through acquisitions, some pharmaceutical manufacturers may have multiple labelers. A labeler is assigned to any firm that manufactures, repacks or distributes a drug product. For more on NDC number, refer to National Drug Code.

Medicaid

Government health insurance funded under the Title XIX program covering low-income adults and children; funded by federal and state government and administered by the state.

Medicaid Drug Rebate Disputes

The Medicaid Drug Rebate Program agreement allows pharmaceutical manufacturers to dispute claims they believe are invalid by indicating units to be disputed and the applicable CMS dispute code(s) on the Reconciliation of State Invoice/Prior Quarter Adjustment Statement report upon payment. Manufacturers can also dispute claims retroactively.

Medicaid Drug Rebate Program (MDRP)

Medicaid Drug Rebate Program – Challenges Across the Industry

The Medicaid Drug Rebate Program (authorized by Section 1927 of the Social Security Act) is a program that includes CMS, State Medicaid Agencies and participating Pharmaceutical Manufacturers that help to offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid patients. <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>

Medicaid Exclusion File (MEF)

Pursuant to section 340B(a)(5)(A)(ii), HRSA established the 340B Medicaid Exclusion File (MEF) as the mechanism to assist 340B Covered Entities and States in the prevention of duplicate discounts for drugs subject to Medicaid rebates.

Medicaid Health Care Expansion

The Affordable Care Act provides states the opportunity to expand health coverage to low-income families through the Medicaid program.

Medicaid Managed Care Organization (MMCO)

Medicaid managed care provides for the delivery of Medicaid health benefits and additional services through contracted arrangements between state Medicaid agencies and managed care entities.

Medicare

The federal program providing health insurance for people aged 65 and older and people with certain disabilities, regardless of age.

National Drug Code (NDC)

Unique 10-digit, 3-segment number, assigned to each drug product by the FDA. For consistency in billing and reimbursement in the pharmacy services sector of healthcare, the NDC is a unique 11-digit formatted number, a zero is added. This number identifies the labeler/manufacturer, product, and package size of the drug. The first segment is the labeler code and assigned by the FDA. The second segment, the product code, identifies a specific strength, dosage form, and formulation. The third segment, the package code, identifies package sizes. Both the product and package codes are assigned by the labeler/manufacturer.

Office of Inspector General (OIG)

Federal agency whose mission is to protect the integrity of Department of Health & Human Services (HHS) programs as well as the health and welfare of program beneficiaries.

Omnibus Budget Reconciliation Act of 1990, Revised 1993 (OBRA '93)

This Act established the Medicaid Drug Rebate Program that requires covered outpatient drugs to be eligible for Federal financial participation through Medicaid. Pharmaceutical manufacturers who have signed a Medicaid Drug Rebate Agreement must pay rebates to State Medicaid programs on their drugs that have been dispensed or administered to Medicaid patients.

Participating Pharmaceutical Manufacturers

A drug manufacturer who enters into a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs.

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Patient Protection and Affordable Care Act

This is the first part of the comprehensive health care reform law enacted on March 23, 2010. Often referred to as the ACA or PPACA , which is the final amended version of the law.

Rebate Per Unit

See definition of Unit Rebate Amount.

State Pharmaceutical Assistance Program (SPAP)

State run programs that assist low-income residents in paying for their prescription drugs. SPAP coverage varies by state and may be restricted to certain disease states (e.g. kidney, breast cancer, etc.). SPAPs may provide “wrap around” coverage to other benefits.

Supplemental Rebate Agreement

Supplemental rebates are voluntary and paid to State Medicaid agencies on top of statutory rebates by Pharmaceutical Manufacturers for inclusion of their drugs on the Medicaid Preferred Drug List (PDL).

Unit Rebate Amount (URA)

Calculation performed by CMS and Pharmaceutical Manufacturers used to reimburse Medicaid (partially or wholly) for coverage of manufacturer drugs. This may also be referred to as Rebate Per Unit (RPU).

8. APPENDIX B. HISTORY OF CHANGES

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