

All-State Medicaid and CHIP Call May 30, 2023



This communication was printed, published, or produced and disseminated at U.S. taxpayer expense. The information provided in this document is intended only to be a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations, or formal policy guidance that it is based upon. This document summarizes current policy and operations as of the date it was presented. We encourage readers to refer to the applicable statutes, regulations, and other interpretive materials for complete and current information.

Agenda

- School Based Services Claiming Guide
- NPRM: Drug Misclassification

Medicaid Proposed Drug Rule – CMS 2434-P



*Medicaid Program:
Misclassification of Drugs,
Program Administration and
Program Integrity Updates
Under the Medicaid Drug
Rebate Program (CMS-2434-P)
Published May 26, 2023*

*Cynthia Denemark
Acting Division Director
Division of Pharmacy/DEHPG/CMCS*

Three Major Highlights of CMS 2434-P

1. To Implement Drug Misclassification Statute

Proposes requirements and penalties included in the Medicaid Services Investment and Accountability Act of April 2019 (MSIAA) to ensure accurate classification of drug products by manufacturers so they pay correct rebates.

2. To Improve MDRP Integrity and Operations

Proposes to improve Medicaid Drug Rebate Program (MDRP) operations by updating or clarifying certain definitions applicable to the program and clarifying certain regulations as necessary to improve upon the MDRP.

3. To Enhance CMS and States' Ability to Manage Drug Spending

Proposes that CMS verify drug prices through a manufacturer survey and data collection, as well as require Medicaid managed care plans when using a third party (e.g., Pharmacy Benefit Managers) to administer the drug benefit, separately identifies administrative fees from the actual cost of the drug.

Drug Misclassification Proposals



Drug Misclassification Proposals

§ 447.509(d)

CMS Notification criteria: CMS proposes to notify a manufacturer when its drug classification is not supported by the statute and applicable regulations and the rebates to States are at a level other than that associated with a drug's classification.

Deadline to correct misclassification: CMS proposes that the manufacturer has 30 days after CMS notification to correct and certify pricing information.

Deadline to pay back states: CMS proposes manufacturers must pay rebates to the States for the period or periods of time that the covered outpatient drug was misclassified, based on a formula proposed, within 60 calendar days of notification by the agency to the manufacturer of the misclassification, and provide documentation to the agency that the States were contacted by the manufacturer, and that the payments were made to the States within the 60 calendar days.

Proposed Improvements to MDRP Integrity and Operations



Proposed Changes to Definitions

§ 447.502

Proposes to modify or add definitions for:

- Covered Outpatient Drug (COD)
- Drug Product Information
- Internal Investigation (*for purposes of manufacturer pricing metric revision exceptions*)
- Manufacturer (*for purposes of National Drug Rebate Agreement (NDRA) Compliance*)
- Market Date (*for purposes of setting base date Average Manufacturer Price (AMP) for a COD*)
- Noninnovator Multiple Source Drug - (*definition for “generic” type drugs*)
- Vaccine (*for purposes of the MDRP Only*)

Proposals to Improve State Rebate Invoicing

§ 447.510(j) and § 447.520

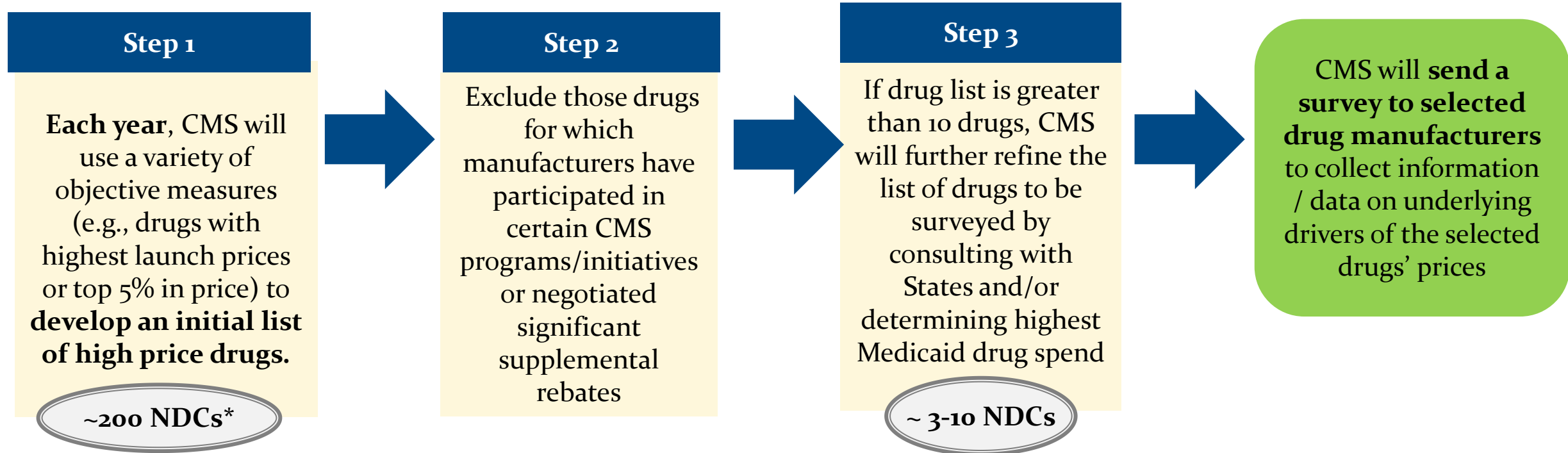
CMS proposes at § 447.510(j) that a manufacturer may only initiate a dispute, request a hearing, or seek an audit of a State regarding State drug utilization data, during a period not to exceed 12 quarters from the last day of the quarter from the date of the State invoice.

CMS proposes at § 447.520 to amend the federal financial participation (FFP) conditions for physician-administered drugs to require States to collect National Drug Code (NDC) information on all covered outpatient physician-administered drugs and to specify that States should be invoicing for rebates for these drugs to receive FFP and secure manufacturer rebates, including for those dispensed by managed care plans.

Proposals to Enhance Drug Price Transparency for States and CMS to Manage High Cost Drug Spending



Proposal for Annual Drug Price Verification Survey Process § 447.510(k)



The survey process is intended for transparency purposes only. It **would not** be used to:

- Limit or deny access to any of the selected drugs
- Assess the cost-effectiveness of any of the selected drugs
- Supplant findings from the FDA's drug approval processes

*NDC: National Drug Code. Identifies the unique product-manufacturer combination for each drug.

Proposal for Drug Cost Transparency in Medicaid Managed Care Contracts § 438.3(s)(8)

CMS proposes that managed care plans structure any contract with any subcontractor (e.g., Pharmacy Benefit Managers) for the delivery or administration of the COD benefit to require the subcontractor to report separately the amounts related to:

- (i) The incurred claims described in § 438.8(e)(2) such as reimbursement for the COD, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a COD; and,
- (ii) Administrative costs, fees and expenses of the subcontractor.

Additional Provisions



Proposal for Medicaid Managed Care Contract Requirements Identifiers on Medicaid Managed Care Cards - § 438.3(s)

Proposes managed care plan assign and exclusively use unique Medicaid-specific Bank Identification Number (BIN), Processor Control Number (PCN), and group number identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits, beginning no later than the State's next rating period for the applicable Medicaid managed care contract, following effective date of the final rule.

Request for Information (RFI) on Requiring a Diagnosis on Medicaid Prescriptions

CMS is seeking comments on potential impact of proposing a requirement that includes a diagnosis on the prescription as a condition of receiving FFP. Under MDRP, a COD is generally defined as a prescribed drug that is Food and Drug Administration (FDA) approved and used for a medically accepted indication. While the statute limits a COD to products used for “medically accepted indications,” it is difficult to determine whether a drug is being used for a medically accepted indication without a diagnosis on a prescription drug claim.

Therefore, CMS is seeking comments on patient care, clinical, and operational impact of requiring that a patient’s diagnosis be included on a prescription as a condition of a State receiving FFP, as well as information on any operational implications, privacy related concerns, the burden associated, and how to negate any foreseeable impact on beneficiaries and providers, including what steps would be needed by States to successfully implement a Medicaid requirement for diagnosis on prescriptions.

Proposal for Payment of Claims § 433.139

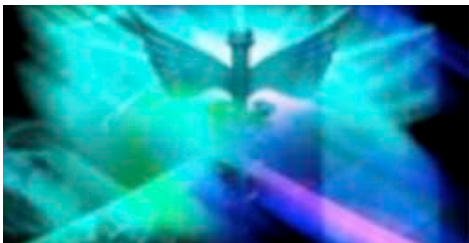
CMS proposes to revise the coordination of benefits regulation to align with statutory requirements.

- These revisions would codify the exception to standard coordination of benefits cost-avoidance policy that allow pay and chase for pediatric preventive services claims and medical child support services claims, as well as detail the timeframe allowed prior to Medicaid paying these claims.
- These revisions would permit states to pay claims sooner than the specified waiting periods, when appropriate.



Medicaid and School-Based Services

Delivering Services in School-Based Settings: A Comprehensive Guide to Medicaid Services and Administrative Claiming



Session Objectives

1. Understand the current policies in School Based Services (SBS)
2. New SBS Comprehensive Guide 2023 and CIB
 - New Flexibilities
 - Compliance Time Frame
3. BSCA Timeline & Future Work – Technical Assistance Center, \$50M State Grants

SBS is an Administration Priority

It is a top Biden-Harris priority to strengthen and expand access to Medicaid and the Children's Health Insurance Program (CHIP).

- **Schools are important providers** of Medicaid direct medical services for children
- Medicaid and CHIP **cover more than half of all children** in the United States
- SBS can include all services covered under EPSDT, including **physical and mental health care**
- **Schools can face a high administrative burden** when seeking reimbursement for SBS
- It is CMS's goal to **help states ease the administrative burden on schools**, to promote the delivery of SBS

About SBS (1/2)

- **Schools are primarily providers of education and other non-medical services**
- **Most third-party healthcare payers other than Medicaid do not reimburse for services provided in schools**
- **SBS fee-for-service rates should be same as community rates, unless justified**
- **Medicaid-covered services provided in schools must meet applicable statutory and regulatory requirements**

About SBS (2/2)

- There is **no Medicaid benefit category called "School Based Services"** -SBS are Medicaid-covered services that are provided in school settings by qualified Medicaid providers enrolled in the Medicaid program.
- To be eligible for payment by Medicaid, services must be **included among those listed in Title XIX of the Act, such as those described in section 1905(a) of the Act**, and coverable under the State plan (or waiver of such plan).
- **Services must be coverable in the state plan**, which makes services available to all beneficiaries under the EPSDT benefit-which provides a comprehensive array of prevention, diagnostic, and treatment services for most low-income individuals under age 21.

Services Provided in Schools

Medicaid services are not limited to...

- Those included in an Individualized Education Plan (IEP) or **Individualized Family Service Plan (IFSP)***.
- Services included in a child's individual Medicaid-covered health care service plan per section **504 of the Rehabilitation Act of 1973**.
- **Any Medicaid covered services** that are provided to Medicaid enrolled beneficiaries, regardless of whether there would otherwise be any charge for the service to the beneficiary.
- **CHIP Services, EPSDT** and any Medically Necessary Service the child needs.
- Covered services may be delivered to **all Medicaid-enrolled children in school settings**, not just those with a special education plan documented in an IEP, IFSP, or Section 504 plan.

*IFSP is for ages Birth-2; IEP is for ages 3-21

Medicaid School Expansion ("Free Care") SPAs

- States have the option to **allow schools to receive Medicaid funding for SBS delivered to all children with Medicaid**, rather than only those children with an IEP, a plan or program tailored for children with disabilities
- **States often need a SPA to expand SBS**
- As of the date of this presentation, **13 states have expanded Medicaid payment for SBS** under their state plans: AZ, CA, CO, CT, GA, IL, KY, LA, MA, MI, NM, NV, NC, OR
- **CMS encourages all states to adopt Medicaid school expansion to expand access to services for children**

SBS Releases Timeline (1/2)

June 2022: Bipartisan Safer Communities Act (BSCA) passes. Requires CMS to:

1. Update claiming guide
2. Launch technical assistance center (TAC)
3. Release \$50 million in grants

August 2022: CMS releases CMS Informational Bulletin (CIB): School-based health services under Medicaid, including CHIP

May 2023: CMS releases the Delivering Services in School-Based Settings: A Comprehensive Guide to Medicaid Services and Administrative Claiming Guide

- Provides series of new flexibilities
- Updates the Medicaid School-Based Administrative Claiming Guide 2003 & Medicaid and Schools Technical Assistance Guide 1997

SBS Releases Timeline (2/2)

June 2023: Technical Assistance Center

1. Support State Medicaid agencies, LEAs, & school-based entities seeking to expand their capacity for providing Medicaid SBS
2. Reduce administrative burden
3. Support such entities in obtaining payment for providing Medicaid SBS
4. Ensure ongoing coordination and collaboration between ED and CMS regarding Medicaid SBS
5. Provide guidance with regard to utilization of various funding sources

2024: \$50 million in discretionary grant funding to states in support of implementing, enhancing, or expanding the provision of medical assistance through school-based entities under Medicaid or CHIP

SBS Claiming Guide 2023

Delivering Services in School-Based Settings: A Comprehensive Guide to Medicaid Services and Administrative Claiming Guide

Released May 2023

CMS, with the U. S. Department of Education (ED), issued a new SBS claiming guide to improve the delivery of covered Medicaid and CHIP services to enrolled students in school-based settings and to meet the requirements of Section 11003 of BSCA.

Overview of SBS Claiming Guide 2023

The new claiming guide includes:

- **New flexibilities** for billing, random moment in time study (RMTS), billing, provider, and third-party liability that states can adopt to make it easier for schools to get reimbursed for Medicaid and CHIP SBS
- Recommendations for **how states can work with managed care plans**
- Ways states can **simplify the interim billing process**, when used, including in rural, small, or under-resourced communities, where access to care may be particularly problematic
- **Examples of approved methods that state agencies have used to pay for covered services**

How Medicaid Can Support SBS

As a reminder and noted above, Medicaid SBS can promote health, educational equity, and increase school attendance in a series of ways, including by:

1. Helping eligible students enroll in the Medicaid program
2. Connecting students' Medicaid-eligible family members with Medicaid health coverage
3. Providing Medicaid-covered health services in schools and seeking payment for services furnished (any covered service under EPSDT)
4. Offering Medicaid-covered services that support at-risk Medicaid eligible students
5. Performing Medicaid administrative activities to improve student wellness
6. Providing Medicaid-covered services that reduce emergency room visits
7. Providing Medicaid-covered services and performing Medicaid administrative activities that promote a healthy, learning environment

New Flexibilities: Billing Using Cost

Roster Billing Methodology: allows States to compute a representative rate of services delivered, then multiply that rate, on a quarterly or monthly basis, by the number of Medicaid-enrolled students that receive a covered service within that service period.

Per Child, Per Month (PCPM) Interim Rate: allows States to create an interim rate that can be based on the provider's previous year's actual cost, paid out each month on a PCPM-basis or on an average cost per service basis.

Option to Not Submit Bills for Each Service: If you choose roster billing or PCPM, LEAs in State would not be required to submit a bill for each service to Medicaid, as long as the interim rates and payments are reconciled to actual costs at the end of each year.

New Flexibilities: Billing Using Rates

Fee Schedule Rates that Exceed the Community Rate: allows States to pay higher fee schedule rates for services offered in schools - State MUST demonstrate that the rate is economic and efficient, as required by section 1902(a)(30)(A) of the Social Security Act (the Act).

Clarification of Restrictions on Bundled Payment Rates: CMS in a 1999 State Medicaid Director's Letter (SMDL) prohibited use of bundled rates in school-based settings based. CMS recognizes States often implement SBS with reconciled cost methodologies. Bundled rates are permissible as interim payments (reconciled to the actual cost of providing Medicaid services)

New Flexibilities: Time Studies

Time Study Error Rate: allows States to increase error rate in time study implementation plans from +/-2% to +/-5%. Can conduct unified time studies with far fewer moments, which also eases administrative burden

Time Study Notification and Response Period: allows States to submit time study implementation plans to include up to 2-day notification window & up to 2-day response period for queried moments in their time studies for SBS, instead of a 0-day notification window and 2-day response window

New Flexibilities: Documentation

De-identified Data: allows LEAs to furnish some deidentified or masked data to support Medicaid Enrollment Ratios (MERs). Does not supersede the requirement for minimum documentation requirements.

Utilization of a General Allocation Ratio: most LEAs reimburse actual costs utilized in IEP/IFSP- based ratio to allocate costs to Medicaid

- MER = Number of Medicaid enrolled students with an IEP divided by number of students with an IEP. (NOT receiving medical services!)
- May use more general ratio: Number of Medicaid enrolled students divided by total number of students in the LEA

New Flexibilities: Documentation

Utilization of Time Study Moments as a One-step Allocation

Methodology: usual two-step process to allocate costs to Medicaid
1- time study, 2-MER

1-Step- Can design time study activity codes to capture time study moments that are both medical & Medicaid activities

New Flexibilities: Provider Qualifications

SBS provider qualifications: Prior CMS guidance made it difficult for State Medicaid agencies to rely on ED provider qualifications or to establish different provider qualifications for school-based and non-school-based providers of the same Medicaid services.

- State Medicaid agencies can **establish provider qualifications for school-based providers that differ from the qualifications of non-school-based providers of the same Medicaid services**, as long as that State's provider qualifications are not unique to Medicaid-covered services.
- Enrolling qualified health care providers to participate in Medicaid within school settings.

New Flexibilities: Third Party Liability

Third Party Reimbursement: Allow States to suspend or terminate efforts to seek reimbursement from a liable third party if they determine that the recovery would not be cost-effective pursuant to 42 C.F.R. §433.139(f), including for IDEA or 504-plan services. This could ease administrative burden at schools.

Implementation of New Flexibilities

- In the comprehensive guide, we discuss new policies, provide policy clarifications, and reiterate existing federal requirements
- If States are not already adhering to applicable federal standards and requirements as discussed in this guide, submit SPAs, administrative claiming plan amendments, and/or amendments to time study implementation plans to comply as soon as possible, but no later than **the start of the first quarter at least three years after the publication date of the guide (June 1, 2026)**.
- Review the timing requirements in 42 C.F.R. § 430.20 to ensure amendments are effective when needed. For example, a State would need to submit a SPA to CMS by September 30, 2023, in order for it to be effective as of July 1, 2023 (and must comply with public notice requirements and tribal consultation, as applicable)

SBS Resources

Please reach out to your state lead for additional technical assistance.

SBS Resources

- **2014 - Medicaid services provided without charge in schools - “Free Care” SMDL 14-006:** <https://www.medicaid.gov/federal-policy-guidance/downloads/smd-medicaid-payment-for-services-provided-without-charge-free-care.pdf>
- **August 2022 - CMCS Informational Bulletin on SBS:** <https://www.medicaid.gov/federal-policy-guidance/downloads/bhccibo8182022.pdf>
- **May 2023 – Medicaid and School Based Services web landing page (includes New 2023 Guidance Document & CIB):** <https://www.medicaid.gov/resources-for-states/medicaid-state-technical-assistance/medicaid-and-school-based-services/index.html>
- **IDEA:** basis for IEP/IFSP <https://sites.ed.gov/idea/>
- **Federal Cost Principles:** <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75>
- **Medicaid & Telehealth Toolkit:** <https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf>
- **Administrative Claiming SHO:** 2010 SHO letter: allowable admin and enhanced CHIPRA match: <https://www.medicaid.gov/federal-policy-guidance/downloads/SHO10007.pdf>
- **Email for Technical Assistance:** SchoolBasedServices@cms.hhs.gov or your state lead

Questions
