

Department of Health and Human Services

Office of Inspector General



Medicaid Managed Care: States Do Not Consistently Define or Validate Paid Amount Data for Drug Claims

Ann Maxwell
Deputy Inspector General
for Evaluation and Inspections



May 2024, OEI-03-20-00560

REPORT HIGHLIGHTS




May 2024 | OEI-03-20-00560


Medicaid Managed Care: States Do Not Consistently Define or Validate Paid Amount Data for Drug Claims


Why OIG Did This Review

- In Medicaid managed care, consistent and accurate data on the amount pharmacies were reimbursed for filling prescriptions are critical for [CMS](#) and States to administer the program and oversee drug spending. Such data are particularly important in light of concerns that pharmacy benefit managers' (PBMs') use of spread pricing could inflate Medicaid drug costs.
- In the Transformed Medicaid Statistical Information System (T-MSIS), the Medicaid Paid Amount data elements that States report for managed care drug claims could—in practice—represent (1) the amount that the plan or its PBM reimbursed to the pharmacy or (2) the amount that the plan paid to its PBM, which may include PBM administrative fees, such as spread.
- If these paid amount data do not consistently and accurately reflect pharmacy reimbursement, this could undermine States' use of these data to determine actual Medicaid drug spending; to develop plans' capitation rates; and to combat fraud, waste, and abuse in Medicaid managed care. Also, CMS has emphasized the importance of these data for Federal oversight, including financial management of Medicaid managed care.

What OIG Found

 **State requirements varied for how plans should report the paid amount for drug claims.** Of the 36 States that covered outpatient prescription drugs for Medicaid through managed care in January 2022, 28 States required Medicaid managed care plans to report the paid amount for drug claims as the amount the plan or its PBM reimbursed to the pharmacy; 2 States required plans to report the amount the plan paid to its PBM; and 6 States had no reporting requirements.

 **For 37 of 252 managed care drug claims in our review, the T-MSIS paid amount did not equal pharmacy-reported reimbursement, raising concerns about the accuracy or consistency of the paid amounts on these claims.** Twenty-two non-matching claims in our sample were from States where the T-MSIS paid amounts should have equaled pharmacy-reported reimbursement amounts for all claims according to States' requirements and practices.

 **Although all States relied on drug claim paid amounts to safeguard and administer the Medicaid program, many States did not conduct certain activities to validate these data.** Most States relied on these data to develop capitation rates and identify fraud, waste, and abuse. Ten States did not validate these data by comparing them to another data source—a recommended, but not required, activity.

What OIG Recommends

CMS should (1) revise the T-MSIS Data Dictionary to instruct States to report the paid amount as the amount paid to the pharmacy for all Medicaid managed care drug claims; (2) provide additional technical assistance to States to clarify what to include or exclude from the reported paid amounts to providers for Medicaid managed care drug claims; and (3) follow up with States that did not verify that paid amounts for managed care drug claims were complete. CMS concurred with all three recommendations.

TABLE OF CONTENTS

BACKGROUND.....	1
FINDINGS.....	9
State requirements varied for how plans should report the paid amount for drug claims.....	9
For 15 percent of managed care drug claims in our review, the T-MSIS paid amount did not equal pharmacy reimbursement, raising concerns about the accuracy or consistency of the paid amounts on these claims.....	11
All States relied on paid amount data from drug claims to safeguard and administer the Medicaid managed care program.....	12
Many States did not conduct certain activities to validate the paid amounts on Medicaid managed care drug claims	13
Half of States in our review faced challenges in using and/or validating drug claim paid amount data	14
CONCLUSION AND RECOMMENDATIONS.....	16
Revise the T-MSIS Data Dictionary to instruct States to report the paid amount as the amount paid to the pharmacy for all Medicaid managed care drug claims.....	17
Provide additional technical assistance to States to clarify what to include or exclude from the reported paid amounts to providers for Medicaid managed care drug claims.....	17
Follow up with States that did not verify that paid amounts for managed care drug claims were complete.....	18
AGENCY COMMENTS AND OIG RESPONSE	19
APPENDICES.....	20
Appendix A: Sampling Frame Criteria	20
Appendix B: Agency Comments.....	21
ACKNOWLEDGMENTS AND CONTACT	26
ABOUT THE OFFICE OF INSPECTOR GENERAL.....	27

BACKGROUND

OBJECTIVES

1. To identify States' requirements for Medicaid managed care plans to report the paid amount on claims for covered outpatient prescription drugs (hereinafter drugs).
 2. To determine the extent to which the paid amount equaled the amount Medicaid reimbursed the pharmacy for selected managed care drug claims in the Transformed Medicaid Statistical Information System (T-MSIS).
 3. To identify the actions that States have taken to validate and use paid amount data for Medicaid managed care drug claims.
-

Prescription Drug Coverage in Medicaid Managed Care

States administer Medicaid according to Federal requirements to provide health coverage to eligible groups, such as low-income adults, pregnant women, children, older adults, and individuals with disabilities. At the time of our review, Medicaid programs in all 50 States and the District of Columbia (hereinafter States) covered drugs for Medicaid enrollees. States offer Medicaid services, including drugs, (1) through a fee-for-service (FFS) model; (2) by contracting with Medicaid managed care plans (hereinafter plans) to provide coverage to enrollees; or (3) through a combination of FFS and managed care.¹

In January 2022, 36 States contracted with plans to provide drug coverage for Medicaid enrollees.² In fact, plans were responsible for the majority of Medicaid drug utilization and reimbursement, accounting for 66 percent of Medicaid prescriptions in 2022.³ That year, plans reimbursed 62 percent (\$56.4 billion) of total Medicaid drug expenditures.⁴

¹ The term "managed care plans" may refer to managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), or prepaid ambulatory health plans (PAHPs). 42 CFR § 438.2.

² OIG analysis of State survey data, 2022.

³ OIG Analysis of "Number of Prescriptions" from CMS's *State Drug Utilization Data 2022 – National Totals*. Accessed at <https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html> on July 7, 2023.

⁴ OIG Analysis of "Medicaid Amount Reimbursed" from CMS's *State Drug Utilization Data 2022 – National Totals*. For capitated payment arrangements, a zero value could be appropriate for managed care data reported to this field. Accessed at <https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html> on July 7, 2023.

Pharmacy Reimbursement in Medicaid Managed Care

Under the managed care model, States pay plans a periodic (usually monthly) fee known as a capitation payment for each enrollee for services covered in the contract, which can include drugs, regardless of whether the enrollee uses any covered services each month. In turn, when enrollees obtain covered drugs, plans pay the pharmacies that dispensed them. Many plans subcontract with pharmacy benefit managers (PBMs) to administer their Medicaid drug benefit, which could include paying pharmacies' drug claims.⁵

PBM Spread Pricing

PBMs recently have come under scrutiny for a lack of transparency in the practice of spread pricing, which could result in higher drug costs for plans, States, and the Federal government.⁶ Spread pricing occurs when a PBM charges a plan more for a drug than the amount that the PBM pays a pharmacy to dispense the drug.⁷ The PBM retains the difference, or "spread," for itself. This practice—if undetected—could prevent a plan from determining what portion of its costs is for the drug itself and what portion is retained by the PBM as administrative fees. In turn, this could lead to higher costs for States and the Federal government because plans' spending affects future capitation rates that States pay to plans. These State payments to plans include Federal matching funds.

If a plan includes administrative costs, such as PBM spread, as part of its medical costs, the plan's medical loss ratio (MLR) could be inflated—which could undermine MLRs as an important tool in the development of capitation rates and the protection of Medicaid managed care funds.⁸ MLRs help to ensure that plans spend most of their premium revenue on covered health care services and quality-improvement activities, thereby limiting the amount that plans can spend on administration and

⁵ Hereinafter, we use "PBMs" to include pharmacy benefit managers, pharmacy benefit administrators, and similar entities.

⁶ CMS, *CMS Issues New Guidance Addressing Spread Pricing in Medicaid, Ensures Pharmacy Benefit Managers are not Up-Charging Taxpayers*, May 2019. Accessed at <https://www.cms.gov/newsroom/press-releases/cms-issues-new-guidance-addressing-spread-pricing-medicaid-ensures-pharmacy-benefit-managers-are-not> on April 13, 2023. Kaiser Family Foundation, *Costs and Savings under Federal Policy Approaches to Address Medicaid Prescription Drug Spending*, June 2021. Accessed at <https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/> on February 7, 2024.

⁷ CMS, *CMS Issues New Guidance Addressing Spread Pricing in Medicaid, Ensures Pharmacy Benefit Managers are not Up-Charging Taxpayers*, May 2019. Accessed at <https://www.cms.gov/newsroom/press-releases/cms-issues-new-guidance-addressing-spread-pricing-medicaid-ensures-pharmacy-benefit-managers-are-not> on April 13, 2023.

⁸ The MLR is the percentage of premium revenue that a managed care plan spent on covered health care services and quality-improvement activities. CMS requires States to set their managed care plans' capitation rates so that plans will "reasonably achieve" MLRs of at least 85 percent. As part of the process for setting capitation rates, States must take into account the MLRs that their managed care plans have reported. States also have the option to require plans to meet a minimum MLR of at least 85 percent. 42 CFR § 438.4(b)(9), 42 CFR § 438.8(c), and 42 CFR § 438.5(b)(5).

keep as profit.⁹ According to CMS, PBMs must give plans sufficient data so that plans can count any PBM spread as administrative costs, not medical costs, in their MLR calculations.¹⁰

Although no Federal prohibition of PBM spread pricing exists in Medicaid, as of January 2022, 27 States reported to OIG that they prohibited all or some plans' use of spread pricing.¹¹ The Federal Trade Commission and the House Oversight Committee announced investigations focused on PBMs' role in health care costs in June 2022 and March 2023, respectively.^{12, 13} Both the U.S. Senate and the House of Representatives have introduced legislation that would prohibit PBM spread pricing if the legislation is enacted.

Medicaid Managed Care Drug Payment Data

CMS established Medicaid's national database, T-MSIS, to provide CMS, States, and other stakeholders with accurate and consistent Medicaid data, including payment data, to safeguard and administer the program. For example, CMS requires its Medicaid program integrity contractors—the Unified Program Integrity Contractors—to use T-MSIS data to conduct their Medicaid program integrity activities.¹⁴

According to Federal regulations, States must require plans to submit complete and accurate encounter records, including managed care drug claims, to States for all covered services provided to Medicaid enrollees.¹⁵ In turn, CMS requires States to submit these records to T-MSIS, which includes the amounts paid for drug claims.¹⁶ The T-MSIS Data Dictionary communicates the requirements for States to correctly

⁹ Medicaid and CHIP Payment and Access Commission, *Medical Loss Ratios in Medicaid Managed Care*, January 2022. Accessed at <https://www.macpac.gov/publication/medical-loss-ratios-in-medicaid-managed-care/> on December 28, 2023.

¹⁰ CMS, *Informational Bulletin: Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors*, May 2019. Accessed at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib051519.pdf> on October 2, 2019.

¹¹ OIG analysis of State survey data, 2022.

¹² Federal Trade Commission, *FTC Launches Inquiry Into Prescription Drug Middlemen Industry*, June 2022. Accessed at <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry> on March 22, 2023.

¹³ U.S. House Committee on Oversight and Accountability, *Comer Launches Investigation into Pharmacy Benefit Managers' Role in Rising Health Care Costs*, March 2023. Accessed at <https://oversight.house.gov/release/comer-launches-investigation-into-pharmacy-benefit-managers-role-in-rising-health-care-costs> on March 22, 2023.

¹⁴ CMS, *Availability and Use of Transformed Medicaid Statistical Information System (T-MSIS) Data for Program Integrity (PI) Purposes, Technical Direction Letter (TDL) #U-2021-0005*, August 2021.

¹⁵ 42 CFR § 438.242(b) and (c).

¹⁶ 42 CFR § 438.242(d) and 42 CFR § 438.818(a)(3).

submit data to CMS.¹⁷ CMS also provides States with coding guidance in the T-MSIS Coding Blog that gives additional context about CMS’s reporting requirements and expectations.¹⁸

Medicaid Paid Amount in T-MSIS

In its 2020 Medicaid Managed Care Final Rule, CMS emphasized the importance of the paid amount in T-MSIS for “proper monitoring and administration of the Medicaid program, particularly for capitation rate setting and review, financial management, and encounter data analysis.”¹⁹ This Final Rule also clarified, in response to a comment, that the paid amount reflects the amount that the plan or subcontractor (e.g., a PBM) actually reimburses to a pharmacy after adjudicating a claim. However, the T-MSIS Data Dictionary does not instruct States to report the paid amount for managed care drug claims as the amount plans or their PBMs reimbursed to the pharmacy, except for certain sub-capitated encounters (which do not include all encounters in which plans contract with PBMs). According to CMS, the Medicaid Paid Amount data element for managed care drug claims in T-MSIS could—in practice—represent (1) the amount that the plan or its PBM reimbursed to the pharmacy at the point of sale (i.e., pharmacy reimbursement) or (2) the amount that the plan paid to its PBM (i.e., PBM reimbursement), which may include PBM fees such as spread.²⁰

Validation of Encounter Data

CMS defines high-quality encounter data, including payment data, as consistent, accurate, complete, and timely, as shown in Exhibit 1. CMS requires States to validate these data by performing various activities which include, but are not limited to, (1) ensuring submission of all enrollee encounter data, including the paid amount; (2) setting requirements that plans validate the accuracy and completeness of encounter data; and (3) auditing the accuracy of each plans’ encounter data.^{21, 22} CMS has the authority to withhold federal financial participation from States that fail to comply with encounter data validation requirements.²³ CMS guidance identifies

¹⁷ CMS publishes an interactive tool, the Data Guide, so that users can easily traverse the T-MSIS Data Dictionary through a modern web interface. The Data Elements section of this Data Guide specifies definitions of each T-MSIS data element. CMS, *T-MSIS Data Guide*. Accessed at <https://www.medicaid.gov/medicaid/data-systems/macbis/transformed-medicaid-statistical-information-system-t-msis/t-msis-data-guide/index.html> on July 12, 2023.

¹⁸ CMS, *T-MSIS Coding Blog*. Accessed at <https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/index.html> on December 11, 2023.

¹⁹ 85 Fed. Reg. 72754, 72807-72810 (November 13, 2020).

²⁰ CMS response to OIG question regarding pharmacy reimbursement data in T-MSIS, February 2020, and CMS response to OIG question regarding Medicaid Paid Amount requirements for managed care drug claims in T-MSIS, April 2023.

²¹ 42 CFR § 438.242(b), (c), and (d) and 42 CFR § 438.818(a)(2).

²² According to Federal regulations at 42 CFR § 438.602(e), States must conduct periodic, independent audits of the accuracy of encounter data submitted by each plan at least once every 3 years.

²³ 42 CFR § 438.818(b) and (c).

activities—though it does not require them—that States should perform, at a minimum, to ensure high-quality encounter data.²⁴ One of these activities is States’ implementation of “back-end” checks that compare encounter data with other data sources (such as comparing paid amounts to plans’ financial reports).

Exhibit 1: Components of High-Quality Encounter Data



Consistency: Data across encounter records use the same definitions, forms, and formats; and data within an individual encounter record align



Accuracy: Data represent the actual services provided, including the amount that was paid for these services



Completeness: Data provide a record of all services provided to managed care enrollees



Timeliness: Plans submit data in accordance with State deadlines so that States can use data for program administration and submit data to CMS on time

Source: CMS, *State Toolkit for Validating and Auditing Medicaid Managed Care Encounter Data*, September 2023.

Related Work

OIG’s body of work on Medicaid managed care and T-MSIS data has identified deficiencies in the completeness of these data.²⁵ Most recently, OIG evaluated T-MSIS claims from January 2020 for the largest plan in each State that offered comprehensive risk-based managed care. OIG found that, in 10 States, at least 10 percent of the plans’ T-MSIS drug claims had inappropriate zeros, negative amounts, or no information in the paid amount field.²⁶ OIG recommended that CMS review States’ managed care payment data in T-MSIS and ensure that States have corrective action plans to improve data completeness and quality, as appropriate. CMS did not concur with this recommendation, noting that it already was undertaking efforts to improve payment data quality.²⁷

In 2018, the Government Accountability Office (GAO) found that CMS had provided States with limited information regarding the scope and methodology of Federally

²⁴ CMS, *State Toolkit for Validating and Auditing Medicaid Managed Care Encounter Data*, September 2023. Accessed at <https://www.medicaid.gov/sites/default/files/2023-10/mmce-data-valdtn-tolkit.pdf> on December 13, 2023.

²⁵ See, for example, OIG, *National Review of Opioid Prescribing in Medicaid Is Not Yet Possible* (OEI-05-18-00480) August 15, 2019; *T-MSIS Data Not Yet Available for Overseeing Medicaid* (OEI-05-15-00050) June 26, 2017; *Not All States Reported Medicaid Managed Care Encounter Data as Required* (OEI-07-13-00120) July 3, 2015.

²⁶ OIG, *Data on Medicaid Managed Care Payments to Providers Are Incomplete and Inaccurate* (OEI-02-19-00180) March 26, 2021.

²⁷ *Ibid.*

required audits of each plan's encounter and financial data. GAO recommended that CMS provide guidance to States on conducting these audits.²⁸ CMS implemented this recommendation and has published guidance to States regarding these audits in its updated encounter data validation toolkit.²⁹

Methodology

To address our study objectives, we used data from (1) a self-administered online survey sent to all States, (2) a purposive sample of managed care drug claims from the T-MSIS pharmacy claims file, and (3) a data request sent to the pharmacies that billed for or dispensed the drugs on sampled T-MSIS drug claims.

State Survey. In May 2022, we sent an online survey to 51 States. We received responses from all 51 States and analyzed the responses from the 36 States that offered Medicaid enrollees drug coverage through managed care in January 2022.³⁰ We reviewed and summarized States' responses regarding their (1) administration of Medicaid managed care drug benefits; (2) requirements for plans to report paid amounts; and (3) validation and use of paid amount data.

T-MSIS Data. To create our sampling frame, we extracted final-action managed care drug claims for prescriptions filled in January 2022 from the T-MSIS pharmacy claims file on CMS's Integrated Data Repository (IDR) in June 2022. We excluded from our sampling frame drug claims that did not meet certain criteria, which included completeness and reliability between summary-level and detail-level data elements. Of the 36 States with managed care drug coverage in January 2022, 35 States had drug claims in T-MSIS that met our sampling frame criteria. Appendix A includes details about our sampling frame criteria.

We selected a purposive (i.e., non-random) sample of 10 drug claims from each of the 35 States, for a total of 350 managed care drug claims. We sampled purposively to maximize the variation of pharmacies and plans selected within each State, to the extent possible. For example, each State's drug claims included five claims for prescriptions filled by chain pharmacies and five claims for prescriptions filled by independent pharmacies. We also reviewed sampled claims to ensure that all pharmacies were not located in the same city.

Pharmacy Data Request. For each sampled drug claim from T-MSIS, we contacted the pharmacy that billed for or dispensed the drug and requested the amounts that

²⁸ GAO, *Medicaid Managed Care – Additional CMS Actions Needed to Help Ensure Data Reliability*, October 2018. Accessed at <https://www.gao.gov/products/gao-19-10> on March 21, 2023.

²⁹ CMS, *State Toolkit for Validating and Auditing Medicaid Managed Care Encounter Data*, September 2023. Accessed at <https://www.medicaid.gov/sites/default/files/2023-10/mmce-data-valdtn-tolkit.pdf> on December 13, 2023.

³⁰ The remaining 15 States responded to our survey that they did not offer Medicaid enrollees drug coverage through managed care in January 2022 and, therefore, did not complete the other survey questions.

were reimbursed to the pharmacy. We obtained pharmacy contact information from the National Council for Prescription Drug Programs' (NCPDP's) provider file using the National Provider Identifiers (NPIs) that appeared on the T-MSIS drug claims in the sampling frame. We requested that the pharmacy provide reimbursement amounts as defined by the NCPDP. Specifically, for each sampled drug claim, we asked pharmacies to report the total amount paid, ingredient cost paid, and dispensing fee paid, as well as other amounts including the patient pay amount, other payer amount, and sales tax. We received pharmacy-reported reimbursement data for 252 of the 350 drug claims in our sample, a 72-percent response rate.³¹

For each of these 252 drug claims, we compared the paid amount in T-MSIS to the pharmacy-reported reimbursement amount and identified claims for which these amounts did not match. We identified a claim as a non-match if the T-MSIS Medicaid Paid Amount did not equal any of the following reimbursement amounts: (1) the pharmacy-reported NCPDP Total Paid Amount; (2) the calculated NCPDP Total Paid Amount, as determined using the amounts pharmacies reported and following the NCPDP Total Paid Amount definition; (3) the total of the pharmacy-reported ingredient cost paid and dispensing fee paid; and (4) the pharmacy-reported ingredient cost paid.³² In addition, we accounted for the amounts of any post point-of-sale adjustments that occurred for the drug claim at the time of our data collection.³³ For the non-matching claims, we determined the direction and magnitude of the difference between the paid amount in T-MSIS and the pharmacy-reported NCPDP Total Paid Amount. In addition, for each non-matching claim, we identified the State's requirements, if any, for plans to report paid amounts.

Limitations

The results of our comparisons of T-MSIS paid amounts to pharmacy-reported reimbursement amounts cannot be generalized to the population of T-MSIS pharmacy claims because we used a purposive, non-random sample. Therefore, those results are specific to the 252 drug claims in our review.

These drug claims were for prescriptions filled in January 2022, and the T-MSIS data for these claims were extracted from CMS's IDR in June 2022. However, any edits made to the paid amount data for these drug claims in T-MSIS after June 2022 are not reflected in our analysis. Some pharmacies reported that post point-of-sale adjustments can happen long after pharmacies dispense or bill for prescriptions. At the time of our data request, only 1 of the 252 drug claims in our review had a post point-of-sale adjustment that we could account for in our analysis. For an additional

³¹ These 252 claims included at least 3 claims associated with each of the 35 States in our sample.

³² For the T-MSIS Medicaid paid amount, we used data elements CRX041 and/or CRX125. If the amount in either of these T-MSIS data elements equaled one of the reimbursement amounts specified, we considered it a match.

³³ For this review, we defined a post point-of-sale adjustment as a payment a pharmacy made to or received from a plan or PBM after the point of sale for a drug claim, regardless of whether the payment was linked to an individual claim or multiple drug claims.

53 drug claims in our review, pharmacies either reported that they were unable to determine whether post point-of-sale adjustments occurred or did not answer our question about post point-of-sale adjustments.

Finally, we did not independently verify the self-reported information from States or pharmacies. We followed up with States and pharmacies when we found incomplete or inconsistent responses or responses that needed further clarification.

Standards

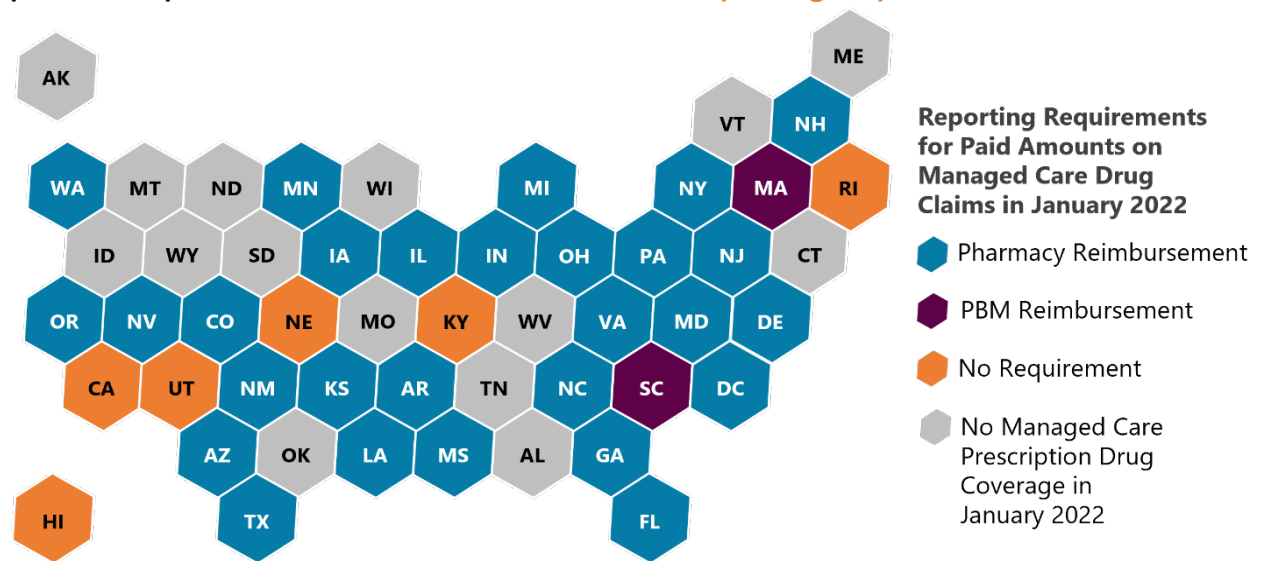
We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

State requirements varied for how plans should report the paid amount for drug claims

The 36 States that covered drugs for Medicaid through managed care in January 2022 responded that they set different requirements for their plans' reporting of paid amounts for drug claims, as shown in Exhibit 2.³⁴ Without uniform standards for plans' reporting to States, the paid amounts that States report in T-MSIS may be inconsistent across States. Lack of consistent paid amount data for managed care drug claims could hinder efforts to safeguard and administer the Medicaid program. Further, T-MSIS paid amount data also may not accurately represent the amounts pharmacies were reimbursed for drugs dispensed to Medicaid enrollees because, in certain States, the reporting requirements allowed paid amount data to equal PBM reimbursement amounts or left it to the discretion of plans. If paid amounts reported as PBM reimbursement contain administrative fees that are improperly counted as medical costs, this could inappropriately inflate Medicaid managed care costs for States and CMS.

Exhibit 2: In January 2022, 28 States required Medicaid managed care plans to report the paid amount for drug claims as pharmacy reimbursement; 8 States required plans to report PBM reimbursement or had no reporting requirements



Source: OIG analysis of State survey data, 2022.

³⁴ We use "paid amount" to refer to the amount that a plan reported to the State as the amount the plan paid for a drug claim. We use "drug claim" to refer to a claim for a prescription drug that was dispensed at a pharmacy and paid by a plan, or its subcontractor, and submitted to the State as an encounter record.

Eight of 36 States did not require their plans to report the paid amount for drug claims as the amount that the pharmacy was reimbursed

Eight States did not require their plans to report the paid amount for drug claims as pharmacy reimbursement. Of these eight States, two required plans to report the paid amount as plan reimbursement to PBMs and six had not issued any requirements or guidance to plans regarding how to report the paid amount for drug claims. In the absence of requirements or guidance, five of these six States stated that plans varied in their practices and reported the paid amount as pharmacy reimbursement only, PBM reimbursement only, or a mix of pharmacy reimbursement or PBM reimbursement (depending on the plan). The sixth State did not know how their plans were reporting the paid amount for drug claims.

Although most States required plans to report paid amounts as pharmacy reimbursement, these States did not define pharmacy reimbursement consistently

The 28 States that required plans to report paid amounts as pharmacy reimbursement included this requirement in their contracts or established this requirement through another mechanism (e.g., a policy document). However, the paid amount data across these States in T-MSIS still may be inconsistent—and, therefore, less reliable for oversight of drug spending—because States' definitions of pharmacy reimbursement differed on whether pharmacy reimbursement must (1) include both the ingredient cost and dispensing fee paid to the pharmacy; (2) equal the amount the pharmacy received at the point of sale; and (3) include or exclude any other specific amounts, such as amounts paid to the PBM or payments from enrollees.

For example, some States specified to their plans that pharmacy reimbursement must include both the ingredient cost and dispensing fee, but these States' definitions of pharmacy reimbursement did not specify whether to include or exclude other amounts, nor whether it must equal the amount received at the point of sale. In contrast, another State did not specify to its plans that pharmacy reimbursement must include the ingredient cost and dispensing fee but did specify that it must equal the amount received at the point of sale and must exclude amounts paid to the PBM. Such inconsistencies may hinder CMS's and other stakeholders' effectiveness in using T-MSIS to conduct program integrity activities and overseeing States, plans, and PBMs.

For 15 percent of managed care drug claims in our review, the T-MSIS paid amount did not equal pharmacy reimbursement, raising concerns about the accuracy or consistency of the paid amounts on these claims

Thirty-seven of 252 T-MSIS managed care drug claims (15 percent) in our purposive sample had paid amounts that did not match pharmacy-reported reimbursement amounts (i.e., non-matching amounts).³⁵ For these 37 drug claims, the paid amounts in T-MSIS may not accurately represent Medicaid drug spending. In addition, States may be limited in using these paid amount data to ensure proper payment because they do not equal the amounts that pharmacies reported they received to fill these prescriptions.

Twenty-two of the 37 non-matching amounts were from 11 States where the T-MSIS paid amounts should have equaled pharmacy-reported reimbursement amounts for all claims according to States' requirements and practices. Specifically, these 22 non-matching amounts were from 10 States that required their plans to report paid amounts as pharmacy reimbursement and one State that indicated that—although it was not required—its plans reported paid amounts as pharmacy reimbursement. Some plans may have been non-compliant with States' paid amount reporting requirements or there may have been data reporting errors.³⁶ For 9 of these 22 drug claims, the paid amounts in T-MSIS ranged from \$0.17 to \$12.31 higher than the pharmacy-reported reimbursement amounts. For another 12 drug claims, the paid amounts in T-MSIS ranged from \$0.01 to \$98.65 lower than the pharmacy-reported reimbursement amounts.³⁷

The remaining 15 of 37 non-matching amounts were from 8 States that either (1) did not require plans to report paid amounts as pharmacy reimbursement (6 States) or (2) required plans to report paid amounts as pharmacy reimbursement but also indicated that they did not always report the plan-reported amount to T-MSIS (2 States).³⁸ For eight of these drug claims, the paid amounts in T-MSIS ranged from \$0.96 to \$57 higher than the pharmacy-reported reimbursement amounts. For

³⁵ For each sampled drug claim, we requested that the pharmacy provide specific reimbursement amounts as defined by the NCPDP, including the total amount paid to the pharmacy, the ingredient cost paid, and the dispensing fee paid. For this analysis, we compared these pharmacy-reported NCPDP amounts to the paid amounts in T-MSIS.

³⁶ For 7 of these 22 claims, pharmacies either reported being unable to determine whether post point-of-sale adjustments occurred or did not answer our question about post point-of-sale adjustments. If such adjustments occurred, they potentially could explain these non-matching amounts.

³⁷ We did not include the direction and magnitude of the difference between the T-MSIS paid amount and the pharmacy-reported reimbursement amount for 1 of these 22 drug claims because T-MSIS contained different amounts for the total encounter paid amount and the detail-level (i.e., line item) paid amount.

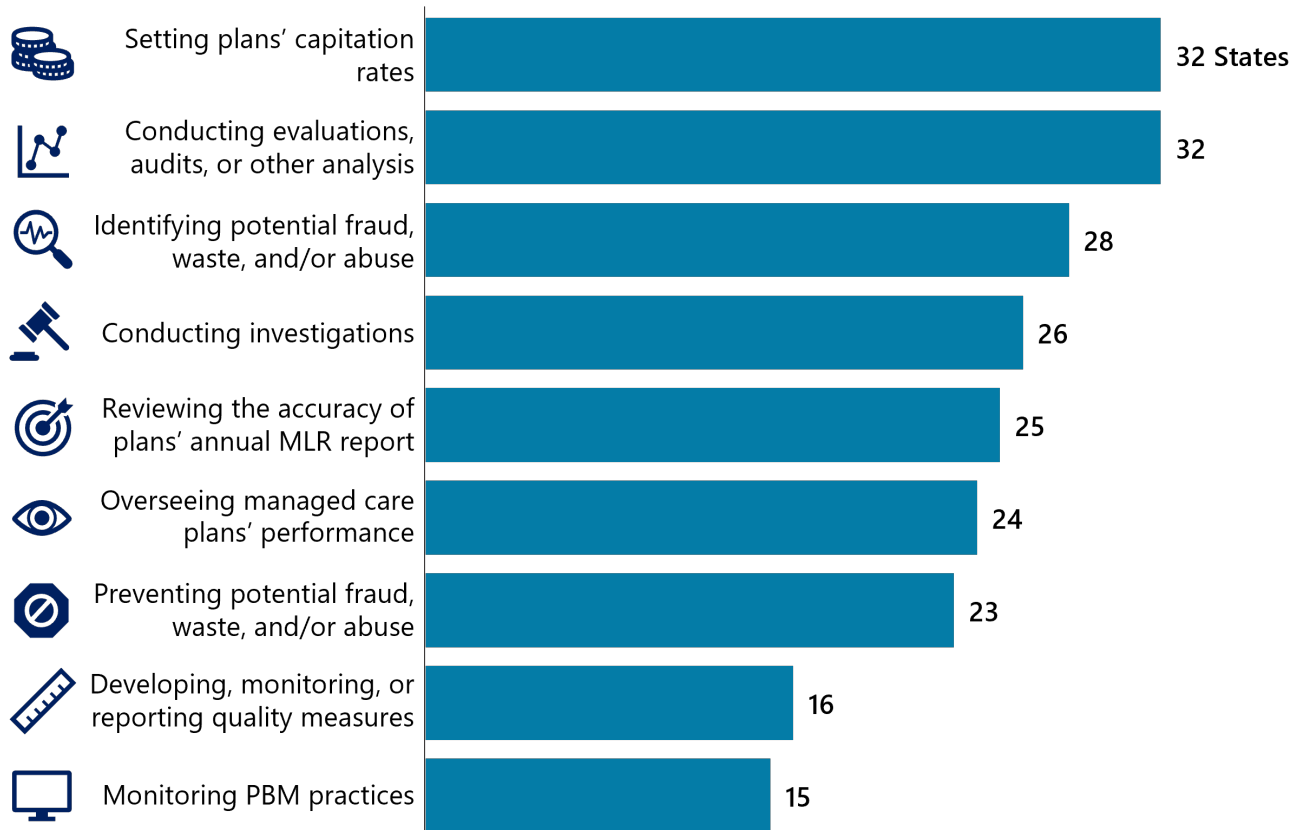
³⁸ For example, one State reported the FFS equivalent amount for all its claims, instead of the plan-reported paid amount, to the Medicaid Paid Amount data element in T-MSIS.

another seven drug claims, the paid amounts in T-MSIS ranged from \$0.82 to \$858 lower than the pharmacy-reported reimbursement amounts.

All States relied on paid amount data from drug claims to safeguard and administer the Medicaid managed care program

All 36 States reported that they relied on paid amount data from drug claims to conduct 3 or more activities—outlined in Exhibit 3—to safeguard or administer their Medicaid programs.³⁹ Notably, 32 of 36 States used the paid amount data in setting their plans’ capitation rates. If these paid amount data are not accurate, States’ rate development calculations—including estimates of future drug spending—may be incorrect. As another example, 28 States reported that they used the paid amount data to identify potential fraud, waste, and abuse, such as identifying outlier payment amounts or aberrant provider behavior. In addition, 24 States used the paid amount data to oversee managed care plans’ performance, such as by monitoring utilization and drug spending.

Exhibit 3: States used paid amount data from managed care drug claims to conduct activities to safeguard and administer Medicaid



Source: OIG analysis of State survey data, 2022.

³⁹ States reported that they used paid amount data for drug claims to conduct these activities in 2020, 2021, and/or 2022.

Many States did not conduct certain activities to validate the paid amounts on Medicaid managed care drug claims

Ten of 36 States did not validate the accuracy of paid amounts for drug claims by comparing them to another data source—a recommended, but not required, activity

Despite States' reliance on drug claim paid amounts to administer and oversee their Medicaid programs, 10 of 36 States did not validate paid amounts by comparing them to another data source (e.g., previous paid amount data or plans' financial reports) in 2021. Though it is not required, CMS guidance identifies comparing encounter data with other data sources as a foundational activity States should perform, at a minimum, to ensure high-quality encounter data.⁴⁰

Among the 26 States that did validate the paid amounts, 19 reported comparing the paid amounts to multiple data sources, most commonly to paid amount data from the plan's previous drug claims, other plans' drug claims, or the plan's financial report. Other data sources States used to validate drug claim paid amounts included drug acquisition cost data (e.g., National Average Drug Acquisition Cost data), paid amount data from drug claims covered under the State's FFS program, and paid amount data from the plan's PBM.

Many States did not conduct at least one of three other data validation activities that we reviewed

Federal regulations require States to validate the completeness and accuracy of encounter data, including the paid amount for drug claims. These requirements include but are not limited to (1) ensuring submission of all enrollee encounter data; (2) setting requirements that States' plans perform validation or other quality checks of encounter data; and (3) auditing the accuracy of each plan's encounter data.^{41, 42} We reviewed 3 specific types of activities States could undertake that align with these 3 requirements, and only 16 States conducted all 3 of these activities for drug claim paid amounts.^{43, 44}

⁴⁰ CMS, *State Toolkit for Validating and Auditing Medicaid Managed Care Encounter Data*, September 2023. Accessed at <https://www.medicaid.gov/sites/default/files/2023-10/mmce-data-valdtn-toolkit.pdf> on December 13, 2023.

⁴¹ 42 CFR § 438.242(b), (c), and (d) and 42 CFR § 438.818(a)(2).

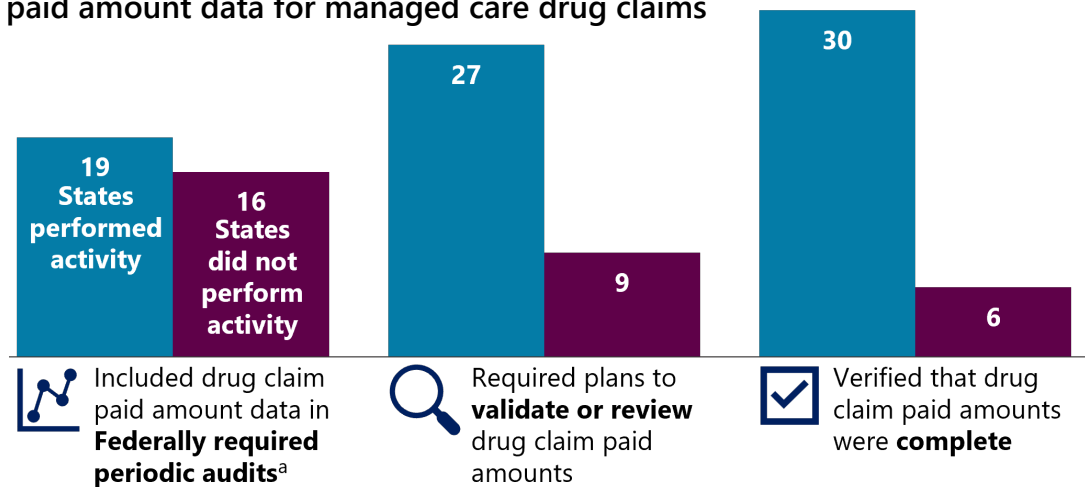
⁴² According to Federal regulations at 42 CFR § 438.602(e), States must conduct periodic, independent audits of the accuracy of encounter data submitted by each plan at least once every 3 years.

⁴³ This was not a compliance assessment because we did not look at all possible activities that could be conducted to achieve compliance. States reported whether they checked for missing paid amounts and set requirements for plans to validate data in 2021. For the Federally required audits, States reported on whether drug claim paid amounts were included in their most recent audit.

⁴⁴ For 1 of the 16 States, only 2 of these validation activities were applicable to the State at the time of our review.

Many States could have improved their efforts to validate the accuracy and completeness of their paid amount data for managed care drug claims, as shown in Exhibit 4. Of the 20 States that did not perform all 3 activities we reviewed, 16 States did not include validation or review of paid amounts for managed care drug claims as part of their most recent Federally required periodic audits; 9 States did not require their plans to perform any validation or other quality checks of the paid amounts for drug claims; and 6 States did not verify that paid amounts were complete.

Exhibit 4: Many States could have performed additional validation of paid amount data for managed care drug claims



Source: OIG analysis of State survey data, 2022.

^aThe total for this validation activity does not equal 36 States because, for 1 State, this audit was not applicable at the time of our review.

Half of States in our review faced challenges in using and/or validating drug claim paid amount data

Eighteen States in our review reported that they faced challenges in using and/or validating paid amounts for drug claims. These challenges included poor-quality encounter data and other barriers to effectively using or validating paid amount data.

Poor-Quality Paid Amount Data. Nine States reported concerns about the quality of their paid amount data, including missing or inaccurate data, and some of these States indicated that these problems made it difficult to use these data to safeguard or administer the Medicaid program. Specifically, some of these States reported challenges in using paid amount data for program integrity activities because of reporting inconsistencies or inaccuracies such as the inclusion of PBM fees in paid amounts. Another State reported that it is a challenge to use paid amount data because paid amounts from managed care drug claims are often missing or reported as “zero.”

Other Data Use and Validation Challenges. Some States reported other data use and validation challenges, including inadequate resources to conduct analysis of paid amount data. For example, one State reported that conducting analysis to

compare managed care paid amounts with FFS paid amounts was both costly and time consuming. Two other States noted that they lacked staff to conduct reviews of drug payment data. Additionally, one State reported that it could not access pharmacy data from PBMs to validate paid amounts because some PBMs' contracts with pharmacies prohibit sharing payment data.

State and Pharmacy Concerns Regarding Post Point-of-Sale Adjustments.

Some States, as well as some pharmacies from our purposive sample of drug claims, reported challenges associated with post point-of-sale adjustments. Post point-of-sale adjustments are payments a pharmacy makes to or receives from a plan or PBM that could ultimately decrease or increase the amount that the pharmacy is paid at the point of sale for a drug claim. For example, a PBM could require a pharmacy to pay a fee to the PBM if the pharmacy does not meet a specified metric. If CMS and States are not aware of post point-of-sale adjustments that reduce pharmacy reimbursements, these amounts could be improperly counted as actual Medicaid drug costs.

Some pharmacies reported concerns that these adjustments lack transparency because they are collected in the aggregate, after claims are adjudicated, and cannot be linked back to individual claims. For example, one pharmacy stated, "Reporting provided by PBM is not [at the] claim-level and the adjustments are aggregated at the end of the year." Another pharmacy stated that "many times these fees are assessed, and the pharmacy doesn't know to which scripts the large clawbacks apply." Two States also reported a similar concern. For example, one State noted that "because the data are aggregated...it is difficult to determine the specific impact" on the State's Medicaid claims.

CONCLUSION AND RECOMMENDATIONS

Consistent, accurate, and complete data on the paid amount for managed care drug claims are critical for CMS and States to safeguard and administer the Medicaid program. If these data do not consistently and accurately reflect pharmacy reimbursement, this could undermine States' use of these data for determining actual Medicaid drug spending, developing plans' capitation rates, reviewing plans' MLR calculations, and combating fraud, waste, and abuse in Medicaid managed care. CMS has also emphasized the importance of these data for Federal oversight, including in its financial management of Medicaid managed care.

High-quality paid amount data that reflect the amount reimbursed to pharmacies for drug claims are particularly important in light of concerns that PBMs' use of spread pricing is not transparent and may inflate Medicaid drug costs. If not properly monitored, spread pricing may constitute a hidden fee that drives up plans' costs, which, in turn, may drive up States' future capitation payments to plans. Further, if a plan includes administrative costs, such as PBM spread, with its medical costs in its MLR, it will appear that this plan is spending more on medical care than it actually is. Federal MLR requirements were established to help ensure that plans spend most of their premium revenue on covered health care services and quality-improvement activities, thereby limiting the amount that plans can spend on administration and keep as profit.

Despite these concerns, the T-MSIS Data Dictionary does not instruct States to report the paid amount for all managed care drug claims as the amount plans or their PBMs reimbursed to the pharmacy. In addition, although CMS clarified in its 2020 Medicaid Managed Care Final Rule that paid amounts should reflect the amount paid to the provider, we found that not all States required their plans to report paid amounts for drug claims as the amount reimbursed to the pharmacy. Moreover, across the States that did require plans to report paid amounts as pharmacy reimbursement, States' definitions of pharmacy reimbursement differed—which may result in inconsistencies in T-MSIS. Further, in our review of 252 managed care drug claims, 15 percent had paid amounts in T-MSIS that did not match pharmacy-reported reimbursement amounts. Finally, many States had significant gaps in their efforts to validate paid amounts.

We recommend that CMS:

Revise the T-MSIS Data Dictionary to instruct States to report the paid amount as the amount paid to the pharmacy for all Medicaid managed care drug claims

Although high-quality paid amount data for drug claims that reflect the amount paid to the pharmacy are essential to safeguard and administer the Medicaid program, we found that some States do not require plans to report the paid amount for managed care drug claims as pharmacy reimbursement. Currently, the T-MSIS Data Dictionary instructs States to report the paid amount as the amount paid on the claim, but it does not specify that this should be the amount paid to the provider, except for certain sub-capitated encounters (which do not include all encounters in which plans contract with PBMs). Therefore, CMS should revise the Data Dictionary's definition of the paid amount (i.e., CRX041 and CRX125) to help ensure that managed care drug claims equal the amount paid to the provider, as CMS clarified in its 2020 Medicaid Managed Care Final Rule. Very minor revisions to the instructions could significantly add clarity on this point. For example, CMS could revise the definition of CRX041 to add the bolded text below:

The total amount paid **to the provider** by Medicaid/CHIP or the managed care plan on this claim or adjustment at the claim header level, which is the sum of the amounts paid **to the provider** by Medicaid or the managed care plan at the detail level for the claim.

Provide additional technical assistance to States to clarify what to include or exclude from the reported paid amounts to providers for Medicaid managed care drug claims

To help ensure consistent and accurate reporting of paid amounts to providers for Medicaid managed care drug claims, CMS should issue additional technical assistance to States to clarify CMS's requirements and expectations for what these paid amounts are intended to represent. CMS should clarify the specific components (e.g., ingredient cost, dispensing fee, amounts paid to the PBM, enrollee copayment) to be included and excluded in reporting of pharmacy reimbursement amounts, and whether reported pharmacy reimbursement amounts should equal the amount the pharmacy received at the point of sale or account for later adjustments. Such assistance is needed because, we found, even among States that required their plans to report paid amounts as pharmacy reimbursement there were differences in how these States defined pharmacy reimbursement. In turn, these differences could lead to inconsistencies that hinder the use of paid amount data in T-MSIS for program oversight. Finally, CMS could also consider reminding States to specify in their contracts with plans that plans must report paid amounts for drug claims as pharmacy reimbursement. CMS could provide this communication to States in the T-MSIS Coding Blog, as a reporting reminder or through other appropriate means.

Follow up with States that did not verify that paid amounts for managed care drug claims were complete

Many States did not perform one or more activities to validate the completeness and accuracy of paid amount data for managed care drug claims. Specifically, six States reported that they did not verify that paid amounts for managed care drug claims were complete (i.e., not missing). At a minimum, CMS should follow up with these six States to help ensure they are taking appropriate measures to verify the completeness of these critical data.

In addition, although all States relied on drug claim paid amounts to administer and oversee their Medicaid programs, 10 States did not compare these paid amounts to another data source—which is an activity that is foundational to ensuring accuracy. Therefore, CMS could take additional steps to strengthen States' validation of paid amounts for drug claims to help ensure these data are suitable for safeguarding and administering the Medicaid program. These steps could include, but are not limited to:

- ensuring that States are setting requirements for their plans to perform validation of paid amount data for managed care drug claims;
- identifying and sharing best practices from States that validate their paid amount data for managed care drug claims by comparing these data to other sources;
- providing targeted technical assistance to States that did not validate their paid amount data for managed care drug claims by comparing these data to other sources; and
- ensuring that the protocols for Federally required periodic audits include review of paid amounts for managed care drug claims.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with all three of OIG's recommendations. In response to our first recommendation, CMS stated that it will update the T-MSIS Data Dictionary to clarify that States should report paid amounts as the amount paid to the provider for all managed care drug claims. To address our second recommendation, CMS stated that it will provide additional technical assistance to States to clarify what should be included and excluded from the reported paid amounts to providers for Medicaid managed care drug claims. Finally, in response to our third recommendation, CMS stated that it will follow up with States that did not verify that paid amounts for managed care drug claims were complete to ensure these States are complying with all the requirements at 42 CFR § 438.242 and 42 CFR § 438.818.

OIG appreciates CMS's commitments, which it appears will address our recommendations when implemented, and looks forward to reviewing CMS's actions when complete.

For the full text of CMS's comments, see the Agency Comments appendix at the end of the report.

APPENDICES

Appendix A: Sampling Frame Criteria

To be included in our sampling frame of T-MSIS pharmacy claims, each claim had to meet certain criteria.

Pharmacy Claims Criteria. Our sampling frame included only final-action, non-denied claims adjudicated after December 2021 that contained (1) a prescription fill date in January 2022; (2) a non-zero Medicaid payment amount; (3) only 1 line item for payment; (4) consistent amounts between the total encounter paid amount and the detail-level (i.e., line item) paid amount;⁴⁵ (5) a type of service code and an 11-digit national drug code (NDC) that both identified a drug; (6) an NPI for the pharmacy that billed for or dispensed the drug; (7) the prescription number; and (8) a plan identification number. Further, we excluded drug claims where non-Medicaid payers paid a portion of the claim and drug claims for a compound drug.

NDC Criteria. In addition, for the claim to be included in the sampling frame, the NDC associated with the claim in the T-MSIS pharmacy claims file had to be (1) listed as a human prescription drug in the Food and Drug Administration's (FDA's) *Comprehensive NDC SPL Data Elements File*; (2) have no marketing end date or have a marketing end date after January 31, 2022; and (3) have an active FDA listing for the entire month of January 2022.

NPI Criteria. Finally, for the claim to be included in the sampling frame, the NPI on the pharmacy claim had to have the following in the NCPDP provider file: (1) a primary contact email address; (2) no store closure date prior to December 2022; (3) a primary type code for a community/retail pharmacy or a mail order pharmacy and a dispenser class code for an independent pharmacy or a chain pharmacy; and (4) a secondary and tertiary provider type code that was missing or that indicated a community/retail pharmacy, mail order pharmacy, managed care organization pharmacy, durable medical equipment supplier, specialty pharmacy, or compounding pharmacy. If neither the billing NPI nor the dispensing NPI associated with a pharmacy claim in T-MSIS matched to the NCPDP provider file, we excluded the claim from the sampling frame.

⁴⁵ For one State, we found many T-MSIS pharmacy claims contained different amounts for the total encounter paid amount and the detail-level (i.e., line item) paid amount in our preliminary analysis. However, the differences between these amounts appeared to follow a logical pattern. Therefore, we did not exclude these claims from our sampling frame.

Appendix B: Agency Comments

Following this page are the official comments from CMS.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: April 3, 2024

TO: Ann Maxwell
Deputy Inspector General
for Evaluation and Inspections

FROM: Chiquita Brooks-LaSure *Chiquita LaS*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicaid Managed Care: States Do Not Consistently Define or Validate Paid Amount Data for Drug Claims (OEI-03-20-00560)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to ensuring the fiscal integrity of the Medicaid program as well as increasing transparency in prescription drug costs.

Most people with Medicaid receive either all or part of their health care benefits, including prescription drugs, through Medicaid managed care plans. Due to the specialized nature of the Medicaid prescription drug benefit, many managed care plans contract with, or have their own Pharmacy Benefit Managers (PBM) to administer the benefit. PBMs negotiate payment rates on behalf of the managed care plans with which they contract, and then pay the medical or pharmacy provider directly for the prescription drugs that are dispensed or administered. The total cost charged to the managed care plan by the PBM often includes both the amount that the PBM paid the medical or pharmacy provider for the prescription drug and the PBM's administrative fees. The margin between the amount charged to a managed care plan and the amount paid by a PBM to a medical or pharmacy provider is referred to as the "spread" or "spread pricing".

Managed care plans are required to submit to the State Medicaid agency encounter data that provide details about the services delivered, such as the type of service, provider name and type, location of service, and amount paid by the plan to the provider. As noted in the OIG's report, the 2020 Medicaid Managed Care Final Rule clarified that the encounter data states submit to CMS through the Transformed Medicaid Statistical Information System (T-MSIS) should reflect the amount the managed care plan, or subcontractor, actually pays to the provider after

adjudicating the claim.¹ Meaning, that states are expected to report to CMS the actual amount their managed care plans, or their PBMs, pay medical or pharmacy providers for prescription drugs. CMS has also included language in the T-MSIS data dictionary specifying that for sub-capitated entities, such as PBMs, states are expected to report the total amount that the sub-capitated entity paid the provider for the service.² Lastly, CMS has issued T-MSIS technical instructions to further support states in their efforts to submit complete and accurate data for pharmacy claims.^{3,4}

Despite CMS's efforts, some states still do not report the amount their managed care plans' PBMs paid directly to the medical or pharmacy providers. To address this, CMS proposed a rule in May 2023 that, if finalized, would further specify that the contracts between states, managed care plans, and third-party contractors, such as PBMs, reflect transparent reporting of drug payment information.⁵ Specifically, CMS proposed to require that managed care plans structure their contracts with PBMs so that PBMs are required to report the prescription drug and dispensing or administration costs separately from any administrative costs, fees, or expenses of the PBM. If finalized, this proposal would help states and managed care plans better understand whether they are appropriately and efficiently paying for the delivery of prescription drugs.

CMS's May 2023 proposed rule, if finalized, would also help ensure the accurate calculation of managed care plans' medical loss ratios (MLRs).⁶ CMS regulations at 42 CFR § 438.8 require each managed care plan that a state contracts with to calculate and report an annual MLR, which is an oversight tool that generally measures how much a managed care plan spends on the provision of covered services compared to the total revenue it receives in capitation payments. MLR calculations are used to develop the capitation rates paid to Medicaid managed care plans, and their accuracy is critical in assuring that Medicaid payments are reasonable, appropriate, and necessary for health care services. In 2019, CMS provided guidance to states regarding the calculation of the MLR when third-party contractors, such as PBMs, are involved.⁷ Specifically, this guidance clarified that when a PBM is performing administrative functions, the expenditures and profits associated with these functions are considered a non-claims administrative expense as described in 42 CFR § 438.8(e)(2)(v)(A), and should not be counted as an incurred claim for the purposes of MLR calculations. If finalized, CMS's May 2023 proposed rule would further assist states and managed care plans in complying with the regulations 42 CFR § 438.8 and any related CMS guidance.⁸

¹ *Federal Register*: Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care; Final Rule (85 FR 72754) (November 13, 2020)

² CMS, T-MSIS/Data Guide/Data Elements/CRX.002.041. 2023. Accessed at: <https://www.medicaid.gov/tmsis/dataguide/data-elements/crx002041/>

³ CMS, CMS Technical Instructions: Reporting Dispensing Fee in the T-MSIS Claim RX File. 2022. Accessed at: <https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/91066#one>

⁴ CMS, CMS MACBIS T-MSIS Reporting Reminder: Reporting Amounts Paid to Providers in T-MSIS. 2022. Accessed at: <https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/136886>

⁵ *Federal Register*: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program; Proposed Rule (88 FR 34238) (May 26, 2023)

⁶ Ibid

⁷ CMS, Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors. 2019. Accessed at: <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib051519.pdf>

⁸ *Federal Register*: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program; Proposed Rule (88 FR 34238) (May 26, 2023)

As noted above, encounter data are the primary source of information about Medicaid enrollees' utilization of covered services, as well as the primary source of details on claims expenditures by managed care plans. As such, accurate encounter data is essential for monitoring the services covered by managed care plans, evaluating plan compliance with contract requirements, and setting capitation rates and performing risk adjustments. CMS regulations at 42 CFR § 438.242 and 438.818 require states to validate the completeness and accuracy of the encounter data that their managed care plans submit before submitting the data to CMS. To support states in meeting these requirements, CMS published a Toolkit that provides practical information states can use to validate and improve the encounter data they receive from their managed care plans.⁹ The Toolkit describes the foundational activities that all states should perform to ensure high quality data, as well as information on data validation activities that states are encouraged to adopt, but that are not required. For example, CMS encourages states to consider comparing total paid amounts from encounter data to financial reports generated from the managed care plans' ledgers to identify discrepancies between the two data sources. CMS is committed to partnering with states to ensure the submission of timely, accurate, and complete encounter data.

The OIG's recommendations and CMS's responses are below.

OIG Recommendation 1

Revise the T-MSIS Data Dictionary to instruct States to report the paid amount as the amount paid to the pharmacy for all Medicaid managed care drug claims.

CMS Response 1

CMS concurs with this recommendation. As noted above, CMS has already included language in the T-MSIS data dictionary specifying that for sub-capitated entities, such as PBMs, states are expected to report the total amount that the sub-capitated entity paid the provider for the service.¹⁰ CMS will further update the T-MSIS data dictionary to clarify that states should be reporting the amount paid to the medical or pharmacy provider for all managed care prescription drug claims.

OIG Recommendation 2

Provide additional technical assistance to States to clarify what to include or exclude from the reported paid amounts to providers for Medicaid managed care drug claims.

CMS Response 2

CMS concurs with this recommendation. CMS will provide additional technical assistance to states clarifying what should be included and excluded from the reported paid amount for

⁹ CMS, State Toolkit for Validating and Auditing Medicaid Managed Care Encounter Data. 2023. Accessed at: <https://www.medicaid.gov/sites/default/files/2023-10/mmce-data-valdtn-tolkit.pdf>

¹⁰ CMS, T-MSIS/Data Guide/Data Elements/CRX.002.041. 2023. Accessed at: <https://www.medicaid.gov/tmsis/dataguide/data-elements/crx002041/>

managed care prescription drug claims. As noted above, CMS has already issued T-MSIS technical instructions to support states in their efforts to submit complete and accurate data for prescription drug claims.^{11,12}

OIG Recommendation 3

Follow up with States that did not verify that paid amounts for managed care drug claims were complete.

CMS Response 3

CMS concurs with this recommendation. As noted above, CMS regulations at 42 CFR § 438.242 and 438.818 already require states to validate the completeness and accuracy of the encounter data from their managed care plans before submitting the data to CMS. CMS provided states with a Toolkit that provides practical information on how to validate and improve the encounter data states receive from their managed care plans.¹³ CMS will follow up with the six states that reported that they did not verify the paid amounts for managed care prescription drug claims were complete to ensure they are complying with all of the requirements at 42 CFR § 438.242 and 438.818.

¹¹ CMS, CMS Technical Instructions: Reporting Dispensing Fee in the T-MSIS Claim RX File. 2022. Accessed at: <https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/91066#one>

¹² CMS, CMS MACBIS T-MSIS Reporting Reminder: Reporting Amounts Paid to Providers in T-MSIS. 2022. Accessed at: <https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/tmsis-blog/136886>

¹³ CMS, State Toolkit for Validating and Auditing Medicaid Managed Care Encounter Data. 2023. Accessed at: <https://www.medicaid.gov/sites/default/files/2023-10/mmce-data-valdtn-tolkit.pdf>

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Craig Diena and Tanaz Dutia served as team leaders for this study. Others in the Office of Evaluation and Inspections who conducted the study include Nancy J. Molyneaux, Matthew Katz, Rebecca Laster, Stefanie Vance, and Linda Ragone. Office of Evaluation and Inspections headquarters staff who provided support include Robert Gibbons, Lyndsay Hopper, and Sara Swisher.

We would also like to acknowledge the contributions of other Office of Inspector General staff, including Kevin Manley, Lauren McNulty, and Devin Sprong.

This report was prepared under the direction of Joanna Bisgaier, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office; Edward K. Burley, Deputy Regional Inspector General; and Amy Sernyak, Assistant Regional Inspector General.

Contact

To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

ABOUT THE OFFICE OF INSPECTOR GENERAL

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG) is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of the people they serve. Established by Public Law No. 95-452, as amended, OIG carries out its mission through audits, investigations, and evaluations conducted by the following operating components:

The Office of Audit Services. OAS provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. The audits examine the performance of HHS programs, funding recipients, and contractors in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations to reduce waste, abuse, and mismanagement.

The Office of Evaluation and Inspections. OEI's national evaluations provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. To promote impact, OEI reports also provide practical recommendations for improving program operations.

The Office of Investigations. OI's criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs and operations often lead to criminal convictions, administrative sanctions, and civil monetary penalties. OI's nationwide network of investigators collaborates with the Department of Justice and other Federal, State, and local law enforcement authorities. OI works with public health entities to minimize adverse patient impacts following enforcement operations. OI also provides security and protection for the Secretary and other senior HHS officials.

The Office of Counsel to the Inspector General. OCIG provides legal advice to OIG on HHS programs and OIG's internal operations. The law office also imposes exclusions and civil monetary penalties, monitors Corporate Integrity Agreements, and represents HHS's interests in False Claims Act cases. In addition, OCIG publishes advisory opinions, compliance program guidance documents, fraud alerts, and other resources regarding compliance considerations, the anti-kickback statute, and other OIG enforcement authorities.