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States Could Do More To Oversee Spending and Contain Medicaid Costs for Specialty Drugs

Suzanne Murrin
Deputy Inspector General
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Report in Brief

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Key Takeaway

As more expensive specialty drugs enter the market, CMS and States may not be using all available tools to contain rising expenditures for specialty drugs in their Medicaid programs.

Why OIG Did This Review

Recent trends have shown that a small number of drugs account for a disproportionately large share of Medicaid spending. This subset of drugs, often referred to as "specialty drugs," is frequently defined as high-cost drugs and/or drugs that may require special handling. Each State may define and pay for these expensive drugs differently, which potentially leads to some States paying more than others. States may also categorize drugs as specialty drugs as part of a strategy to mitigate and control the costs associated with these drugs.

In addition to State fee-for-service (FFS) programs, Medicaid managed care organizations (MCOs) provide coverage for health care services, including prescription drug coverage, to beneficiaries and are responsible for managing utilization and medical costs. Given the high costs of some specialty drugs, as well as the substantial role of Medicaid MCOs, reviewing how programs categorize and reimburse for these drugs is important to ensuring Medicaid's fiscal integrity.

How OIG Did This Review

We surveyed 51 State Medicaid Agencies to determine (1) whether and how States categorized specialty drugs in their Medicaid programs; (2) the extent to which States conducted oversight of how their Medicaid MCOs categorize specialty drug and reimburse for them; and (3) whether States implemented cost-management strategies to control spending for specialty drugs. In addition, we obtained Medicaid reimbursement data to compare reimbursement for drugs that were categorized as specialty drugs across Medicaid programs.

What OIG Found

No standard definition of specialty drugs exists in Medicaid. Overall, State Medicaid programs—FFS programs and Medicaid MCOs—used over 100 distinct criteria to categorize thousands of drugs as specialty drugs. While most Medicaid MCOs chose to categorize certain drugs as specialty drugs, most State FFS programs did not. Additionally, about half of these drugs had no Medicaid reimbursement data reported by States. This may mean that Medicaid programs that choose to categorize drugs as specialty drugs are not updating or proactively managing their lists of these drugs.

States reported limited oversight of their Medicaid MCOs' management of specialty drug categorization and spending. Twenty-four States reported that they were not aware of all the cost-management strategies their MCOs implemented to contain specialty drug spending. Because Medicaid MCOs are responsible for the majority of Medicaid prescription drug reimbursement, a lack of cost containment by MCOs can increase Medicaid expenditures in subsequent years, as States base MCO capitated payment rates on costs and utilization from previous years.

States also may be limited in their ability to set accurate reimbursement for specialty drugs. The Centers for Medicare & Medicaid Services (CMS) conducts the national average drug acquisition cost (NADAC) survey to collect what pharmacies actually pay for drugs. This is a tool States can use to set accurate reimbursement amounts. However, this survey does not include acquisition cost data from specialty or mail order pharmacies. As a result, 60 percent of drugs categorized as specialty drugs with Medicaid reimbursement in 2018 did not have NADAC data available.

What OIG Recommends

We recommend that CMS work with States to expand alternative reimbursement models. However, given the tremendous variation in the definition of specialty drugs in Medicaid and the fact that most State FFS programs do not rely on this categorization, we recommend that CMS work with States to address high-cost drugs, regardless of their categorization. In addition, we recommend that CMS provide States with acquisition cost data for a wider range of specialty drugs. We also recommend that CMS collaborate with States to conduct greater oversight of Medicaid MCOs' management of specialty drugs, which could include a review of contract language that allows States to obtain requested information on specialty drug categorizations, specialty drug reimbursement methodologies, and cost-management strategies from the MCOs. CMS concurred with our first and third recommendations. CMS did not concur with our second recommendation.

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BACKGROUND

Objective

To determine how State Medicaid fee-for-service (FFS) programs and Medicaid managed care organizations (MCOs) categorize and contain costs for specialty drugs.

Medicaid does not have a standard definition of specialty drugs. Therefore, each State Medicaid FFS program and each Medicaid MCO (hereafter referred to collectively as Medicaid programs) may categorize these drugs differently, set a different reimbursement methodology, and implement different cost-management strategies for these drugs. Given the high cost of some specialty drugs, as well as the substantial role of MCOs in Medicaid, reviewing how States and their MCOs categorize these drugs and reimburse for them is important to ensuring Medicaid's fiscal integrity. Further, this review of Medicaid programs' reimbursement methodologies and cost-management strategies can inform State Medicaid programs about additional steps they can take to control rising costs for specialty drugs.

Specialty Drugs: Growing Concerns Over Categorization and Costs

Because Medicaid does not have a standardized method to categorize specialty drugs, each Medicaid program may categorize these drugs differently or not categorize them at all.[1] However, drugs typically considered specialty drugs frequently share several characteristics. For example, they often:

- are expensive;
- are used to treat rare, complex, or chronic conditions such as HIV, hepatitis C, hemophilia, multiple sclerosis, or certain cancers;
- need special handling (e.g., they must be stored at a specific temperature);
- are administered by clinical professionals via injection or infusion; and/or
- are dispensed through specialty pharmacies rather than retail community pharmacies.

States may categorize drugs as specialty drugs as part of a strategy to mitigate and control the costs associated with these drugs. Because each State may define and pay

[1] This stands in contrast to Medicare Part D, where Part D plans may include a specialty tier for certain high-cost drugs. Currently, a drug must cost at least $670 per month for inclusion on a plan's specialty tier.

for specialty drugs differently, this potentially leads to some States paying more than others.

In spite of the various methods used to categorize specialty drugs, recent studies have shown that drugs sharing these characteristics account for a large percentage of drug spending growth.[2] In 2019, the Congressional Budget Office reported that Medicaid spending on specialty drugs increased from 25 percent to 35 percent of total drug spending from 2010 to 2015.[3] These trends will likely continue as research indicates that specialty drug use will continue to rise.

Medicaid Prescription Drug Coverage and Reimbursement

Currently, all 50 States and the District of Columbia (51 States) offer prescription drug coverage as part of their Medicaid benefit packages. For their drugs (including specialty drugs) to be eligible for Medicaid reimbursement, drug manufacturers must enter into rebate agreements and pay rebates to States and the Federal government that offset the cost of their drugs.[4] Medicaid reimbursed $63.4 billion for prescription drugs in 2018.[5]

Each State has the flexibility to administer its Medicaid program within broad Federal guidelines, resulting in various combinations of health care delivery and payment systems across States. Generally, States offer Medicaid services—including prescription drugs—(1) through the FFS model, (2) by contracting with MCOs to provide Medicaid coverage to beneficiaries, or (3) by a combination of both.[6] In the traditional FFS model, States directly reimburse pharmacies for covered prescription drugs each time an enrollee obtains a covered drug. Under the managed care model, States prospectively pay Medicaid MCOs a fixed monthly amount, called a capitated rate, per Medicaid beneficiary. The capitated rate is intended to cover all or most contracted services that a beneficiary receives during a specified time.[7] Medicaid MCOs, in turn, reimburse pharmacies for covered prescription drugs.

As of September 2018, 35 States reported that they contracted with Medicaid MCOs to provide prescription drug coverage. Medicaid MCOs are now responsible for the

[2] Express Scripts. *2018 Drug Trend Report*. Accessed at https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf on February 20, 2020.

[3] The Congressional Budget Office used a proprietary list of specialty drugs provided by IQVIA (a health care data research company) to conduct its analysis. Congressional Budget Office, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis*. March 2019. Accessed at http://www.cbo.gov/publication/55011 on February 20, 2020.

[4] Section 1927(a) of the Social Security Act.

[5] This reimbursement total does not account for drugs for which the payment data were suppressed. This total also does not account for Medicaid rebates.

[6] Some State FFS programs and Medicaid MCOs contract with pharmacy benefit managers (PBMs) to negotiate reimbursement amounts and manage their prescription drug benefits.

[7] CMS, *Managed Care*, accessed at https://www.medicaid.gov/medicaid/managed-care/index.html on December 4, 2019.

majority of Medicaid reimbursement and enrollment. In fact, in 2018 Medicaid MCOs reimbursed $37.7 billion for prescription drugs—approximately 60 percent of total Medicaid drug expenditures. Therefore, Medicaid MCOs play a large role in reducing costs and managing utilization of Medicaid services, including prescription drugs.

Any increases in costs or utilization for medical services, including prescription drugs, will generally lead to higher capitated rates for MCOs in subsequent years. This is because MCOs' capitated rates are calculated with utilization and pricing data from previous years, using actual experiences of the Medicaid (or similar) population in accordance with generally accepted actuarial practices and principles. As part of its oversight, the Centers for Medicare & Medicaid Services (CMS) must review the methods and data used to set MCO capitated rates, as well as each contract between a State and its Medicaid MCOs, to ensure compliance with Federal requirements and CMS guidance.[8, 9]

Estimating Pharmacy Reimbursement Amounts

State FFS programs and Medicaid MCOs may use different methods to estimate drug reimbursement amounts. State FFS programs generally base reimbursement for a drug—as required by Federal regulation—on its actual acquisition cost, which represents the actual price that pharmacies pay to acquire the drug.[10, 11] States have the flexibility to use various benchmark prices and data sources to establish a reimbursement methodology on the basis of actual acquisition cost. In contrast to State FFS programs, Medicaid MCOs are not required to reimburse for drugs based on actual acquisition cost. Instead, CMS allows Medicaid MCOs the flexibility to reimburse at the levels necessary to achieve a network of providers to ensure access to care for each MCO's Medicaid enrollees.[12]

National average drug acquisition cost (NADAC) data. CMS conducts a monthly national survey of acquisition costs at retail community pharmacies to assist States in setting reimbursement amounts on the basis of actual acquisition cost. CMS uses these data to calculate a NADAC for each drug and makes this cost data available to the public. However, the reimbursement amounts for specialty pharmacies are not included in NADAC calculations because specialty pharmacies are not considered retail community pharmacies.

[8] 42 CFR § 438.3

[9] CMS, *State Guide to CMS Criteria for Medicaid Managed Care Contract Review and Approval*, accessed at https://www.medicaid.gov/medicaid/downloads/mce-checklist-state-user-guide.pdf on February 24, 2020.

[10] 42 CFR § 447.502. Actual acquisition costs include the ingredient cost of the drug only. States also may provide the pharmacy with a dispensing fee for each prescription.

[11] CMS, *Implementation of the Covered Outpatient Drug Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program*, accessed at https://www.medicaid.gov/federal-policy-guidance/downloads/smd16001.pdf on February 24, 2020.

[12] 81 Fed. Reg. 5170, 5272-5273 (Feb. 1, 2016).

Methodology

State Survey and Data Request

We sent an online survey to 51 State Medicaid agencies (States) to request information about their coverage of and reimbursement for specialty drugs. We received responses from all 51 States. We reviewed these States' responses to determine the number of State FFS programs and Medicaid MCOs that categorized any drugs as specialty drugs. We then identified and compared the criteria that each program used to categorize drugs as specialty drugs. We also reviewed States' responses to determine whether the cost-management strategies implemented in each State were associated specifically with specialty drugs.

For the 35 States that contracted with Medicaid MCOs to provide prescription drug coverage, we analyzed States' responses about (1) the extent to which they reviewed and conducted oversight of MCOs' coverage and reimbursement of specialty drugs. (2) whether and how specialty drugs affect MCO capitation rates; and (3) challenges they may have faced in obtaining information about specialty drugs from their MCOs.

For Medicaid programs that categorized any drugs as specialty drugs, we reviewed the 11-digit national drug codes (NDCs)[13] and drug names they provided for the drugs they categorized as specialty drugs.[14] We also determined the number of NDCs categorized as specialty drugs in at least one Medicaid program and the number of NDCs categorized as specialty drugs by at least half of Medicaid programs.

Reimbursement and Utilization Data

We downloaded Medicaid State Drug Utilization data from CMS's website to calculate total 2018 Medicaid reimbursement for any NDC that was categorized as a specialty drug by State FFS programs or Medicaid MCOs. We also calculated total 2018 Medicaid reimbursement for the NDCs categorized as specialty drugs by at least half of the State FFS programs and/or Medicaid MCOs. Finally, we compared the State FFS program average unit reimbursement amounts to the Medicaid MCO average unit reimbursement amounts for each of the NDCs categorized as specialty drugs by State FFS programs and by at least half of MCOs that categorized specialty drugs within that same State.

A detailed methodology is provided on page 18.

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.

[13] An NDC is a unique identifier assigned to each drug product. Each NDC represents a distinct labeler, product, and package size.

[14] A drug name can be with associated with multiple NDCs (e.g., when there are multiple strengths and/or package sizes of the same drug).

FINDINGS

Medicaid programs used a wide range of criteria to categorize thousands of drugs as specialty drugs

Medicaid programs considered over 100 distinct criteria to categorize thousands of drugs as specialty drugs. While cost was a common criterion used to categorize specialty drugs, States also broadly considered the types of conditions treated; methods of administration; and the level of followup or maintenance required. In fact, individual Medicaid programs used between 1 and 19 distinct criteria when categorizing specialty drugs. In certain programs, a drug had to meet a minimum of two or more specific criteria—such as requiring special handing, treating rare conditions, and/or having high costs—for a program to categorize it as a specialty drug.

Across Medicaid programs, there was variation in how similar criteria were applied. For example, of the Medicaid programs that used high cost to categorize a drug as a specialty drug, the threshold for what was considered "high cost" ranged from $500 per month to $5,000 per month. Appendix A provides more information about the wide range of criteria used to categorize drugs as specialty drugs in Medicaid.

Most Medicaid MCOs chose to categorize certain drugs as specialty drugs while most FFS programs did not

Although 86 percent of Medicaid MCOs (207 of 242) established criteria to categorize drugs as specialty drugs, only 14 of the 51 State FFS programs (27 percent) categorized any drugs as specialty drugs.[15]

Among the 37 States that did not categorize specialty drugs in their FFS programs, half had considered doing so at some point. However, some States reported that they could not decide on a definition or criteria to distinguish these drugs from other outpatient drugs. One State said that it: "briefly considered categorizing certain drugs as specialty drugs multiple times… [but] we did not complete a full analysis because we did not see immediate value to doing so." Another State responded that it would be beneficial for consistency across Medicaid programs if CMS defined specialty drugs, and an additional State said that it was awaiting guidance from CMS regarding categorization of specialty drugs.

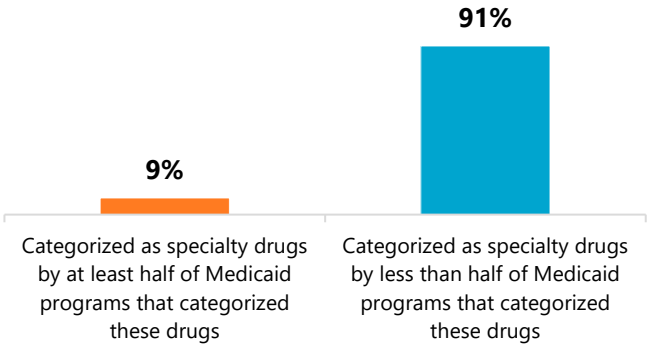
> "There is no national definition of a specialty drug and it is therefore difficult to create artificial parameters in an attempt to classify these medications." State Medicaid Agency

[15] Of the 35 States that reported they contracted with Medicaid MCOs to provide prescription drug benefits, 32 States had at least 1 Medicaid MCO that categorized drugs as specialty drugs.

There was minimal overlap of specialty drugs across Medicaid programs

The substantial number of criteria used to categorize specialty drugs resulted in a total of 15,978 NDCs (associated with 1,614 drug names) being categorized as specialty drugs across Medicaid programs. However, none of these 15,978 NDCs were categorized as a specialty drug by every Medicaid program that categorized specialty drugs. Further, only 9 percent of these NDCs were categorized as specialty drugs by at least half of the Medicaid programs that provided us with their specialty drug NDCs, as shown in Exhibit 1. In addition, 37 percent of these 15,978 NDCs were categorized as specialty drugs by only 1 Medicaid program.

Exhibit 1: Only 9 percent of NDCs were categorized as specialty drugs by at least half of Medicaid programs.



Source: OIG analysis of data from survey of State Medicaid programs, 2019.

Fifty-seven percent of drugs categorized as specialty drugs had no reimbursement data reported by States, an indication that Medicaid programs' lists of specialty drugs may be out of date

Of the 15,978 NDCs that were categorized as specialty drugs by at least 1 Medicaid program, 57.3 percent (9,152 NDCs) had no reimbursement data listed in the 2018 Medicaid reimbursement data file. Because of very low utilization, CMS suppressed all 2018 reimbursement data for an additional 10.2 percent of NDCs that were categorized as specialty drugs. (CMS suppresses NDC-level data when there are 10 or fewer prescriptions dispensed for a specific NDC.) Reimbursement data were available for 32.5 percent of NDCs categorized as specialty drugs by at least 1 Medicaid program.

There are indications that many of the specialty drug categorizations provided by States are out-of-date, which may explain why there is a lack of reimbursement data for these drugs. Ninety percent (8,253 NDCs) of the 9,152 NDCs that did not have reimbursement data are (1) not listed with the Food and Drug Administration (FDA) (5,957 NDCs), (2) not currently available for purchase (1,057 NDCs) or (3) not included on the Medicaid drug product file (1,239 NDCs), as shown in Exhibit 2.

This calls into question the quality of the data Medicaid programs provide because such a large number of these drugs are not found in frequently used databases or available for purchase. Specifically, drug manufacturers are generally required to

provide FDA with a list of all the drugs that they manufacture, repackage, or relabel for commercial distribution.[16] They also identify drugs that are no longer available for purchase. Manufacturers that participate in the Medicaid drug rebate program also report drug product data for all active drugs.

This group of 8,253 NDCs accounted for a substantial majority of the NDCs that did not have reimbursement data, and for over half (52 percent) of all NDCs that were categorized as a specialty drug by at least 1 Medicaid program. If Medicaid programs do not proactively maintain these lists, it could result in their using out-of-date information to manage specialty drug costs and utilization.

Exhibit 2: Of the NDCs with no Medicaid reimbursement, a total of 90 percent were not listed with FDA, not considered active drugs in Medicaid, or not available for sale.

Source: OIG analysis of State Medicaid survey data, 2019.

Medicaid programs reimbursed $36 billion in 2018 for the small percentage of specialty drugs with reimbursement data available

Medicaid reimbursed at least $36 billion in 2018 for NDCs that were categorized as specialty drugs by at least 1 Medicaid program. This represents reimbursement for only 5,191 of the 15,978 NDCs (associated with 1,189 drug names) that were categorized as specialty drugs by at least one Medicaid program. As discussed previously, States did not report any Medicaid reimbursement in 2018 for a substantial number of the 15,978 NDCs categorized as specialty drugs by at least one Medicaid program.

Medicaid MCOs were responsible for the majority of total reimbursement for these five thousand NDCs ($21.2 billion, or 59 percent). For NDCs categorized as specialty drugs by at least half of Medicaid programs—i.e., half of all State FFS programs and/or Medicaid MCOs that categorize drugs as specialty drugs—reimbursement totaled $19.6 billion in 2018, or over one-quarter of Medicaid's total drug reimbursement in that year.

Medicaid reimbursed $7.8 billion for 10 specialty drug names with the highest reimbursement, as shown in Exhibit 3. Reimbursement for these 10 drugs constituted 12 percent of total Medicaid reimbursement for all drugs in 2018.

[16] 21 CFR § 207.41.

Exhibit 3: Top 10 specialty drugs with the highest reimbursement in 2018

	Drug Name	Condition(s) Treated	Medicaid Reimbursement
1	Humira	Certain types of arthritis, Crohn's disease	$1,776,425,562
2	Mavyret	Hepatitis C	$967,361,356
3	Genvoya	HIV	$881,210,823
4	Invega Sustenna	Schizophrenia	$844,345,580
5	Suboxone	Opioid dependence	$765,707,604
6	Enbrel	Certain types of arthritis	$635,395,585
7	Triumeq	HIV	$584,888,272
8	Epclusa	Hepatitis C	$492,967,443
9	Truvada	HIV	$450,666,578
10	Lantus Solostar	Diabetes	$444,043,823
		Total	**$7,843,012,627[a]**

Source: OIG analysis of data from survey of State Medicaid programs and Medicaid drug utilization data, 2019.
[a] Because of rounding, individual drug reimbursement does not sum to the total.

Many States expressed concerns about the coverage of and reimbursement for specialty drugs

Many States (33) expressed ongoing concerns related to the coverage of and reimbursement for drugs often considered specialty drugs in their Medicaid programs. These States' concerns included the high costs for these drugs and their effects on State budgets. For example, a number of States reported concerns about reimbursement for new chimeric antigen receptor T-cells (CAR-T) drugs, which provide for individualized cancer treatments. CAR-T therapy may cost up to $475,000. Further, CAR-T therapy can cause serious side effects that require hospitalization. As a result, total costs can exceed $1 million per beneficiary. Because CAR-T therapy can require both inpatient and outpatient care, four States noted concerns about how to reimburse for CAR-T therapy under these different settings.[17] One

> "Inpatient hospitals report that [CAR-T] costs are currently not adequately covered under the inpatient hospital reimbursement methodology." State Medicaid Agency

> "We feel these drugs are often unfairly priced without justification." State Medicaid Agency

[17] In the preamble to its final rule on the Medicare hospital inpatient prospective payment system, CMS indicated that it established a new diagnosis-related group code for CAR-T immunotherapy. Because this change occurred after our data collection, we do not know whether this change would address any of the States' concerns. See 85 Fed. Reg. 58432 (September 18, 2020).

State commented that it does not have an approved method to sufficiently reimburse for these therapies using the existing inpatient bundled rate, and it must create a new model that reimburses the manufacturer or hospital.

Four States also reported concerns related to coverage of specialty drugs under their respective Medicaid programs. Because States generally must cover all drugs from manufacturers that have a Medicaid rebate agreement, States noted that they have no choice in covering drugs, even those that they believe may have limited effectiveness or questionable safety. One State reported that it was concerned that FDA's accelerated approval process results in specialty drugs available for purchase that may have limited safety and effectiveness.

Medicaid programs do not have NADAC data to help set reasonable reimbursement rates for many drugs categorized as specialty drugs

State FFS programs are required to set reimbursement for drugs based on actual acquisition cost, which represents the actual price that pharmacies pay to acquire the drugs. States may use benchmark prices, such as NADAC, to establish their reimbursement amounts based on acquisition costs. The NADAC was developed to provide States with a better estimate—based on actual drug purchases—of prices paid by pharmacies. Compared to other acquisition-cost or pricing benchmarks, the NADAC has greater accuracy and transparency in how drug acquisition prices are established, and it is generally more resistant to manipulation.[18] However, the NADAC survey does not include acquisition cost data from specialty or mail-order pharmacies.

> "It would be great to have a NADAC for specialty drugs. Being that specialty drugs represent an increasing percentage of drug spend[ing], we would like a better mechanism to establish lower reimbursement." State Medicaid Agency

Many of the drugs with Medicaid reimbursement that were categorized as specialty drugs across Medicaid programs were not included in the NADAC survey data that States often use to set reimbursement for specialty drugs, possibly because this survey does not include specialty pharmacies or mail-order pharmacies. Although 64 percent of State FFS programs reported using NADAC as one method to set reimbursement for specialty drugs, 60 percent of NDCs for specialty drugs with Medicaid reimbursement in 2018 did not have NADAC data.[19] Medicaid reimbursed $14 billion in 2018 for 3,123 specialty NDCs that did not have a NADAC price available. As a result, States

[18] CMS, *Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs*, November 2013. Accessed at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf on March 26, 2020.

[19] Of the top 10 drug names listed in Exhibit 3, each drug name had at least 1 NDC with a NADAC price. However, 40 percent of the NDCs associated with these 10 drug names did not have a NADAC price.

cannot use this publicly available data as a tool to set reimbursement amounts for many specialty drugs using acquisition costs.

While State FFS programs set reimbursement methodologies based on actual acquisition costs, most Medicaid MCOs (81 percent) reported that they set reimbursement for specialty drugs using discounted average wholesale price (AWP) at specialty pharmacies. AWP is an estimate of the price that retail pharmacies pay to wholesalers for a drug and is not based on actual acquisition costs. Medicaid MCOs, unlike FFS programs, are not required to reimburse for drugs based on acquisition costs. CMS allows Medicaid MCOs this flexibility to ensure that each enrollee in a Medicaid MCO has adequate access to a network of providers.

States report that rising specialty drug costs affect capitation payments to Medicaid MCOs

Because States typically base their capitation rates on utilization and spending from previous years, any increase in reimbursement for specialty drugs could lead to higher capitation rates for all beneficiaries enrolled in Medicaid MCOs. Therefore, as more expensive drugs continue to enter the market, utilization of these drugs can increase long-term spending via Medicaid MCO capitation payments.

> "Effectively reimbursing health plans for high-cost/low-volume therapies in a capitated rate methodology while, at the same time, reacting to new drug treatments and market changes in price has proved a formidable task for the State and its actuary." State Medicaid Agency

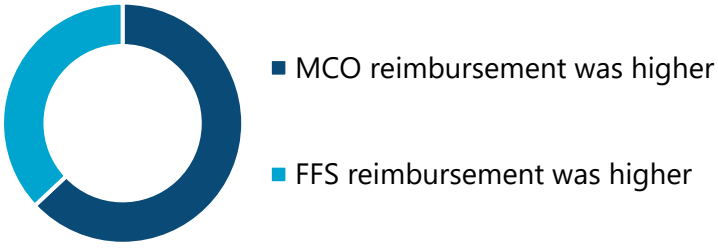
Nineteen States that contract with Medicaid MCOs responded that specialty drug costs affect MCO capitation payments. For example, one State said that the increase in specialty drug costs and utilization "results in significant upward pressure on the prescription drugs portion of the capitation rates, especially in comparison to other cost drivers." Additionally, 10 States said that they provide Medicaid MCOs with supplemental payments to help cover the costs of specialty drugs.

Medicaid MCO reimbursement for specialty drugs was often higher than reimbursement by State FFS programs

In the 6 States where the FFS program and at least 50 percent of Medicaid MCOs both categorized a drug as a specialty drug, MCOs' average unit reimbursement was often higher than the average unit reimbursement for the corresponding State FFS program.

As shown in Exhibit 4, MCO reimbursement was higher than FFS reimbursement for 63 percent of instances for which we could compare reimbursement within a State.[20]

Exhibit 4: MCO reimbursement was higher than FFS reimbursement in 63 percent of instances in which a drug was categorized as a specialty drug in both programs in a State.



Source: OIG analysis of data from survey of State Medicaid programs, 2019.
Note: there were 252 drug comparisons included in this analysis.

States have limited oversight of Medicaid MCOs' management of specialty drug categorization and spending

In spite of the concerns that many States expressed regarding specialty drugs, a majority of them did not take action to conduct oversight of MCO spending on these drugs. For example, a majority of States were unaware of which drugs their respective MCOs considered as specialty drugs. In fact, only five States contractually required their Medicaid MCOs to provide the State with their specialty drug lists, and only seven States performed any analyses or reviews of their Medicaid MCOs' specialty drug lists. Nearly one-quarter of the States (7 of 32) with Medicaid MCO(s) that categorized specialty drugs were not aware of any criteria that their Medicaid MCOs used to categorize these drugs. These oversight tools could assist States in ensuring that their Medicaid MCOs pay appropriately for specialty drugs.

States also reported challenges in accessing data from their MCOs, and these challenges could inhibit a State's ability to conduct robust and effective oversight. Six States noted that they experienced barriers to reviewing at least some of their MCOs' specialty drug categorizations or specialty drug lists. One State said an MCO eventually provided a list, but at first the MCO refused as the MCO (or its pharmacy benefit manager (PBM)) considered it to be proprietary. Another State reported that

[20] There were 177 NDCs that met the criteria for our analysis—i.e., the NDC was categorized as a specialty drug by both the State FFS program and by at least 50 percent of Medicaid MCOs that categorized specialty drugs in that State, and both programs had reimbursement data available. Because some of these NDCs had reimbursement in multiple States, this resulted in 252 individual comparisons of average unit reimbursement amounts for State FFS programs to average unit reimbursement amounts for Medicaid MCOs.

managed care plans did not submit reimbursement rates for individual drugs because of PBM confidentiality.

Finally, 19 of the 32 States with MCOs that categorized specialty drugs responded that they did not know whether their MCOs reimbursed specialty drugs differently from other outpatient drugs, even though States must review their Medicaid MCO contracts. One of these 32 States said its Medicaid MCOs used the same reimbursement methodologies for both specialty and nonspecialty drugs. The remaining 12 States reported that at least some of their Medicaid MCOs used different reimbursement methodologies or dispensing fees for specialty drugs than for other outpatient drugs.

Three-quarters of States with Medicaid MCOs that categorized specialty drugs did not know all the specific cost-management strategies that their Medicaid MCOs implemented for these drugs

If States are not effectively overseeing their Medicaid MCOs' cost-management strategies, they cannot ensure that Medicaid MCOs are taking all appropriate actions to control expenditures for these drugs. Many States reported they were unaware of whether their MCOs implemented strategies to control specialty drug costs. Specifically, 24 of the 32 States with Medicaid MCOs that categorized specialty drugs reported they did not know all the cost-management strategies their Medicaid MCOs implemented to control specialty drug spending.

State FFS programs typically use the same cost-management strategies for specialty drugs as for nonspecialty drugs; few had efforts targeted specifically at specialty drugs

While cost-management strategies can be important tools for reducing State FFS program expenditures for specialty drugs, States reported having cost-management strategies that specifically targeted specialty drugs in only 2 of the 14 State FFS programs that categorized these drugs. One of these two State FFS programs has a waiver to negotiate prices with a limited number of preferred specialty pharmacies. The other State FFS program implemented a care management program for high-cost drugs to optimize adherence and thereby improve patient outcomes and reduce medical spending.[21]

While only a few States had cost-management strategies that specifically targeted drugs categorized as specialty drugs, all Medicaid programs implemented cost-management strategies for at least some outpatient drugs, as shown in Exhibit 5.

[21] According to CMS, it has approved proposals from nine States to allow them to implement value-based purchasing (VBP) models. These models allow States to negotiate supplemental rebates with drug manufacturers using evidence and outcome-based measures. In addition, CMS issued a proposed rule that would advance its efforts to support State flexibility to enter into innovative VBP arrangements with manufacturers. See 85 Fed. Reg. 37286 (June 19, 2020).

While these approaches are not always targeted specifically towards lowering the spending on specialty drugs, they may cover specialty drugs.

Specific examples of how States implemented cost-management strategies for their specialty drugs include the following:

- criteria for prior authorization were developed based on clinical studies and for patients where a drug's value had been observed;
- preferred drug lists were developed based on drugs' clinical superiority, brand preference, and rebate opportunity; and
- a single preferred drug list applied to both the State FFS program and the State's Medicaid MCOs.

Exhibit 5: Cost-Management Strategies Commonly Used To Control Drug Costs

Cost-management strategy	Description	Number of States that implemented strategy for any outpatient drugs	Number of States that implemented strategy specific to specialty drugs[a]
Prior authorization	Provider must obtain preapproval before dispensing specific medications.	51	33
Quantity limits	Program limits the amount of a drug that it will cover during a specific time period.	51	31
Preferred drug lists	Select drugs receive preference over other medications within the same therapeutic class.	50	31
Supplemental rebates	Program negotiates additional manufacturer rebates in return for preferred status (see preferred drug lists).	49	28
Step therapy	Beneficiary must try a cheaper drug (that also is medically indicated) before receiving a more expensive drug.	47	27
Maximum allowable cost lists	Program sets maximum reimbursement for a specified list of drugs.	43	13

Source: OIG analysis of State survey data, 2019.
[a] This column includes only the 38 States in which the FFS program or at least 1 Medicaid MCO categorized specialty drugs.

Several States have implemented alternative payment policies to address the rising costs of drugs. For example, Oklahoma became the first State to implement value-based rebate agreements for certain drugs, including specialty drugs, in its Medicaid drug program.[22] In this particular model, the drug manufacturer pays higher rebates if a beneficiary taking its drug is hospitalized for conditions the drug is intended to treat. This State reported: "The cost management aspect [of value-based rebate contracts] is yet to be seen, but these will be very important when it comes to managing one-time gene therapies and other similar treatments." In another effort to control drug costs, New York passed a cap on Medicaid drug spending that ties growth in drug spending to medical inflation.[23]

Nearly all State FFS programs negotiate supplemental rebates to control Medicaid drug spending

States and MCOs may negotiate supplemental rebates for outpatient drugs to reduce Medicaid drug spending. Nearly all State FFS programs (13 of 14) that categorize drugs as specialty drugs negotiated supplemental rebates for specialty drugs. In contrast, only 56 percent of States reported that at least some of their Medicaid MCOs negotiated supplemental rebates for specialty drugs. In the remaining 37 States that did not define specialty drugs in their FFS programs, 33 States (89 percent) implemented supplemental agreements for their outpatient drugs. These rebates can provide significant savings for Medicaid programs and their beneficiaries.

States attempted to shield beneficiaries from paying high out-of-pocket costs for any drugs, including specialty drugs

States used different approaches to limit beneficiaries' out-of-pocket costs. While States are generally required to limit aggregate cost-sharing to 5 percent of a family's income, some States attempted to further shield beneficiaries from increased costs due to rising drug prices in their Medicaid programs by implementing cost-sharing caps.[24] In fact, 20 States reported that their FFS programs and/or MCOs implemented cost-sharing caps or limits to prevent beneficiaries from having to pay expensive copayments or coinsurance for specialty drugs. For example, some States reported that they do not have any cost-sharing requirements for any drugs for beneficiaries enrolled in their Medicaid programs. Other States implemented caps on cost-sharing requirements, such as a $1 copayment or a $200 maximum on annual drug costs.

[22] The National Academy for State Health Policy (NASHP), *Oklahoma Signs the Nation's First State Medicaid Value-Based Contracts for Rx Drugs*, Accessed at https://nashp.org/oklahoma-signs-first-medicaid-value-based-contracts-for-rx-drugs/ on October 3, 2019.

[23] N.Y. Public Health Law, Article 2-A § 280.

[24] 42 CFR § 447.56(f).

RECOMMENDATIONS

As specialty drugs continue to account for an increasing percentage of drug spending, it is important that CMS and States effectively employ all available tools and strategies to contain rising expenditures for specialty drugs in Medicaid. However, our findings indicate that despite concerns about high-cost drugs—including those drugs categorized as specialty drugs—States face challenges in containing these costs and in overseeing MCOs' reimbursement for these drugs.

States also reported challenges in their oversight of Medicaid MCOs' management of specialty drug spending. Specifically, 19 States were unaware of the differences in their Medicaid MCOs' reimbursement methodologies for specialty drugs, and 24 States reported they did not know all the cost-management strategies that their MCOs implemented to contain specialty drug spending. In addition, we found that the average unit reimbursement for Medicaid MCOs was higher than the average unit reimbursement for State FFS programs in 63 percent of instances in which both program types categorized a drug as a specialty drug (and reimbursement data were available). If Medicaid MCOs—which are responsible for the majority of reimbursement for prescription drugs in Medicaid—are not appropriately containing specialty drug costs, this can increase long-term Medicaid expenditures, as MCO capitated payment rates are based on costs and utilization from previous years.

Additionally, States may be limited in their ability to set accurate reimbursement for specialty drugs. Sixty percent of drugs categorized as specialty drugs that had Medicaid reimbursement in 2018 did not have NADAC data available. This means that State Medicaid programs do not have NADAC data to help set reasonable reimbursement rates for many specialty drugs.

We recommend that CMS:

Work with States to expand alternative reimbursement models to address the rising costs for drugs often categorized as specialty drugs

Some States are already working with CMS to explore alternative reimbursement models that address increased spending for high-cost drugs. For example, CMS has already approved in at least one State a value-based payment model that aims to lower drug costs. Additional States may want to consider implementing similar value-based rebate agreements with drug manufacturers or developing maximum-allowable-cost lists to limit reimbursement for specialty drugs. However, given the tremendous variation in the definition of specialty drugs in Medicaid, and

the fact that most State FFS programs do not rely on this categorization, we recommend that CMS work with States to address high-cost drugs, regardless of their categorization.

Provide States with acquisition cost data for a wider range of specialty drugs

States reported difficulty in setting reimbursement rates for specialty drugs paid for by Medicaid FFS programs, and three out of five specialty drugs with reimbursement data did not have NADAC data available. If CMS provided States with acquisition cost data for a wider range of specialty drugs covered by Medicaid, States may be able to more accurately set reimbursement rates and potentially reduce the inflated costs for specialty drugs.

Collaborate with States to conduct greater oversight of Medicaid MCOs' management of specialty drugs; this oversight could include a review of contract language that allows States to obtain requested information on specialty drug categorizations, specialty drug reimbursement methodologies, and cost-management strategies

Although States pay Medicaid MCOs to serve beneficiaries, many States responded that they had limited knowledge of Medicaid MCOs' activities related to specialty drugs. Few States required Medicaid MCOs to provide lists of specialty drugs or performed any review of those lists. In addition, some States noted difficulty in obtaining information regarding specialty drugs that was labeled proprietary or confidential by MCOs. Given these difficulties, CMS should take steps (e.g., issuing guidance) that encourages States to strengthen their oversight of Medicaid MCOs' specialty drug categorizations, reimbursement methodologies, and cost-management strategies. This could include guidance to ensure that contracts with Medicaid MCOs provide States with access to information regarding specialty drugs covered by MCOs and dispensed to Medicaid beneficiaries.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with the first and third recommendations but did not concur with the second recommendation.

CMS concurred with our recommendation for it to expand alternative reimbursement models to address the rising costs for drugs often categorized as specialty drugs. CMS stated that it has taken several steps to support States in creating alternative reimbursement models. Specifically, CMS approved proposals from nine States to implement value-based purchasing models. CMS also cited a proposed rule that it has issued to assist other States in implementing similar models.

CMS concurred with our recommendation for it to collaborate with States to conduct greater oversight of Medicaid MCOs' management of specialty drugs. CMS stated that it will take steps, e.g., issuing guidance, to encourage States to strengthen their oversight of their MCOs' specialty drug categorizations, reimbursement methodologies, and cost management strategies. These steps could include encouraging States to contractually require MCOs to provide States with access to information on covered specialty drugs.

CMS did not concur with our recommendation for it to collect information about specialty pharmacy acquisition costs and provide these data to States. CMS stated that it does not have clear statutory authority to conduct a nationwide survey of prices for specialty pharmacies. CMS also stated that extending the current NADAC survey to cover specialty pharmacies, would be a significant financial burden. Further, CMS responded that retail pharmacies distribute many drugs identified as specialty drugs, which means that specialty drugs are included on the NADAC file. CMS also responded that it believes that resources should be prioritized on finalizing the proposed pharmacy rule that would provide States with greater clarity and additional options regarding value-based purchasing.

In response to CMS's comments, we revised the recommendation text to address their concerns over expanding the NADAC methodology to include all specialty drugs. However, OIG continues to see the value in providing States with accurate acquisition cost data for a wider range of specialty drugs. Providing this data to States could result in more accurate drug reimbursement rates and reduce the risk of paying inflated prices for high-cost specialty drugs.

Please see Appendix C for the text of CMS's comments.

DETAILED METHODOLOGY

State Survey

In December 2018, we sent an online survey to 51 State Medicaid agencies to request information about how they cover outpatient specialty drugs and reimburse for them in their State FFS programs. We received responses from all 51 States. Specifically, we asked States:

- whether they categorized any drugs as specialty drugs;
- to provide the criteria that they used to categorize specialty drugs;
- to provide the payment methodologies that they used to set reimbursement rates for specialty drugs;
- to list any cost-management strategies that they implemented to control spending for specialty drugs;
- to describe how they ensured that cost-management strategies did not inappropriately prevent beneficiaries from having access to specialty drugs; and
- to describe any concerns about Medicaid coverage of and reimbursement for specialty drugs.

In addition, we asked States whether they contract with Medicaid MCOs to provide prescription drug coverage to Medicaid beneficiaries, and if so, to provide information about how their Medicaid MCOs categorize specialty drugs. We asked States:

- whether Medicaid MCOs in their States categorized any drugs as specialty drugs;
- to provide the criteria that Medicaid MCOs used to categorize specialty drugs;
- whether their contracts with Medicaid MCOs included requirements on how Medicaid MCOs should categorize specialty drugs;
- to describe how they reviewed or oversaw their Medicaid MCOs' specialty drug programs;
- to provide the payment methodologies that Medicaid MCOs used to set reimbursement rates;
- to list any cost-management strategies that Medicaid MCOs implemented to control spending for specialty drugs; and
- to describe the potential impact that specialty drug policies may have on beneficiary access, cost sharing, and capitation rates.

We analyzed States' responses to determine whether and how they categorized and identified specialty drugs in their FFS programs and Medicaid MCOs. This included

determining the number and percentage of State FFS programs and Medicaid MCOs that did and did not categorize specialty drugs or maintain specialty drug lists. We also evaluated and counted the criteria States reported that their FFS programs and Medicaid MCOs used to categorize specialty drugs.

We then analyzed States' responses to evaluate concerns related to the coverage of and reimbursement for specialty drugs, as well as the methods that States used to conduct oversight of their Medicaid MCOs' categorizations of specialty drugs. We determined the extent to which States reviewed Medicaid MCOs' criteria for categorizing specialty drugs, and the extent to which they performed any monitoring, reviews, or analyses of their Medicaid MCOs' specialty drug lists.

Next, we reviewed reimbursement methodologies for specialty drugs reported by State FFS programs and Medicaid MCOs. For this analysis, we counted the frequency with which State FFS programs and/or Medicaid MCOs considered specific reimbursement methodologies (e.g., discounted AWP) to set reimbursement rates for specialty drugs.

We then determined whether and how State FFS programs and Medicaid MCOs used specific cost-management strategies (e.g., prior authorization, quantity limits, preferred drug lists, and supplemental rebates). Additionally, we reviewed States' responses about managing costs for specialty drugs and how their policies might affect beneficiary access, cost sharing, and capitation rates.

We requested the 11-digit NDCs and names for all drugs categorized as specialty drugs by State FFS programs and Medicaid MCOs, when applicable. We also determined the number of NDCs categorized as specialty drugs in at least one Medicaid program and the number of NDCs categorized as specialty drugs by at least half of Medicaid programs.

Reimbursement and Utilization Data

We downloaded Medicaid State drug utilization data from CMS's website, which contains utilization and reimbursement for specialty drugs in 2018.[25] This file includes Medicaid reimbursement amounts and utilization by NDC in each State's FFS program and Medicaid MCOs. We calculated total Medicaid reimbursement for any NDC that was categorized as a specialty drug by at least one State FFS program or one Medicaid MCO in 2018. We counted the total number of Medicaid programs that provided NDCs that were categorized as specialty drugs, and we determined total 2018 Medicaid reimbursement for the NDCs categorized as specialty drugs by at least half of these programs. We also determined the number of NDCs categorized as specialty drugs without 2018 Medicaid utilization that were not listed on FDA's Comprehensive NDC Structured Product Labeling Data Elements file or the Medicaid Drug Rebate Program product file. Additionally, we calculated the percentage of

[25] This file does not include reimbursement data that CMS suppressed. CMS suppresses reimbursement and utilization data when there are 10 or fewer prescriptions dispensed for a specific NDC.

specialty drug spending for which Medicaid MCOs were responsible. We then determined total reimbursement for the 10 drug names categorized as specialty drugs in at least 1 Medicaid program that had the highest Medicaid reimbursement in 2018.

We also calculated a State FFS program average unit reimbursement amount and a Medicaid MCO average unit reimbursement amount for every NDC that was categorized as specialty in both a State's FFS program and by at least 50 percent of Medicaid MCOs that categorized specialty drugs within the same State. There were 177 NDCs that met the criteria for our analysis—i.e., the NDC was categorized as a specialty drug by both a State's FFS program and at least half of Medicaid MCOs that categorized specialty drugs in that same State. We then compared the State FFS program's average unit reimbursement amount to the Medicaid MCOs' average unit reimbursement amount for each drug in each State. We determined the number and percentage of instances in which the State FFS program reimbursement was higher than Medicaid MCO reimbursement for the same drugs in 2018.

Limitations

We did not independently verify State-reported responses to our survey.

State drug utilization data is aggregated by FFS and MCO reimbursement in each State. Therefore, we were unable to identify the reimbursement for each MCO in a State. For example, if only four out of five MCOs in a State categorized a certain drug as a specialty drug, we were unable to determine how much of the total MCO reimbursement for that drug was associated with those four MCOs. Our Medicaid reimbursement totals do not reflect Medicaid drug rebates collected by States.

This analysis does not account for any changes that a State FFS program or Medicaid MCO may have made to its list(s) of specialty drugs after submitting them to OIG.

APPENDIX A

Criteria that States used to categorize specialty drugs

This appendix includes the individual criteria used by 14 State FFS programs and 176 Medicaid MCOs to categorize specialty drugs.[26] Not all of these criteria were used to categorize specialty drugs in each Medicaid program; for example, some States considered two or more of these criteria when determining which drugs to categorize as specialty drugs. This appendix also includes the number of State FFS programs and/or Medicaid MCOs that reported considering each criterion, as well as the number of States in which its FFS program or at least one of its Medicaid MCOs reported considering each criterion.

In certain programs, a drug may need to meet multiple criteria—such as requiring special handing, treating rare conditions, and having high costs—for a program to categorize it as a specialty drug. As shown in Exhibit A-1, there also was variation within each of these methods of categorization. For example, of the Medicaid programs that used high cost to categorize a drug as a specialty drug, the threshold for what was considered "high cost" ranged from $500 per month to $5,000 per month.

Exhibit A-1: The criteria that State FFS programs and Medicaid MCOs used to categorize specialty drugs

#	Criterion	Number of FFS and MCO programs in which criterion was applied	Number of States in which criterion was applied in either FFS or MCO
1	Requires intensive monitoring, care management, adherence monitoring, side effect management and/or clinical oversight	107	32
2	Requires special handling	104	31
3	Treats a chronic condition	96	28
4	Administered through injection	85	27
5	Drug cost (unspecified amount)	75	28

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[26] An additional 31 Medicaid MCOs categorized drugs as specialty drugs, but they did not provide the criteria they used for these categorizations.

Exhibit A-1: The criteria that State FFS programs and Medicaid MCOs used to categorize specialty drugs (continued)

#	Criterion	Number of FFS and MCO programs in which criterion was applied	Number of States in which criterion was applied in either FFS or MCO
6	Has limited, exclusive, or restricted distribution	68	31
7	Biotechnology products, biosimilars, large molecular entities, or other protein entities	68	24
8	Treats a complex condition	68	23
9	Typically, not routinely stocked at or beyond the capabilities of community retail pharmacies; dispensed at a specialty pharmacy	59	25
10	Requires member education or training	57	27
11	Administered through infusion	55	24
12	Requires special storage	54	23
13	Rare condition or condition treating limited/targeted populations	52	26
14	Treats multiple sclerosis	37	16
15	Requires complex dosing (therapies) or advanced treatment protocols	36	19
16	Administered orally	36	18
17	Treats hemophilia (antihemophilic factor)	34	16
18	Condition (unspecified)	32	16
19	Treats a life-threatening condition	32	15
20	Treats rheumatoid arthritis	30	14
21	Treats genetic diseases	26	15
22	Noninjectable drugs	24	17
23	Requires certifications, registries, or additional administration	23	18
24	Treats orphan or ultra-orphan diseases	23	13

(Continued on next page)

Exhibit A-1: The criteria that State FFS programs and Medicaid MCOs used to categorize specialty drugs (continued)

#	Criterion	Number of FFS and MCO programs in which criterion was applied	Number of States in which criterion was applied in either FFS or MCO
25	Treats cancer (including support agents for chemotherapy)	22	15
26	Treats cystic fibrosis	21	7
27	Certain exclusion criteria (e.g., drugs administered in inpatient settings)	20	15
28	Determined by provider committee (e.g. Pharmacy & Therapeutics Committee)	19	14
29	Requires special inventory	19	5
30	Cost equal to or greater than $670 per month[a]	18	14
31	Identified by another party (e.g. Pharmacy Benefits Manager)	18	10
32	Requires special distribution	18	5
33	Other (unspecified) issues	17	14
34	Requires special delivery	16	13
35	Administered by a healthcare professional	16	9
36	Requires risk evaluation and mitigation strategies or has a high risk	16	9
37	Used by a small percentage of the population or has low claim volume	15	15
38	Special Coordination or Coordination of Care	15	12
39	Requires special shipping	15	9
40	Cost equal to or greater than $600 per month	14	7
41	Treats condition with no cure or limited treatments	14	2
42	Treats a progressive condition	13	1
43	Administered through inhalation	12	8
44	Treats hepatitis	12	8

(Continued on next page)

Exhibit A-1: The criteria that State FFS programs and Medicaid MCOs used to categorize specialty drugs (continued)

#	Criterion	Number of FFS and MCO programs in which criterion was applied	Number of States in which criterion was applied in either FFS or MCO
45	Method of administration (unspecified)	11	7
46	Associated with comorbidities	9	9
47	Requires additional oversight to limit waste	9	9
48	Hormonal therapy	9	7
49	Requires temperature control	8	5
50	Treats acute diseases	7	7
51	Treats HIV/AIDs	7	6
52	Form (unspecified)	7	5
53	Cost equal to or greater than $1,000 per month	6	6
54	Treats respiratory conditions or respiratory syncytial virus prevention	6	5
55	Requires additional lab testing to ensure safety	6	4
56	Treats pulmonary arterial hypertension	6	4
57	Administered through implantation	6	3
58	Part of an existing specialty drug program	6	3
59	Administered through potentially any method	5	5
60	Is difficult to administer	5	4
61	Treats anemia	5	4
62	Treats osteoporosis	5	4
63	Potential for adverse reactions	5	4
64	Treats autoimmune diseases (including TNF inhibitor)	5	3
65	Treats Crohn's disease	4	4
66	Treats psoriasis	4	4
67	Immunoglobulin	4	3

(Continued on next page)

Exhibit A-1: The criteria that State FFS programs and Medicaid MCOs used to categorize specialty drugs (continued)

#	Criterion	Number of FFS and MCO programs in which criterion was applied	Number of States in which criterion was applied in either FFS or MCO
68	New drug	4	3
69	Treats eye disorders	4	3
70	Administered through instillation	4	2
71	Missing NADAC for all or majority of drugs in therapeutic class	3	3
72	Administered during transplantation	3	3
73	Cost equal to or greater than $10,000 per year	3	3
74	Delivered via mail or mail-order pharmacy	3	3
75	Requires additional maintenance or followup (unspecified)	3	3
76	Type of FDA approval	3	3
77	Administered through insertion	3	2
78	Self-administered	3	2
79	Treats ankylosing spondylitis	3	2
80	Treats chronic renal failure	3	2
81	Cost equal to or greater than $3,000 per month	3	1
82	Blood derivative products	2	2
83	Cost equal to or greater than $500 per month	2	2
84	Hematopoietic agent	2	2
85	Limited to a 30-day supply	2	2
86	Member safety concerns	2	2
87	Pharmacy type (unspecified)	2	2
88	Population served	2	2
89	Require special dispensing	2	2
90	Require special handling or storage (unspecified)	2	2
91	Requires prior authorization	2	2

(Continued on next page)

Exhibit A-1: The criteria that State FFS programs and Medicaid MCOs used to categorize specialty drugs (continued)

#	Criterion	Number of FFS and MCO programs in which criterion was applied	Number of States in which criterion was applied in either FFS or MCO
92	Treats allergic asthma	2	2
93	Treats limited conditions	2	2
94	Treats lupus	2	2
95	Treats metabolic disorders	2	2
96	Treats primary immune deficiency	2	2
97	Administered topically	2	1
98	Botulinum toxin	2	1
99	Treats angioedema	2	1
100	Treats cardiovascular conditions	2	1
101	Treats enzyme deficiencies	2	1
102	Access to care issues	1	1
103	Administered during a medical procedure	1	1
104	Anticoagulants	1	1
105	Availability of therapeutically equivalent drugs	1	1
106	Coagulants	1	1
107	Compounded product	1	1
108	Cost equal to or greater than $750 per month	1	1
109	Cost equal to or greater than $1,500 per month	1	1
110	Cost equal to or greater than $5,000 per month	1	1
111	Cost equal to or greater than $35,000 per year	1	1
112	Cost greater than $500 (time period unspecified)	1	1
113	Covered by Medicare Part B	1	1
114	Current delivery system	1	1
115	Drug complexity (unspecified)	1	1
116	Hazardous material	1	1

(Continued on next page)

Exhibit A-1: The criteria that State FFS programs and Medicaid MCOs used to categorize specialty drugs (continued)

#	Criterion	Number of FFS and MCO programs in which criterion was applied	Number of States in which criterion was applied in either FFS or MCO
117	Immunology therapies	1	1
118	Immunosuppressants	1	1
119	Initiated by or in consultation with a specialist	1	1
120	Line extension of an existing specialty product	1	1
121	Not available through the mail	1	1
122	Potentially any drug form	1	1
123	Requires ancillary supplies	1	1
124	Small molecule products	1	1
125	Standard of Care	1	1
126	Treats infertility	1	1
127	Treats neurologic disorders	1	1
128	Treats neutropenia	1	1
129	Treats nonemergent conditions	1	1
130	Treats osteoarthritis	1	1
131	Treats psoriatic arthritis	1	1
132	Treats sickle cell disease	1	1

Source: OIG analysis of data from survey of State Medicaid programs, 2019.

[a] In Medicare Part D, a drug must cost at least $670 per month to meet the criteria for inclusion on a plan's specialty tier.

APPENDIX B

Cost-Management Strategies for Specialty Drugs

This appendix provides information about commonly used cost-management strategies implemented for specialty drugs in the 38 States where the State FFS program and/or at least 1 Medicaid MCO categorized specialty drugs. This appendix excludes 13 States because they neither categorized specialty drugs in their FFS programs nor contracted with at least 1 Medicaid MCO that categorized specialty drugs.

Exhibit B-1: Cost-management strategies implemented for specialty drugs in States that categorized specialty drugs

State	Prior Authorization	Quantity Limits	Step Therapy	Preferred Drug List	Supplemental Rebates	Maximum Allowable Cost
AZ[a]	●					
CA	●	●	●	●	●	●
CO[a]						
DE[a]	●	●	●	●	●	
DC[a]	●	●	●	●	●	
GA[a]	●	●	●	●	●	
HI[a]	●	●	●	●	●	
IL[a]	●	●	●	●		●
IN	●	●	●	●	●	●
KS	●	●	●	●	●	●
KY[a]						

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Exhibit B-1: Cost-management strategies implemented for specialty drugs in States that categorized specialty drugs (continued)

State	Prior Authorization	Quantity Limits	Step Therapy	Preferred Drug List	Supplemental Rebates	Maximum Allowable Cost
LA[a]						
ME	●	●	●	●	●	
MD	●	●	●	●		
MA[a]	●	●	●	●	●	
MI	●	●	●	●	●	●
MN[a]	●	●		●	●	●
MS	●	●	●	●	●	
MO	●	●	●	●	●	●
NE[a]	●	●	●	●		●
NV[a]	●	●		●	●	
NH[a]	●	●	●	●	●	
NJ[a]	●	●	●	●	●	
NM[a]	●			●		
NY[a]	●	●			●	●
ND	●	●	●	●	●	
OH	●	●	●	●	●	●
OK	●	●	●	●	●	●
OR[a]	●	●	●	●	●	
PA[a]	●	●	●	●	●	

(Continued on next page)

Exhibit B-1: Cost-management strategies implemented for specialty drugs in States that categorized specialty drugs (continued)

State	Prior Authorization	Quantity Limits	Step Therapy	Preferred Drug List	Supplemental Rebates	Maximum Allowable Cost
SC	●	●	●	●	●	
TN	●	●	●	●	●	
TX[a]						
UT[a]						
VT	●	●	●	●	●	●
VA[a]	●	●		●	●	
WA[a]	●	●	●	●	●	
WI	●	●	●	●	●	●
Total	**33**	**31**	**27**	**31**	**28**	**13**

Source: OIG analysis of data from survey of State Medicaid programs, 2019.

[a] State reported that it did not know whether at least one of its Medicaid MCOs implemented at least one of these cost-management strategies. Therefore, any cost-management strategies implemented by these Medicaid MCOs are not included in Exhibit B-1.

APPENDIX C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: October 6, 2020

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections

FROM: Seema Verma
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: States Could Do More to Oversee Spending and Contain Medicaid Costs for Specialty Drugs (OEI 03-17-00430)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on this draft report regarding reimbursement for specialty drugs. CMS strives to maximize the affordability and availability of drugs for Medicaid beneficiaries while protecting taxpayer dollars.

The Medicaid program is jointly funded by states and the Federal Government, and is administered by states within Federal guidelines, and as such, both CMS and states have key roles as stewards of the program, and work together closely to carry out these responsibilities. CMS relies on states to define specialty drugs in the manner each state finds most appropriate. Although there is no singular definition for a specialty drug, these drugs are usually high cost, used to treat rare or complex conditions, need special handling, distributed by specialty pharmacies, or a combination of these factors.

CMS has released the cost data of many specialty drugs to promote transparency.[1] To assist states in setting reimbursement amounts, CMS conducts a monthly national survey of acquisition costs at retail community pharmacies. The results of these surveys create national average drug acquisition cost (NADAC) data for each drug, which is then released to the public and can be used as guidelines for setting drug pricing. Although specialty pharmacies are excluded from these surveys, many specialty drugs dispensed by retail pharmacies do have NADAC data available.

In addition to providing NADAC data for many specialty drugs, CMS supports states in exploring value-based purchasing (VBP) options for better managing and predicting of drug spending. Currently, CMS has approved the state plan amendments (SPAs) submitted by nine states that allow states to negotiate supplemental rebates under CMS-authorized rebate agreements with drug manufacturers based on evidence or outcomes-based measures for a patient or beneficiary based on use of the drug. In addition, CMS has released a proposed rule[2]

[1] Retail Price Survey, https://www.medicaid.gov/medicaid/prescription-drugs/retail-price-survey/index.html

[2] Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements https://www.federalregister.gov/documents/2020/06/19/2020-12970/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and

that, if finalized, would ask states to provide specific data elements on an annual basis associated with these VBP supplemental rebate agreements to ensure that payments associated with Medicaid patients receiving a drug under a VBP structure are consistent with efficiency, economy, and quality of care.

OIG Recommendation

Work with States to expand alternative reimbursement models to address the rising costs for drugs often categorized as specialty drugs.

CMS Response

CMS concurs with this recommendation. As mentioned above, CMS has already taken several steps to support states in creating alternative reimbursement models. Nine states have been approved for SPAs that allow them to implement VBP models to address rising drug costs. In addition, CMS has released a proposed rule to assist other states in implementing similar models.

OIG Recommendation

Collect information about specialty pharmacy acquisition costs and provide these data to States.

CMS Response

CMS non-concurs with this recommendation. CMS does not have clear statutory authority to contract with a vendor and execute a nationwide survey of prices for specialty pharmacies. In addition to lacking clear statutory authority, extending the current NADAC survey to cover specialty pharmacies, (or to develop a separate and distinct survey for them) would be a significant financial burden. Additionally, as noted above, many drugs identified as specialty drugs that are distributed by retail pharmacies are included on the NADAC file and therefore already available. As such, CMS believes that resources should be prioritized on finalizing the proposed pharmacy rule that would provide states with greater clarity and additional options around value-based purchasing, which we believe will have the greatest potential to address the rising costs of specialty drugs.

OIG Recommendation

Collaborate with States to conduct greater oversight of Medicaid MCOs management of specialty drugs, which could include a review of contract language that allows States to obtain requested information on specialty drug categorizations, specialty drug reimbursement methodologies, and cost-management strategies

CMS Response

CMS concurs with this recommendation. CMS will take steps (e.g., issuing guidance) to encourage States to strengthen their oversight of their MCOs' specialty drug categorizations, reimbursement methodologies, and cost-management strategies, including encouraging states to contractually require MCOs to provide States with access to information on covered specialty drugs.

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This report was prepared under the direction of Linda Ragone, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Edward K. Burley, Deputy Regional Inspector General.

Contact

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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

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections 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. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.