July 2015

MEDICAID

Additional Reporting May Help CMS Oversee Prescription-Drug Fraud Controls

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Why GAO Did This Study

Medicaid is a significant expenditure for the federal government and the states, with total federal outlays of $310 billion in fiscal year 2014. CMS reported an estimated $17.5 billion in potentially improper payments for the Medicaid program in 2014.

GAO was asked to review pharmacy-related program-integrity efforts at selected states. Among other reporting objectives, this report (1) identifies and analyzes indicators of potentially fraudulent or abusive prescribing activities in fiscal year 2011, and (2) examines the extent to which federal and state oversight policies, controls, and processes are in place to prevent and detect instances of prescription-drug fraud and abuse.

GAO analyzed Medicaid claims paid in fiscal year 2011, the most-recent reliable data available, for four states: Arizona, Florida, Michigan, and New Jersey. These states were chosen, in part, because they were among those with the highest Medicaid expenditures; the results are not generalizable to all states. GAO performed data matching with various databases to identify indicators of potential fraud, reviewed CMS and state Medicaid program-integrity policies, and interviewed CMS and state officials performing oversight functions.

What GAO Recommends

GAO recommends that CMS require states to report information about specific drug-utilization review controls to determine whether additional guidance is needed. The agency concurred with the recommendation and stated that it will consider requiring states to report on these areas.

View GAO-15-390. For more information, contact Seto J. Bagdoyan at (202) 512-6722 or bagdoyans@gao.gov.

What GAO Found

GAO found indicators of potential prescription-medication fraud and abuse among thousands of Medicaid beneficiaries and hundreds of prescribers during fiscal year 2011—the most-recent year for which reliable data were available in four selected states: Arizona, Florida, Michigan, and New Jersey. These states accounted for about 13 percent of all fiscal year 2011 Medicaid payments. Specifically, in these four states, GAO found the following:

- More than 16,000 of the 5.4 million beneficiaries potentially engaged in "doctor shopping," by visiting five or more doctors to receive prescriptions for antipsychotics or respiratory medications valued at about $33 million.
- About 700 beneficiaries received more than a 1-year supply of the same drug in 2011 at a cost to Medicaid of at least $1.6 million. This is an indicator of diversion, which is the redirection of prescription drugs for illegitimate purposes.

As required by federal law, the Medicaid Drug Utilization Review program is a two-phase review process states use to promote safety while also monitoring prescription-drug activity for fraud. Federal law requires each state to report on the operation of its review program, a key monitoring tool that the Centers for Medicare & Medicaid Services (CMS) uses to oversee the review process in states, but GAO identified additional actions that could improve oversight. In the first phase, states use tools and eligibility screening to promote patient safety and avoid abuse before the drugs are dispensed. The second phase involves ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care, and implement corrective action when needed.

However, GAO identified two potential controls that are not included in CMS's current reporting requirements:

- **Lock-in programs for noncontrolled substances.** Lock-in programs address doctor shopping by restricting beneficiaries who have abused the Medicaid program to one health-care provider, one pharmacy, or both, for receiving prescriptions. Lock-in programs have typically been used on controlled substances. Expanding lock-in programs that currently focus on controlled substances to restrict abusers of noncontrolled substances, such as the human immunodeficiency virus medications Atripla and Truvada, to a single prescriber or pharmacy may help address potential fraud and abuse.
- **Prohibition of automatic refills.** Pharmacies permitting automatic refills automatically refill prescriptions for certain medications without any customer action. Concerns with pharmacy automatic refill include the potential for stockpiling, continued fill of discontinued medications, and increased cost and waste of prescription medications. Two states GAO reviewed—Florida and Arizona—have prohibited the practice.

CMS does not collect information about lock-in programs for noncontrolled substances or automatic refill prohibitions, but doing so would help the agency determine whether additional guidance is needed.

_____ **United States Government Accountability Office**

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Figure

Abbreviations

2013 CMS DUR Summary	Medicaid Drug Utilization Review State Comparison Annual Report
AHCA	Florida Agency for Health Care Administration
AHCCCS	Arizona Health Care Cost Containment System
CMS	Centers for Medicare & Medicaid Services
DMAHS	State of New Jersey, Department of Human Services, Division of Medical Assistance and Health Services
DMF	Death Master File
DUR	Drug Utilization Review
FFS	fee-for-service
GSA	General Services Administration
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
MCO	managed-care organization
MMIS	Medicaid Management Information System
MSIS	Medicaid Statistical Information System
OIG	Office of Inspector General
SAM	System for Award Management
SSA	Social Security Administration
SSN	Social Security number
T-MSIS	Transformed Medicaid Statistical Information System

July 8, 2015

Congressional Requesters

Established in 1965 by Title XIX of the Social Security Act, Medicaid is a joint federal–state program that finances health care for low-income and medically needy individuals. The Centers for Medicare & Medicaid Services (CMS), within the Department of Health and Human Services (HHS), is responsible for overseeing the Medicaid program, including disbursing federal matching funds, and provides guidance, technical assistance, and periodic assessments of state Medicaid programs. Federal laws prescribe responsibility for both federal and state entities to protect the Medicaid program from fraud, waste, and abuse. Specifically, federal law requires CMS to issue regulations to improve Medicaid program integrity, with which state Medicaid programs must comply.

Medicaid is a significant expenditure for the federal government and the states, with total federal outlays of $310 billion in fiscal year 2014. In February 2015, we reported that Medicaid remains at high risk because of concerns about the adequacy of fiscal oversight of the program, including improper payments to Medicaid providers.[1] In fiscal year 2014, CMS reported an estimated improper payment rate of 6.7 percent, or $17.5 billion for the Medicaid program, which is an increase over its 2013 estimate of 5.8 percent, or $14.4 billion.[2]

While most improper payments are not related to fraud, and the full extent to which fraud, waste, and abuse related to prescription drugs affects Medicaid is unknown, we have previously identified potentially fraudulent or abusive practices in CMS's health-care programs.[3] For example, in

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[1]GAO has designated Medicaid as a high-risk program since 2003.

[2]An improper payment is defined by statute as any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements.

[3]Fraud involves an intentional act or representation to deceive with the knowledge that the action or representation could result in gain. Waste includes inaccurate payments for services, such as unintentional duplicate payments. Abuse represents actions inconsistent with acceptable business or medical practices.

September 2009, we found tens of thousands of potential "doctor shoppers" of controlled substances in Medicaid.[4] Doctor shopping is a beneficiary fraud scheme in which patients visit several doctors and pharmacies, receiving more drugs than any single physician would have prescribed. Additionally, in September 2011, we reported on indications of doctor shopping in the Medicare Part D program, which provides voluntary, outpatient prescription-drug coverage for eligible individuals 65 years and older and eligible individuals with disabilities.[5] As part of that work, we found that about 170,000 Medicare beneficiaries received prescriptions from five or more medical practitioners for frequently abused controlled substances. In both of those reports we made recommendations that CMS improve efforts to address doctor shopping. CMS agreed with our recommendations and implemented them. In May 2015, we issued a report on our work associated with Medicaid beneficiary and provider fraud.

Because of the substantial amount of funds that are expended in the Medicaid program and our prior work detailing potential fraudulent or abusive practices, you asked us to review any pharmacy-related program-integrity efforts at selected states. Specifically, for this review we

1. evaluated the reliability of Medicaid data from CMS and selected states for the purpose of identifying indicators of potential fraud or abuse;

2. identified and analyzed indicators, if any, of potentially fraudulent or abusive activities related to prescription drugs in Medicaid; and

3. examined the extent to which federal and selected state oversight policies, controls, and processes are designed to prevent and detect instances of prescription-drug fraud in Medicaid.

To evaluate the reliability of Medicaid data from CMS and state Medicaid programs for our selected states that could be used to identify indicators of potential fraud or abuse, we took several steps. We vetted 11 states for

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[4]GAO, *Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected State*s, GAO-09-957 (Washington, D.C.: Sept. 9, 2009).

[5]GAO, *Medicare Part D: Instances of Questionable Access to Prescription Drugs*, GAO-11-699 (Washington, D.C.: Sept. 6, 2011).

possible inclusion in our study.[6] We selected states based on high Medicaid beneficiary enrollment, geographic diversity, and availability of data. In the selection process, we also considered whether drugs were paid under fee-for-service (FFS) or managed care, by including states that included these program types in our review. We performed electronic testing to determine the validity of specific data elements in the federal and selected states' databases that we used to perform our work. We also reviewed related documentation, including data layouts and agency reports. Specifically, we used a January 2013 *Mathematica Policy Report* that details Medicaid Statistical Information System (MSIS) state data characteristics and anomalies to further vet states selected for our audit work.[7] We also used published GAO and HHS Office of Inspector General (OIG) reports that detailed the limitations of the MSIS data we used for our study.[8] Additionally, we interviewed officials responsible for their respective databases to discuss data-reliability considerations, and reviewed prior work related to the quality of the MSIS data used for our study.[9] On the basis of our discussions with agency officials and our own testing, we concluded that the data elements from four states—Arizona, Florida, Michigan, and New Jersey—used for this report were sufficiently reliable for the purpose of identifying indicators of potential fraud or abuse. However, in assessing the reliability of the data, we observed reportable shortcomings such as issues with timeliness, completeness, and accuracy in the data that may affect Medicaid administrators' ability to effectively oversee their program. However, the results of the data-reliability evaluation only apply to the states we selected for fiscal year 2011 and cannot be generalized to other states or periods. We discuss these shortcomings in greater detail later in this report.

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[6]The states vetted were: Arizona, California, Florida, Illinois, Maryland, Michigan, New Jersey, New York, Ohio, Pennsylvania, and Texas.

[7]Mathematica Policy Research, Inc., *MSIS State Data Characteristics/Anomalies Report* (Jan. 7, 2013).

[8]Department of Health and Human Services, Office of Inspector General, *Early Assessment of Review of Medicaid Integrity Contractors*, OEI-05-10-00200 (Washington, D.C.: February 2012). GAO, *National Medicaid Audit Program: CMS Should Improve Reporting and Focus on Audit Collaboration with States*, GAO-12-627 (Washington, D.C.: June 14, 2012); and *Medicaid: Data Sets Provide Inconsistent Picture of Expenditures*, GAO-13-47 (Washington, D.C.: Nov. 29, 2012).

[9]Mathematica Policy Research serves as CMS's contractor and performs reviews to ensure and report on the quality of MSIS data. The organization publishes information on unreconciled data in its anomalies report.

To identify indicators of potentially fraudulent or abusive activities related to prescription drugs in Medicaid, we obtained and analyzed Medicaid claims paid in fiscal year 2011, the most-recent period from which we could draw reliable data, for four states: Arizona, Florida, Michigan, and New Jersey. Medicaid payments to these states constituted about 13 percent of all Medicaid payments made during fiscal year 2011. These states were selected primarily because they had consistently comparable and reliable data and were among the states with the highest Medicaid expenditures. The results of our analysis of these states are not generalizable to other states.

We obtained MSIS beneficiary, provider, prescription-drug, and other services claims data, as well as state Medicaid Management Information Systems (MMIS) crosswalk data (with personal identifiers) to perform our work.[10] The crosswalk data we used contained specific identifying information on prescribers, pharmacies, and beneficiaries that were not collected in the MSIS data, such as name and address.

We reviewed literature related to health-care fraud, including reports discussing fraud, waste, and abuse related to prescription drugs. We interviewed federal, state, and private-sector auditors, program administrators, and other relevant officials that had published work that investigated or researched prescription-drug fraud. On the basis of this research, we identified areas at greater risk of fraud and abuse such as drugs at high risk for diversion and types of prescribing patterns that warranted additional review. We used this information to develop our analytic approach to identify indicators of potential fraud and abuse related to prescription drugs in Medicaid. To identify potential overuse, we reviewed beneficiaries who received more than a 480-day supply of the same medication in a single year based on the national drug code. To identify potential doctor-shopping activities, we examined beneficiaries who received prescriptions for drugs within one of two therapeutic classes of drugs from five or more prescribers. We focused on beneficiaries who received prescriptions for antipsychotics or respiratory medications from five or more different prescribers over the course of 1 year. We selected medications in these therapeutic classes because they had a large number of individuals who received drugs from five or more prescribers

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[10]MMIS crosswalk data contained information such as provider and beneficiary name and address. The quality of this information was not used to vet states for inclusion in this work.

relative to other classes of noncontrolled substances we considered, have a known diversion risk, and are relatively expensive.[11] We selected the five-or-more prescribers threshold based on our review of drug diversion literature and prior GAO work. We also looked for prescribers and pharmacies with a high proportion of prescribing or dispensing activities for brand-name drugs (versus generics) compared to the average activity of other prescribers and pharmacies[12] and we looked for pharmacies without any adjusted or voided claims.[13] To identify potentially unnecessary prescription-drug activities, we reviewed claims paid on behalf of beneficiaries who received human immunodeficiency virus (HIV) and diabetes medications despite having no HIV or diabetes-related indicators related to such ailments in their fiscal year 2011 Medicaid outpatient claims listed in the MSIS "other services" file.[14]

We also matched the Medicaid data to other external sources to identify potential fraud and improper payments. These matches sought to identify individuals who may be ineligible to receive Medicaid benefits or providers who should not have received Medicaid payments due to residency, death, or other exclusionary factors. We used the beneficiary files to identify individuals who had payments made on their behalf concurrently by two or more of our selected states. We compared the beneficiary and prescriber identity information shown in the Medicaid claims data to the Social Security Administration's (SSA) complete file of death information to determine whether any individuals were reportedly deceased when they purportedly prescribed, dispensed, or received

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[11]Drugs and other substances that are considered controlled substances under the Controlled Substances Act are divided into five schedules. An updated and complete list of the schedules is published annually in 21 C.F.R. §§ 1308.11 – 1308.15. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Drugs that are not considered controlled substances are known as noncontrolled substances.

[12]Our analysis did not control for medications where there was not a generic version available.

[13]When a change to a prescription is made or when a beneficiary fails to pick up the prescribed drugs, the pharmacy must adjust the claim transaction. According to officials in New Jersey, instances of pharmacies with too many or too few adjustments may be red flags for concern.

[14]This analysis was based on diagnosis codes for HIV or diabetes. We did not account for prescribing of these medications for other ailments.

prescription drugs from Medicaid. To identify prescription-drug claims that might have been improperly processed and paid by the Medicaid program because either the prescribers or beneficiaries were incarcerated, we compared the Medicaid claims to data files listing incarcerated individuals from the four selected states. To identify claims that might have been improperly processed and paid by the Medicaid program because the federal government had banned the corresponding prescribers from providing services to Medicaid beneficiaries, we compared the Medicaid claims to the exclusion and debarment files from the HHS OIG and the General Services Administration (GSA). We compared files from the different states to identify beneficiaries who received concurrent benefits from multiple states.

To determine the extent to which federal and state oversight policies, controls, and processes are designed to prevent and detect indicators of prescription-drug fraud in Medicaid, we reviewed CMS and state Medicaid policies pertinent to program integrity over pharmaceuticals, met with CMS officials, and visited state Medicaid offices that perform oversight functions for the four states we selected. We used federal standards for internal control,[15] GAO's Fraud Prevention Framework,[16] and Medicaid statutes and regulations addressing the administration of pharmacy benefits to evaluate these functions.

To determine the reliability of the data used in our analysis, we performed electronic testing to determine the validity of specific data elements in the federal and selected states' databases that we used to perform our work. We also interviewed officials responsible for their respective databases and reviewed documentation related to the databases and literature related to the quality of the data. On the basis of our discussions with agency officials and our own testing, we concluded that the data elements used for this report were sufficiently reliable for our purposes.

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[15]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

[16]GAO, *Individual Disaster Assistance Programs: Framework for Fraud Prevention, Detection, and Prosecution*, GAO-06-954T (Washington, D.C.: July 12, 2006).

We conducted this performance audit from March 2014 to July 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our audit findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. More details on our objectives, scope, and methodology can be found in appendix I.

Background

Medicaid Prescription-Drug Programs

State Medicaid programs do not directly purchase prescription drugs but instead reimburse pharmacies for covered prescription drugs dispensed to Medicaid beneficiaries. States operate their Medicaid programs by paying qualified health-care providers (including prescribers and pharmacies) for a range of covered services provided to eligible beneficiaries and then seeking reimbursement for the federal share of those payments. States may directly pay health-care providers for services rendered using a FFS delivery system or may delegate these responsibilities to managed-care organizations (MCO). Under managed-care arrangements, states contract with MCOs to deliver care through networks. States typically pay the MCOs a fixed amount each month, called a capitation payment. All four of the states included in our review—Arizona, Florida, Michigan, and New Jersey—had MCO arrangements in place.

Although the federal government establishes broad requirements, each state has flexibility in managing its Medicaid program. Guidelines established by federal statutes, regulations, and policies allow each state to (1) broaden its eligibility standards; (2) determine the type, amount, duration, and scope of services; (3) set the rate of payment for services; and (4) administer its own program, including enrollment of providers and beneficiaries, processing and monitoring of medical claims, payment of claims, and maintenance of fraud-prevention programs. CMS is responsible for administering legislation and regulations affecting the Medicaid program. CMS also provides guidelines, technical assistance, and periodic assessments of state Medicaid programs.

The federal government requires coverage for certain mandatory services under Medicaid, but states may decide to include other optional services as well. Some of the largest and most commonly included services include nursing facilities, home and community-based care, and hospital inpatient care. Although pharmacy coverage is an optional service under federal Medicaid law, all 50 states currently provide coverage for prescription drugs. States may pay for drugs dispensed through MCOs using either the "carve-in" or the "carve-out" approach. To use the carve-in approach, states include payment for the drugs dispensed to beneficiaries in the MCOs' fixed monthly payment amounts. In the carve-out approach, states exclude payment for the drugs dispensed to beneficiaries from the MCOs' fixed monthly payment amounts and instead pay for these drugs using the traditional FFS system. States may also use a combination of carve-out and carve-in approaches.

Medicaid Data Collection and Reporting

The Medicaid prescription-drug programs, such as the Drug Utilization Reviews (DUR), include the management, development, and administration of systems and the data collection necessary to operate them. As part of data-collection efforts, states are mandated to report FFS claims and individual encounter data for managed-care enrollees to CMS. MSIS is the mechanism by which CMS requires states to report these data on a quarterly basis, although delays in reporting data occur.[17] The database is used for analytical research, program integrity, planning, budgeting, and policy analyses associated with Medicaid.

Medicaid Pharmacy Fraud

Federal law prohibits Medicaid providers and beneficiaries from taking certain actions related to billing for or receiving Medicaid services. For example, the Federal False Claims Act makes it illegal to submit false claims to Medicare, Medicaid, and other government health-care programs for payment.[18] Violation of these or other relevant laws and regulations may constitute fraud. We and other federal oversight entities have recently issued a number of reports related to fraud and other types

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[17]GAO-13-47. Changes to MSIS, including requirements for reporting time frames, began implementation in July 2014. The updated system is known as the Transformed Medicaid Statistical information System (T-MSIS).

[18]The False Claims Act prohibits certain actions, including the knowing presentation of a false claim for payment by the federal government. 31 U.S.C. § 3729(a)(1)(A).

of improper payments in CMS's health-care programs, including Medicaid.[19] For example, in May 2014 we reported that neither state nor federal Medicaid entities were well positioned to identify improper payments made to MCOs due to a gap in state and federal efforts to ensure Medicaid managed-care program integrity. A report released by the HHS OIG in August 2014 found over 1,500 Medicare beneficiaries who had questionable utilization patterns for HIV drugs, including beneficiaries who had no indication of HIV in their Medicare histories, received an excessive dose or supply of HIV drugs, or received HIV drugs from a high number of pharmacies or prescribers. In October 2014, we reported on 23 practices for addressing prescription-drug fraud, waste, and abuse in Medicare developed from a detailed literature review as well as interviews with relevant stakeholders.[20]

Reliability Issues Limit Usefulness of Medicaid Data for Identifying Indicators of Potential Fraud and Abuse

According to CMS guidance to state Medicaid directors, programs with the size and scope of Medicaid require robust, timely, and accurate data to identify potential fraud or waste. However, CMS's MSIS data continue

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[19]See for example: GAO, *Medicaid Program Integrity: Increased Oversight Needed to Ensure Integrity of Growing Managed Care Expenditures*, GAO-14-341 (Washington, D.C.: May 19, 2014); *Medicaid Program Integrity: CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse*, GAO-15-66 (Washington, D.C.: Oct. 24, 2014); and Department of Health and Human Services, Office of Inspector General, *Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs*, OEI-02-11-00170 (Washington, D.C.: August 2014).

[20]GAO-15-66.

to have limited usefulness for identifying fraud, waste, and abuse due to issues with accuracy, completeness, and timeliness.[21]

We analyzed 11 states to possibly include in our study, but had to exclude data from four states—California, Maryland, Ohio, and Pennsylvania—due to fiscal year 2011 data-availability and quality issues.[22]

- In California, officials expressed concerns regarding the reliability of their data due to issues of reporting from the health plans and data conversions to other systems. Officials also had concerns about the ability to identify prescribing providers in the MCO data.

- The January 2013 Mathematica Policy Research report noted that for Maryland fiscal year 2011 MSIS data, National Provider Identifier (a unique identifier for Medicaid providers) and physician-specialty information were missing on managed-care prescription transactions.

- Similarly, the January 2013 Mathematica Policy Research report identified that Ohio MSIS data were missing provider-identifying information and prescription-drug and pharmacy information.

- The January 2013 Mathematica Policy Research report identified that Pennsylvania had not reported any data related to managed-care encounters through at least the fourth quarter of fiscal year 2011, even though the majority of the state's Medicaid-eligible population was enrolled in comprehensive managed care.

Although the MSIS data from Arizona, Florida, Michigan, and New Jersey were sufficiently reliable for the purpose of identifying indicators of potential fraud or abuse, we identified issues with their timeliness and completeness. For example, the most-recent validated data available

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[21]The results of our data-reliability work are not generalizable to other states or time frames other than fiscal year 2011.

[22]State Medicaid officials from Illinois, New York, and Texas reported that their programs were shifting away from FFS to an MCO system. We excluded data from these three states because the most-recent data available (fiscal year 2011) would not reflect this transition and not because of data availability or quality concerns. We did not independently analyze data from California, Maryland, Ohio, or Pennsylvania to corroborate state officials' statements or findings in the January 2013 Mathematica Policy Research report.

from CMS for Arizona, Florida, Michigan, and New Jersey were more than 3 years past the date when they should have been validated.[23] The fiscal year 2011 claim files were the most-current claim files contained in the MSIS system.[24] In addition, about 20 million (26 percent) of the records included filler data (e.g., 01-01-0001) in the prescribed date fields. While the data help identify potential vulnerabilities to Medicaid prescription-drug fraud, waste, and abuse, they are not sufficiently timely to enable investigation of specific transactions. These problems with the MSIS data used for this review are consistent with concerns raised in previous GAO and HHS OIG reports.

In October 2012, we reported that MSIS data were not timely because of late state submissions and the time it takes CMS to review and validate data.[25] In that report we found that 37 states were late with their quarterly data by six quarters in July 2012. We further reported that even though CMS requires states to submit MSIS data within 45 days, states' reporting of MSIS data and the subsequent validation process can be up to 3 years late. In interviews for this review, both CMS and state Medicaid officials agreed that this validation process can be lengthy. For example, CMS officials may identify a data-quality issue during the validation process in which they analyze the data and ensure that errors do not exceed a predetermined threshold. If the threshold is exceeded, CMS will then request the state to resubmit corrected data, which can take several additional months, according to both CMS and state Medicaid officials.

In addition, we reported in June 2012 that MSIS-based audits were hampered by deficiencies in the data, and noted that CMS had initiatives to transition into a new system called the Transformed Medicaid

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[23]In response to a draft of this report, New Jersey Medicaid program officials stated that for New Jersey the concern regarding the timely submission of MSIS data is related solely to the time required for CMS to validate New Jersey claims file submissions. According to the New Jersey officials, CMS was validating the state's quarterly claims file submissions for calendar years 2012 and 2013 in calendar year 2014.

[24]At the time of our data request, the most-recent validated CMS claims data available for Michigan were from the second quarter of fiscal year 2013. However, for consistency in our analysis, we used fiscal year 2011 data for all states. The oldest claims in our data were paid in October 2010, more than 3 years before we received the last file in February 2014.

[25]GAO-13-47.

Statistical Information System (T-MSIS).[26] According to August 2013 CMS guidance to state Medicaid directors, T-MSIS is intended to modernize and enhance the way states will submit operational data about beneficiaries, providers, claims, and encounters and will be the foundation of a robust state and national analytic data infrastructure. Additionally, in the August 2013 CMS guidance to state Medicaid directors, CMS stated that this change will enhance the agency's ability to observe trends or patterns indicating potential fraud, waste, and abuse in the state Medicaid programs to prevent or mitigate the effect of these activities. States may also have enhanced capabilities to counter fraud, waste, and abuse capabilities. The guidance also indicates CMS and the states will be able to analyze the data submitted by the states along with other information in the CMS data repositories, including Medicare data, enhancing abilities to better identify potential anomalies for further investigation. CMS officials stated that they will not begin to analyze the benefits derived from T-MSIS until the transition reaches the point where data for at least half of the Medicaid population in the United States are included in T-MSIS.

Our review of prior HHS OIG work and our discussions with officials from our four selected states indicate there may be challenges related to implementing the T-MSIS initiative. In January 2013, the HHS OIG analyzed results of the early implementation of T-MSIS among 12 volunteer states to refine and enhance the MSIS data set and modernize the ongoing submission and quality-review process for the data set.[27] The HHS OIG found that, as of January 2013, CMS and 12 volunteer states had made some progress in implementing T-MSIS; however, early T-MSIS implementation outcomes raised questions about the completeness and accuracy of T-MSIS data upon national implementation. According to the HHS OIG report, none of the 12 volunteer states could make all T-MSIS data elements available. Both CMS and the 12 states expressed concerns about the accuracy of the data they could provide upon implementation. The HHS OIG recommended that CMS ensure that states report complete, accurate,

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[26]GAO, *National Medicaid Audit Program: CMS Should Improve Reporting and Focus on Audit Collaboration with States*, GAO-12-627 (Washington, D.C.: June 14, 2012).

[27]Department of Health and Human Service, Office of Inspector General, *Early Outcomes Show Limited Progress for the Transformed Medicaid Statistical Information System*, OEI-05-12-00610 (Washington, D.C.: September 2013).

and timely information to T-MSIS to support effective oversight. According to the Fiscal Year 2016 HHS OIG Justification of Estimates for Appropriations Committees, this recommendation remains a priority unimplemented recommendation.[28]

CMS began implementing T-MSIS with states on a rolling basis in July 2014 and is working towards full implementation in 2015. Specifically, CMS officials stated that the T-MSIS project is in the midst of implementation with all states. Moreover, all states are working towards completion of the T-MSIS implementation in 2015, according to CMS. CMS went live with its federal T-MSIS platform in May 2015, and estimates that at least half the Medicaid population in the United States will be available through submitted T-MSIS files by the end of 2015. However, officials from the four states included in our review told us that they are experiencing challenges with implementing T-MSIS requirements. Specifically, officials from three of the states explained that CMS continues to change data-field requirements for the data submissions.

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[28]The HHS OIG 2015 Compendium of Unimplemented Recommendations did not provide a timeline for implementing this recommendation, but noted that CMS work in this area was ongoing from March 2014.

Medicaid Prescription-Drug Claims Data Contained Indicators of Potential Fraud and Improper Payments in Four Selected States

Our analysis of fiscal year 2011 Medicaid prescription claims data from four selected states identified several indicators of potential fraud.[29] Specifically, we found indicators of potential fraud among beneficiaries, prescribers, and pharmacies (1) with questionable patterns related to received, prescribed, and dispensed drugs; (2) who received drugs for certain conditions for which the beneficiaries had no other indicators in their fiscal year 2011 Medicaid outpatient claims; and (3) with concerns identified using data matching—such as prescribers who appeared to be deceased by the prescribed date. Because of the age of the data, we did not independently investigate individual transactions to confirm whether a particular beneficiary, prescriber, or pharmacy actually engaged in fraud, waste, or abuse.[30]

Questionable Patterns Related to Drugs Received in Four Selected States Indicate Potential Fraud

Potentially Excessive Prescription Claims

Beneficiaries who receive large numbers of drugs, especially of the same drug, can indicate possible overutilization and, in more-egregious cases, drug diversion.[31] Additionally, beneficiaries obtaining services from many different prescribers can raise questions. In our analysis of potentially excessive prescription claims, we found the following:

- **Beneficiaries with high quantities of the same drug.** About 700 of the 5.4 million beneficiaries we reviewed received more than a 1-year supply (a 480-day supply) of the same drug in 2011 at a cost to

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[29]We reviewed prescription-drug activity for about 5.4 million beneficiaries, 251,000 prescribers, and 26,000 pharmacies that received, prescribed, or dispensed prescriptions drugs paid for by Medicaid during fiscal year 2011. These counts are based solely on fields in the MSIS data so it is possible that a beneficiary, prescriber, or pharmacy with multiple records in the MSIS data may have been counted multiple times.

[30]The categories for our analysis are not mutually exclusive. Individuals may be included in more than one analysis detailed in the report.

[31]Drug diversion is the redirection of prescription drugs for illegitimate purposes. Data errors and legitimate need due to severe illness may also explain why certain beneficiaries received large quantities of drugs during our analysis.

Medicaid of at least $1.6 million.[32] About 50 of these beneficiaries received more than 2 years' worth (a 730-day supply) of the same drug. One beneficiary appeared to receive more than 3-1/2 years' worth of the same respiratory medication at a cost to Medicaid of at least $10,000. Another beneficiary received more than 1 year's worth of seven different drugs at a cost to Medicaid of at least $30,000.

- **Beneficiaries visiting five or more prescribers.** Doctor shopping is a beneficiary fraud scheme in which Medicaid beneficiaries visit multiple prescribers to obtain more prescriptions for the same or similar drugs than a single physician would prescribe.[33] Specifically, when a beneficiary obtains drugs from many prescribers or pharmacies, it could mean the beneficiary is seeking drugs to divert for profit or that the beneficiary's identification number was stolen. Another concern is that the beneficiary is getting excessive doses or supplies. According to CMS data, more than 16,000 beneficiaries out of the 5.4 million we reviewed visited five or more prescribers to receive prescriptions for antipsychotics or respiratory medications valued at about $33 million.[34] For example, a single beneficiary visited 15 prescribers and 10 pharmacies to obtain various antipsychotics at a cost to Medicaid of about $23,000 in 1 year. Another beneficiary

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[32]We calculated the days of supply using 365 days or 1 year's worth of Medicaid data based on the dispense date. While it is possible that the beneficiary had a legitimate medical reason for obtaining a high volume of drugs, we considered it to be potentially fraudulent or improper if the total was more than 480 days for the same drug. We used 480 days instead of 365 to allow for one 90 day prescription for use in the next fiscal year and because it was divisible by 30. This is also the threshold HHS OIG officials used in their work on HIV medications in Medicare Part D (see HHS OIG, OEI-02-11-00170).

[33]The excess drugs are then consumed by the beneficiary, often for recreational purposes, or are diverted to another party for financial gain. The Medicaid program incurs excessive costs for both the prescription drugs purchased during the doctor-shopping scheme as well as the associated office visits. Estimates suggest costs associated with the office and emergency room visits used to illicitly obtain drugs by means of doctor shopping can cost 14 times more than the drugs themselves. In this regard, our prior work has shown that Medicaid is vulnerable to doctor shopping for controlled substances. See GAO-09-957.

[34]For this analysis, we focused on beneficiaries who received prescriptions for antipsychotics or respiratory medications from five or more different prescribers over the course of 1 year. We selected medications in these therapeutic classes because they had a large number of individuals who received drugs from five or more prescribers relative to other classes of noncontrolled substances we considered, had the strongest doctor-shopping indicators (among noncontrolled substances), have a known diversion risk, and are relatively expensive.

received prescriptions for respiratory medications at 11 pharmacies written by 21 prescribers at a cost to Medicaid of at least $4,800 in 1 year. Table 1 shows the number of potential doctor shoppers and the costs associated with the purchased drugs for these therapeutic classes, by prescribers visited.[35]

Table 1: Estimated Number of Beneficiaries in Four Selected States Who Received Prescriptions for the Same Drug Class from Five or More Prescribers during Fiscal Year 2011

Drug class		Received prescriptions from 5 to 6 providers	Received prescriptions from 7 to 10 providers	Received prescriptions from 11 or more providers	Total
Antipsychotic	Number of beneficiaries	4,800	850	30	**5,720**
	Cost (dollars in thousands)	$17,200	$3,400	$224	**$20,865**
Respiratory	Number of beneficiaries	9,100	1,560	90	**10,730**
	Cost (dollars in thousands)	$10,100	$2,300	$163	**$12,620**
Total	**Number of beneficiaries**	**13,900**	**2,400**	**130**	**16,440**
	Cost (dollars in thousands)	**$27,400**	**$5,700**	**$387**	**$33,485**

Source: GAO analysis of Arizona, Florida, Michigan, and New Jersey data. | GAO-15-390

Note: Totals do not add up due to rounding.

Beneficiaries may have a justifiable reason for receiving prescriptions from multiple medical practitioners. For example, a beneficiary may legitimately receive prescriptions from different prescribers within the same practice. Also if a beneficiary moves multiple times over the course of the year, he or she may still require the same prescriptions, which will necessitate visits to additional prescribers. There may be other legitimate medical reasons for receiving prescriptions for the same drug from multiple prescribers, such as visiting multiple specialists.

Questionable Prescribing and Dispensing Patterns

Analysis of prescribing and dispensing patterns can also help identify indicators of potential fraud, waste, and abuse. Excessive patterns of prescribing or dispensing, relative to peers, can indicate potential fraud. For example, we examined and identified prescribers and pharmacies

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[35]We cannot determine from data analysis alone which cases represent actual doctor shoppers and which cases represent instances in which the beneficiary had a legitimate reason for visiting multiple prescribing physicians. However, certain cases have stronger fraud indicators than others, such as those cases in which more than one pharmacy is involved.

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with an unusually high proportion of activity for brand-name drugs.[36] In addition, analysis of pharmacy adjustments on claims can indicate whether pharmacies are properly billing Medicaid. In our analysis of prescription claims for questionable prescribing and dispensing patterns, we found the following:

- **Prescribers and pharmacies associated with high numbers of brand-name drugs.** In our discussions with officials that had investigated or researched prescription-drug fraud, we found that brand-name drugs can be at greater risk of diversion due to their relatively high expense. In more egregious examples, an unusually high proportion of brand-name drugs could represent a kickback scheme benefitting the prescriber or indicate a substitution of generic drugs scheme where the pharmacy dispenses generics but bills for more-expensive brand-name drugs.[37] Our analysis identified 119 out of about 28,000 prescribers associated with at least 500 claims for which at least 75 percent of the prescriptions were written for brand-name drugs. Among the 8,800 pharmacies we reviewed with at least 500 claims, we found about 300 pharmacies for which over half of the prescriptions filled were for brand-name drugs. We also found 37 pharmacies with at least 500 claims that only dispensed brand-name drugs.[38]

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[36]Other possible patterns such as number of drugs prescribed per beneficiary or number of pharmacies filling their prescriptions can provide indications of prescribers that are more susceptible to fraud, waste, and abuse. In addition, pharmacies being billed extremely high numbers of drugs per beneficiary or per prescriber, extremely high cost per beneficiary or claim, or extremely high numbers of refills and adjustments relative to other pharmacies can also indicate potential fraud.

[37]Michigan Medicaid officials noted that Michigan state law prohibits Medicaid from requiring prescription-medication preauthorizations for brand-name medications for specific protected conditions, including HIV and transplant recipients. Arizona Medicaid officials stated that some states continue to require specific brand name medication coverage because it is more costly to the state to purchase the generic product.

[38]We identified about 27,800 prescribers and 8,800 pharmacies with at least 500 claims. For each prescriber with at least 500 claims, we measured the proportion of all prescriptions written that were brand-name drugs. The average proportion was 16.5 percent (median = 19.9 percent). For each pharmacy with at least 500 claims, we measured the proportion of all prescription dispensed that were brand-name drugs. The average proportion was 19.3 percent (median = 21.7 percent). Our analysis did not control for medications where there was not a generic version available. Additionally, Arizona Medicaid officials stated that some specific specialty pharmacies may be expected to have a high percentage of branded medications.

- **Pharmacies without adjustments.** When a change to a prescription is made or when a beneficiary fails to pick up the prescribed drugs, the pharmacy must adjust the claim transaction. According to officials in New Jersey, instances of pharmacies with too many or too few adjustments may be red flags for concern. We identified about 70 out of approximately 4,000 pharmacies that filed over 5,000 claims without a single adjustment. These pharmacies received at least $23 million from Medicaid during fiscal year 2011. In contrast, among pharmacies that filled over 5,000 claims, the median pharmacy adjusted about 2 percent of its claims and the mean pharmacy adjusted about 5 percent of its claims. As we stated previously, adjustments may reflect changes to claims for medications that are not picked up by beneficiaries. While there may be legitimate reasons for a pharmacy to have low percentages of adjustments to claims, such pharmacies may warrant follow-up review by state oversight officials. For example, Michigan officials stated that there are some long-term nursing care facilities that only bill for the medications consumed by patients at the end of the month. These facilities would not have adjustments in their claims because the bill at the end of the month reflects the accurate amount of medication used by the patient.

Beneficiaries in Four Selected States Receiving Drugs for Conditions Not Identified in Their Fiscal Year 2011 Medicaid Outpatient Claims Indicate Potential Improper Payments

We identified beneficiaries in our four selected states who received prescription drugs only used to treat HIV and medications primarily used to treat diabetes but who had no additional (beyond receiving the HIV or diabetes medications) indicators of HIV or diabetes in their outpatient Medicaid activity from fiscal year 2011.[39] The absence of such evidence does not prove that the beneficiary did not have HIV or diabetes or that there was inappropriate off-label use:[40] the claims files we used were for a limited period and did not reflect the beneficiary's entire medical history, and our search may not have included every possible diagnosis or service code related to HIV and diabetes.[41]

HIV Medications Prescribed to Beneficiaries without Indicators of HIV in Their Fiscal Year 2011 Medicaid Outpatient Claims

The HHS OIG reported in August 2014 that antiretroviral drugs that treat HIV are a target for fraud, waste, and abuse because they can be very expensive and can have psychoactive effects.[42] Our analysis showed that the majority (94 percent) of the approximately 13,000 beneficiaries who received prescriptions for one of five HIV drug treatments had an HIV-related diagnosis indicator documented in their fiscal year 2011 Medicaid outpatient claims. In contrast, more than 750 of the 13,000 beneficiaries received HIV medications despite having no apparent indicator of having HIV in their fiscal year 2011 Medicaid outpatient claims. These beneficiaries received the HIV medications Atripla, Combivir, Norvir, Reyataz, and Truvada, which according to Food and Drug Administration indications and usage labeling are used to treat HIV-positive patients.

Medicaid paid about $3.7 million in claims for HIV medications for beneficiaries with no other indications in their fiscal year 2011 outpatient

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[39]We used the MSIS "other services" file to examine each beneficiary's Medicaid activity. We excluded beneficiaries who did not have any activity whatsoever in the MSIS other services file from this analysis. The MSIS other services file covers all Medicaid or Children's Health Insurance Program claims that are not included in the MSIS inpatient, long-term, or prescription-drug claims files. This includes payments for provider claims for all noninstitutional Medicaid services.

[40]Off-label use refers to the prescription of a medication for uses other than what the Food and Drug Administration has approved. Our review did not include all drugs that may be used to treat HIV or diabetes. See appendix I for additional details about our drug selection criteria.

[41]The results of this analysis may also be caused by off-label use, record-keeping, or data-coding issues. In addition, one state suggested that timing differences in its prior-authorization process could explain some of these observations.

[42]HHS OIG, OEI-02-11-00170.

claims of having HIV. For example, 60 beneficiaries each received Truvada at least 12 times despite not having a HIV diagnosis code or other indicator for HIV, costing Medicaid at least $523,000. About 30 beneficiaries with no HIV indicators each received the HIV medication Atripla at least 12 times at a cost to Medicaid of at least $418,000. One such beneficiary had 52 claims for multiple different HIV medications at a cost to Medicaid of over $50,000. Our analysis found that about 20 pharmacies dispensed HIV medications to at least 10 different beneficiaries who had no HIV indicators according to their fiscal year 2011 Medicaid claims. Table 2 summarizes the costs associated with each drug under review received by beneficiaries who did not have a Medicaid HIV indicator in the fiscal year 2011 outpatient claims file, broken out by beneficiaries with 1 to 11 claims and beneficiaries with 12 or more claims.

Table 2: Estimated Costs Associated with Beneficiaries in Four Selected States in Fiscal Year 2011 Who Received Human Immunodeficiency Virus (HIV) Medications but Did Not Have Outpatient Claims in Fiscal Year 2011 Indicating HIV

HIV drug	Beneficiaries with 1 to 11 claims		Beneficiaries with 12 or more claims	
	Number of beneficiaries	Medicaid paid amount (dollars in thousands)	Number of beneficiaries	Medicaid paid amount (dollars in thousands)
Atripla	190	$728	30	$418
Combivir	80	114	20	85
Norvir	280	283	60	155
Reyataz	140	348	40	215
Truvada	310	853	60	523
Total	**640**	**$2,326**	**140**	**$1,397**

Source: GAO analysis of Arizona, Florida, Michigan, and New Jersey data. | GAO-15-390

Note: Totals do not add up because beneficiaries may receive multiple medications. The claims files we used were for a limited period and did not reflect the beneficiary's entire medical history. Therefore, we cannot determine from data analysis alone which cases represent inappropriate prescriptions and which are permissible prescribing patterns.

We cannot determine from data analysis alone which cases represent inappropriate prescriptions and which permissible prescribing patterns are. Such determinations would require additional review of the facts and circumstances of each individual case by state oversight officials.

Diabetes Medications Prescribed to Beneficiaries without Indicators of Diabetes in Their Fiscal Year 2011 Medicaid Outpatient Claims

Our analysis showed that the majority (96 percent) of the approximately 57,000 beneficiaries who received prescriptions for one of four diabetes treatments had diabetes-related indicators elsewhere in their fiscal year 2011 Medicaid outpatient claims. However, we identified about 2,300 beneficiaries who received diabetes medications, including Actos, Humalog, Lantus, and Novolog, without other indicators for the disease in

their Medicaid outpatient claims. The costs for providing these medications amounted to at least $680,000. For example, about 100 beneficiaries each received 12 or more prescriptions for Actos at a total cost to Medicaid of at least $96,000. Another 72 beneficiaries each received 12 or more prescriptions for Lantus costing Medicaid at least $46,000. Table 3 summarizes the costs associated with each drug under review received by beneficiaries who did not have a diabetes-related indicator in the fiscal year 2011 outpatient claims file, broken out by beneficiaries with 1 to 11 claims and beneficiaries with 12 or more claims.

Table 3: Estimated Costs Associated with Beneficiaries in Four Selected States in Fiscal Year 2011 Who Received Certain Diabetes Medications but Did Not Have Outpatient Claims in Fiscal Year 2011 Related to the Disease

Diabetes drug	Beneficiaries with 1 to 11 claims		Beneficiaries with 12 or more claims	
	Number of beneficiaries	Medicaid paid amount (dollars in thousands)	Number of beneficiaries	Medicaid paid amount (dollars in thousands)
Actos	600	$191	100	$96
Humalog	520	149	20	32
Lantus	1,210	161	70	46
Novolog	410	13	10	0
Total	**2,160**	**$514**	**190**	**$174**

Source: GAO analysis of Arizona, Florida, Michigan, and New Jersey data. | GAO-15-390

Note: Totals do not add up because beneficiaries may receive multiple medications. The claims files we used were for a limited period and did not reflect the beneficiary's entire medical history. Therefore, we cannot determine from data analysis alone which cases represent inappropriate prescriptions and which are permissible prescribing patterns.

We cannot determine from data analysis alone which cases represent inappropriate prescriptions and which represent permissible prescribing patterns or anomalies within the data. Again, such determinations would require additional review of the facts and circumstances of each individual case by oversight officials.
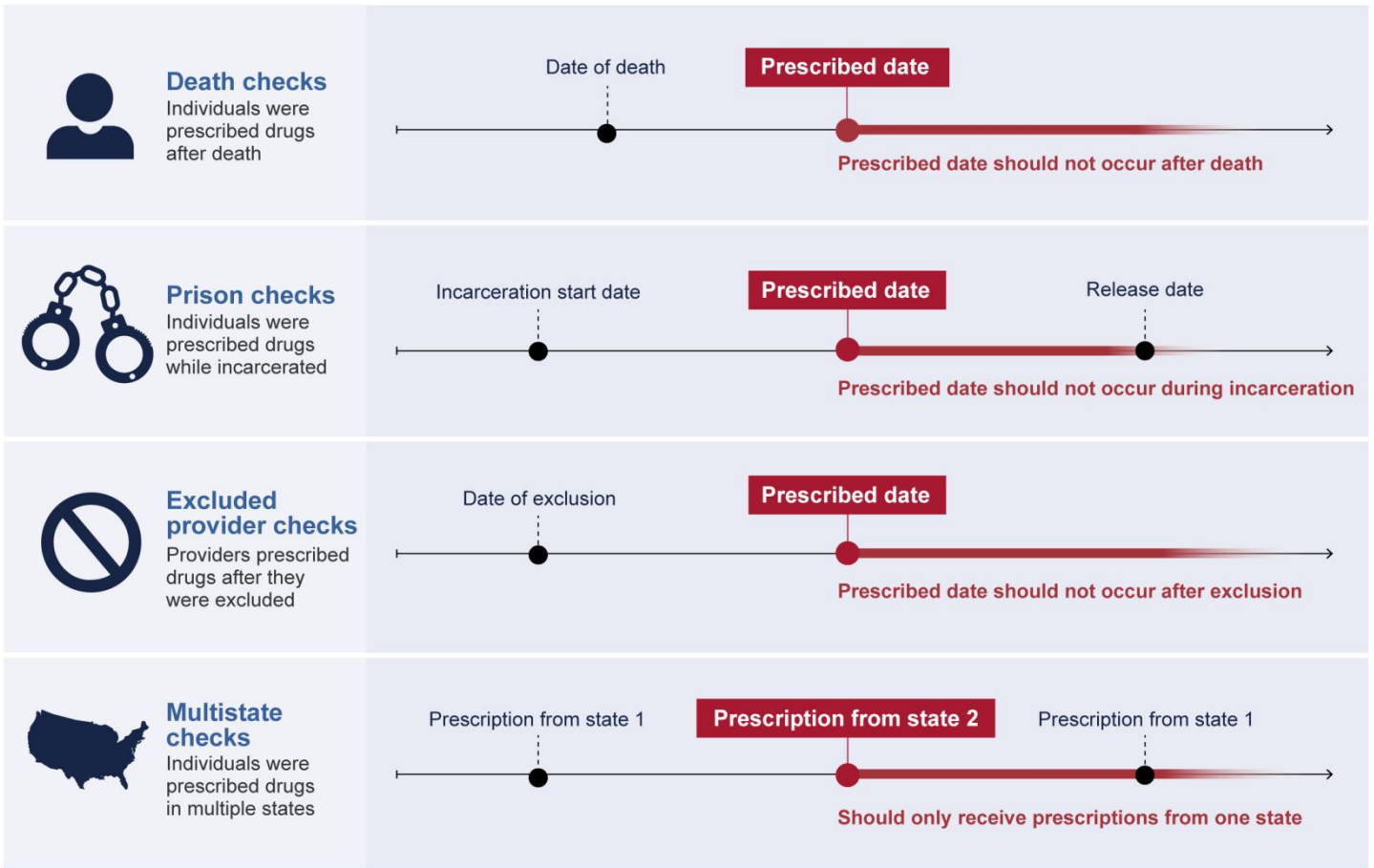
Indicators of Potential Improper Payments Identified Using Data Matching

Of the 5.4 million beneficiaries in the four states we examined, we found hundreds of cases from the fiscal year 2011 data that showed potential indicators of improper payments, which may include fraudulent activity (e.g., prescriptions written by apparently deceased prescribers), due to concerns about the beneficiary, prescriber, or pharmacy. Figure 1 summarizes the results of our matching data to external sources to identify indicators of potential improper payments or fraud. Additional investigation would be required to definitively determine whether improper payment or fraud occurred.

Figure 1: Potential Improper-Payment Indicators Related to Medicaid Claims for Prescription Medication for Four Selected States during Fiscal Year 2011

Indicators of potentially fraudulent or abusive activities relating to prescription drugs

GAO found indicators of potentially fraudulent or abusive activities related to prescription drugs, including prescriptions written by or for deceased, incarcerated, and excluded individuals, as well as patients receiving prescriptions from more than one state.

Death checks
Individuals were prescribed drugs after death

Date of death | Prescribed date
Prescribed date should not occur after death

Prison checks
Individuals were prescribed drugs while incarcerated

Incarceration start date | Prescribed date | Release date
Prescribed date should not occur during incarceration

Excluded provider checks
Providers prescribed drugs after they were excluded

Date of exclusion | Prescribed date
Prescribed date should not occur after exclusion

Multistate checks
Individuals were prescribed drugs in multiple states

Prescription from state 1 | Prescription from state 2 | Prescription from state 1
Should only receive prescriptions from one state

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS), General Services Administration (GSA), Department of Health and Human Services (HHS), Social Security Administration (SSA), and state data. | GAO-15-390

Note: Data are from the Medicaid Statistical Information System (MSIS), Excluded Parties List System, List of Excluded Individuals and Entities, Social Security Administration (SSA) death data, and state prison records.

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- **Deceased prescribers.** The identities of 290 deceased prescribers in the four states we examined were used to prescribe drugs to individuals who received Medicaid benefits. The cost of the drugs totaled at least $77,000 for fiscal year 2011.[43]

- **Deceased beneficiaries.** The identities of about 170 deceased beneficiaries in the four states we examined were used to obtain prescriptions that were subsequently filled and paid for by Medicaid. The cost of the drugs totaled at least $32,000 for fiscal year 2011.[44]

- **Incarcerated beneficiaries and prescribers.** Federal law prohibits states from obtaining federal Medicaid matching funds for health-care services provided to inmates, with the exception of inmates who are patients in medical institutions. The intent of the federal prohibition is to ensure that federal Medicaid funds are not used to finance care that is the responsibility of state and local authorities. For the four states that we examined, however, about 200 Medicaid beneficiaries received prescription-drug benefits while incarcerated in state prisons at some point in fiscal year 2011. According to the MSIS data, Medicaid approved at least $41,000 in benefits for these incarcerated individuals. This suggests possible identity theft or phantom billing since the beneficiary's incarceration would have physically prevented him or her from receiving prescriptions.[45] We also found one prescriber who appears to have written one prescription while incarcerated in a state prison.

- **Excluded prescribers.** The federal government can exclude health-care providers from participating in the Medicaid program for a variety of program-integrity reasons, such as criminal convictions or major problems related to health care (e.g., patient abuse or neglect). Excluded providers can be placed on one or both of the following lists,

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[43]Michigan Medicaid officials stated that there are instances in which a dead prescriber may appear to be billing after the day of death. In their program, they stated that this is usually because another member of the physician's practice writes the prescription and the pharmacy does not update the physician information. Michigan officials have identified this clerical data error in their own review of deceased prescribers.

[44]These results only include claims where the prescribed date occurred after death.

[45]Identity theft is stealing identifying information from providers and patients and using it for nefarious purposes. Phantom billing is billing for prescription drugs (or other services) that were not provided to the beneficiary.

which Medicaid officials must check before paying for a prescription claim: the List of Excluded Individuals and Entities, managed by HHS, and the System for Award Management, managed by GSA.[46] The primary effect of these exclusions is that no payment will be provided for any items or services furnished, ordered, or prescribed by an excluded individual or entity. This includes Medicare, Medicaid, and all other federal plans and programs that provide health benefits funded directly or indirectly by the United States. We found about 200 excluded prescribers who wrote prescriptions that were then used to obtain prescription drugs that were paid for by Medicaid. The selected states approved and paid the claims at a cost of over $1 million.[47]

- **Beneficiaries concurrently receiving benefits in two or more states.** Beneficiaries are entitled to Medicaid prescription-drug benefits in the states in which they currently reside but are not eligible to receive Medicaid benefits in more than one state concurrently.[48] We identified about 618 beneficiaries that received prescription drugs from Medicaid in two or more of our selected states concurrently. The costs associated with these drugs were at least $186,000.

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[46]42 C.F.R. § 455.436(c)(2) requires states to check the List of Excluded Individuals and Entities and the Excluded Parties List System. However, GSA discontinued the Excluded Parties List System in 2012 and moved its content to the System for Award Management. In August 2012, CMS officials instructed states to use the System for Award Management instead of the Excluded Parties List System to fulfill their regulatory responsibilities.

[47]We also looked for pharmacies in the four states that had been excluded from federal health-care programs including Medicaid, but did not find any that billed Medicaid for prescription drugs dispensed during fiscal year 2011.

[48]Our analysis may have included Medicaid beneficiaries who moved back and forth between two of the selected states who appropriately terminated their Medicaid benefits after each move. For example, officials in Florida suggested individuals who move in and out of the area may have accounted for a portion of this analysis.

Drug Utilization Reviews Help States Detect and Prevent Unnecessary Prescriptions, and Additional Reporting Would Help CMS Determine Whether More Guidance on Controls Is Needed

CMS monitors state Medicaid programs' efforts to prevent and detect instances of prescription-drug fraud in Medicaid, but we identified areas that may require additional guidance for oversight. Required by federal law, the Medicaid Drug Utilization Review (DUR) program is one process states use to promote patient safety and monitor prescription-drug activity for fraud, waste, and abuse.[49] In the first phase (prospective DUR) the states use tools such as point-of-sale edits, preferred-drug lists, and eligibility screening to promote patient safety and avoid abuse. The second phase (retrospective DUR) involves ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care and implements corrective action when needed. For example, these measures can include postpayment reviews, lock-in programs, and pharmacy automatic refill restrictions.[50] An effective DUR can reduce states' exposure to potential fraud schemes, such as those described earlier in this report.[51] Federal statute and regulation require that states report on their DUR activities as well as cost savings generated from their DUR programs.[52]

CMS also collects information from states about DUR program operations, cost savings from DUR programs, and innovative DUR practices by means of the Medicaid Drug Utilization Review Annual Report Survey. CMS compiles this information into an annual summary report that is publicly available, and may be used to highlight innovative practices that state Medicaid programs have implemented. According to the fiscal year 2013 Medicaid Drug Utilization Review State Comparison Annual Report (2013 CMS DUR Summary), DUR activities saved an average of about 18 percent on drug costs, adding up to about $3.9 billion in savings. CMS does not collect information about lock-in programs for

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[49]42 U.S.C. § 1396r-8(g).

[50]Lock-in programs are one DUR tool that can address doctor shopping by locking beneficiaries who have abused the Medicaid program in to one prescriber, one pharmacy, or both for receiving prescriptions.

[51]For the purposes of this section, we examined CMS's oversight role of the entire Medicaid program (as opposed to just in the selected states). Observations presented in this section are derived from a review of key documents such as the 2013 Medicaid Drug Utilization Review State Comparison Annual Report, state DUR plans, and interviews with Medicaid officials from Arizona, Florida, Michigan, and New Jersey. Due to the scope of our review, we focused on DUR measures related to the prevention and detection of fraud, waste, and abuse.

[52]42 U.S.C. § 1396r-8(g)(3)(D) and 42 C.F.R. § 456.712.

noncontrolled substances or automatic refill prohibitions, despite the concerns detailed below.

Prospective DUR

Prospective DUR screens prescription-drug claims to identify possible safety and overuse indicators before the drugs are dispensed. Key prospective DUR controls include the following:

- **Point-of-sale edits.** Point-of-sale edits are alerts that occur at the pharmacy point of sale and promote patient safety and program integrity by sending alerts to pharmacies during the process of filling the prescription to determine whether certain criteria are met. Effective point-of-sale edits can address issues such as the potentially excessive and unnecessary prescriptions described earlier in this report. Alerts, such as drug–drug interactions or therapeutic duplication, appear when there is a drug interaction risk or when a patient is to be dispensed a drug that is in the same therapeutic class as another recently dispensed drug, respectively.[53] These alerts also work to promote patient safety as well as program integrity. A DUR can also include alerts such as a gender-specific alert that occurs when a drug is dispensed that is not recommended for use by the gender indicated on the recipient's eligibility file. Other alerts such as early-refill warnings are routine edits that may signal that the patient is not taking the drug according to the directions or may be misusing the medication. Early-refill alerts also help to prevent Medicaid from paying for excessive amounts of medication above and beyond what is necessary. According to the 2013 CMS DUR Summary, all states set early-refill thresholds as a way of preventing prescriptions from being refilled too soon, which is categorized as a point-of-sale edit.

- **Preferred-drug list.** DUR often include a preferred-drug list, which is designed to help keep health-care costs down by encouraging use of preferred, generic and over-the-counter drugs. The preferred-drug list drives a market shift to generic drugs when the generic drug pricing is less than the brand-name drug pricing (net of CMS and supplemental rebates), although prescribers can override the preferred-drug list

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[53]A therapeutic duplication DUR alert identifies instances of prescribing multiple medications for the same medical symptom or indication without a clear distinction of when one agent should be administered over another. The drug-disease contraindication DUR alert is activated when a drug is prescribed for an individual who has a disease for which the drug may be harmful.

using a prior-authorization request. Use of the preferred-drug list may limit or prevent wasteful spending.

- **Eligibility screening.** As described earlier in this report, states are to screen for the eligibility of beneficiaries, prescribers, pharmacies, and other entities to ensure that they have coverage under or participate in a health-insurance program. States are to use federal death sources such as SSA's Death Master File as well as local sources such as the state's vital statistics office and prisoner files to check for the death and incarcerations of beneficiaries. Per CMS regulations, states are also required to use tools such as the List of Excluded Individuals and Entities, managed by HHS, and the System for Award Management, managed by GSA, to screen prescribing providers or pharmacies for federal exclusions and debarments.[54]

Retrospective DUR

Retrospective DUR involves ongoing and periodic examination of claims data to identify potentially problematic patterns. Key retrospective DUR fraud controls include postpayment reviews, lock-in programs, and automatic refill prohibitions.

- **Postpayment reviews.** Postpayment reviews involve reviewing claims and other documents after payment to ensure compliance with payment rules, and to determine whether the prescription was medically necessary. These reviews permit states to suspend payments and obtain and review medical records. Specific tactics states may choose to employ to find fraud in these payments include examining claims by amount paid, average costs, number of claims, adjustment rates, or percentage of claims for brand-name or Drug Enforcement Administration Schedule II drugs.[55] States can vary the

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[54]42 C.F.R. § 455.436(c)(2).

[55]States have other requirements they must meet, such as timely payment that would be examined in a postpayment review. Drugs, substances, and certain chemicals used to make drugs are classified into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. The abuse rate is a determinate factor in the scheduling of the drug. Schedule II drugs, substances, or chemicals are defined as drugs that have a high potential for abuse, a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and abuse may lead to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are: combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.

period of review depending on available data and may monitor overall activity as well as activity within subsections of the population. For example, states can look for top beneficiary recipients of a certain drug or therapeutic class, prescribers who most frequently prescribe controlled substances, or pharmacies that dispense certain drugs at an average cost that is significantly higher than that of their peers. There are numerous ways the data can be analyzed and checks can be combined to strengthen detection of indicators of potential fraud. Effective strategies can then be repeated. While it is likely not possible to determine from data analysis alone whether any given prescription was appropriate, such analysis can detect anomalies that might warrant additional audit and investigation outside the DUR process. For example, as we discussed previously in this report, a pharmacy may dispense an unusually high proportion of brand-name medications. States can use pharmacy audits to ensure dispensary compliance with program rules and regulations while looking for fraud and abuse.

- **Lock-In Programs (also known as Restricted Recipient Programs).** As noted earlier in this report, we identified about 16,000 individuals whose visits to multiple prescribers for antipsychotics and respiratory medications raise questions.[56] Lock-in programs are one DUR tool that can address doctor shopping by locking beneficiaries who have abused the Medicaid program in to one prescriber, one pharmacy, or both for receiving prescriptions. Lock-in allows both prescribers and pharmacies to develop a more-complete picture of the beneficiary's drug-utilization history. Lock-in programs historically have applied to those beneficiaries in an FFS arrangement, although MCOs may employ similar measures to "lock-in" enrollees when such actions are warranted.

  Lock-ins are typically triggered by abuse of controlled substances. Officials in Arizona and New Jersey stated that their lock-in program has historically focused on lock-in for controlled substances, although lock-ins for other drugs were permitted. Officials in Florida stated that their program does not use lock-in for noncontrolled substances and has trended towards using point-of-sale edits to restrict doctor-shopping activities related to controlled substances. Michigan officials stated that the state Medicaid program has two categories of lock-ins:

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[56]As noted earlier, we recognize that in some cases legitimate reasons exist to visit multiple prescribers.

beneficiaries may be locked in to a specific prescriber for controlled substances, or beneficiaries may be locked in to specific prescribers and pharmacies for all medications. Michigan officials indicated that they apply specific criteria to determine the lock-in category a beneficiary is assigned.

According to CMS officials, CMS does not have specific guidance for the state Medicaid programs on lock-ins. They said that states decide the requirement for placing a beneficiary in a lock-in program. Given that we found more than 16,000 beneficiaries who received prescriptions for relatively high-value medications from at least five prescribers in 1 fiscal year, there is a risk that Medicaid is wasting funds on prescriptions that are medically not necessary, and potentially fraudulently diverted. Although there is no federal requirement for states to implement a lock-in program, according to the 2013 CMS DUR Summary all but one of the states has a lock-in program for controlled substances. However, the report does not contain information on lock-in programs for noncontrolled substances.

- **Pharmacy Automatic Refill.** Pharmacies may automatically refill prescriptions for certain medications without any customer action. Automatic refill services can be employed at both retail and mail-service pharmacies. In retail settings, medications that are not picked up by the patient within a finite period must be returned to stock. However, mail-service pharmacies are unable to return the medication to stock once the prescription is delivered. Concerns with pharmacy automatic refill include the potential for stockpiling, continued fill of discontinued medications, and an increase in the cost and waste of prescription medications. In 2013, CMS banned pharmacy automatic refills in the Medicare Part D program because these practices were potentially generating significant waste and unnecessary additional costs for the Medicare Part D program overall.

Unlike Medicare Part D, CMS currently does not have specific guidance on pharmacy automatic refills for the Medicaid program.[57]

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[57]CMS administers the Medicare program as well as oversees the design and operation of state Medicaid programs. To receive federal matching funds for services provided to Medicaid beneficiaries, each state must submit a state Medicaid plan for approval by CMS. The state Medicaid plan defines how the state will operate its Medicaid program, including which populations and services are covered. States must operate their Medicaid programs within broad federal parameters. While complying with these federal requirements, however, states have the flexibility to tailor their Medicaid programs.

CMS officials stated that policy on pharmacy automatic refills is a state-specific decision and states may have information in their billing instructions to pharmacies on their policy regarding automatic refills. In addition, CMS officials said that each state's Board of Pharmacy may have a policy on this subject and that these boards may audit pharmacies regarding their compliance with state regulations. Currently, Florida and Arizona are the states in our review that do not allow automatic refills. When asked why such prohibitions were in place, officials in Arizona noted that its Medicaid population was transient, and automatic refills could lead to prescriptions mailed to old addresses where the beneficiary no longer lived, at the state's expense. Officials in Florida cited concerns about beneficiaries stockpiling medications and not wanting to pay for prescriptions that were no longer needed.

Federal regulations define abuse as provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary. Automatic refill programs may result in Medicaid beneficiaries obtaining medications far in excess of what was utilized or needed, resulting in wasted Medicaid resources. In fact, officials in New Jersey stated that automatic refills pose a problem for both fraud and waste of government funds, but at the time of our review did not have a policy preventing this practice.

According to the Standards for Internal Control in the Federal Government, internal controls should generally be designed to ensure that ongoing monitoring occurs in the course of normal operations, and that it is performed continually and ingrained in the agency's operations.[58] Our review of CMS monitoring activities found that CMS surveys states on a variety of different measures for fraud and waste prevention as well as cost-savings measures. Our discussions with officials in the selected states and CMS indicated that lock-in programs for noncontrolled substances and automatic refill prohibitions may warrant additional review. As discussed previously, state Medicaid programs varied in the type of medications that are included in lock-in programs. Additionally, we found more than 16,000 beneficiaries who received prescriptions for

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[58]GAO/AIMD-00-21.3.1.

relatively high-value medications from at least five prescribers in 1 fiscal year, indicating that there is a risk that Medicaid is wasting funds on prescriptions that are medically not necessary, and potentially fraudulently diverted. The Medicare Part D program, as well as Florida and Arizona Medicaid programs, prohibit automatic refills, citing both patient safety and unnecessary costs as concerns for implementing these practices. However, CMS does not collect this information in the DUR survey or other collection methods. As a result, CMS does not know the number of state Medicaid programs that prohibit automatic refills or have lock-in programs for noncontrolled substances. Additional information would allow CMS to determine whether additional guidance for locking in recipients of noncontrolled substances and prohibiting automatic refills in Medicaid could prevent some of the problems we identified in our analysis and lead to cost savings.

Conclusions

Our review of fiscal year 2011 prescription-drug claims data from four states uncovered indicators of potential fraud, waste, and abuse throughout the Medicaid prescription-drug program in those states, including potential doctor shopping of noncontrolled substances. In addition, interviews with officials from these four states highlighted Medicaid practices that were prone to waste and abuse, such as pharmacy automatic refills. Ensuring that cost-effective controls are in place and working properly requires additional improvements from the MCOs, states, and CMS responsible for administering Medicaid. While CMS oversees the administration of state Medicaid programs, CMS does not currently identify whether states have implemented lock-in programs for noncontrolled substances or automatic refill prohibitions. Lock-in programs are an important tool that can be used to address doctor shopping by locking beneficiaries who have abused the Medicaid program in to one prescriber, one pharmacy, or both for receiving prescriptions. Automatic refill prohibitions may help limit waste and unnecessary program expenditures. Expanding monitoring efforts to examine these matters in greater depth would provide CMS with more-complete information to help determine whether there is a need to issue guidance to address these potential problems more consistently to help ensure greater program integrity and additional cost savings.

Recommendation for Executive Action

To enhance monitoring of potentially wasteful or abusive practices in the Medicaid program, we recommend that the Acting Administrator of CMS require states to report to CMS whether their state has lock-in programs for abusers of noncontrolled substances and prohibitions on pharmacy

automatic refills, and examine the results to determine whether additional guidance is appropriate.

Agency Comments and Our Evaluation

We provided a draft copy of this report to HHS, SSA, and state Medicaid program offices for Arizona, Florida, Michigan, and New Jersey. Written comments from HHS; SSA; the Arizona Health Care Cost Containment System (AHCCCS); the Florida Agency for Health Care Administration (AHCA); and the State of New Jersey, Department of Human Services, Division of Medical Assistance and Health Services (DMAHS) are summarized below and reprinted in appendixes II–VI. HHS concurred with our recommendation. The letter from SSA stated the agency had no comments on our report. AHCCCS disagreed with our methodology and provided detailed comments on our findings, as described below. AHCA did not comment on the report's findings but stated that the state Medicaid program already prohibits pharmacy automatic refills and will work with CMS to implement a lock-in program for noncontrolled substance abusers. DMAHS did not comment on the report's findings but outlined several steps the state has taken that could address the types of issues raised in our report, which are summarized below. In an e-mail received on May 28, 2015, officials from the Michigan Department of Community Health did not comment on the report's findings but provided technical comments, which we incorporated as appropriate. In addition, we provided excerpts of this draft report related to the reliability issues of Medicaid data to state Medicaid program offices for California, Illinois, Maryland, New York, Ohio, Pennsylvania, and Texas for technical comment. In an e-mail received on May 19, 2015, the Deputy Director, Division of Program Development and Management of the New York Department of Health, provided suggestions regarding CMS's implementation of T-MSIS, which was outside the scope of our review, so we did not incorporate these comments in our draft report. Officials from California, Illinois, Maryland, New York, Ohio, Pennsylvania, and Texas did not provide technical comments.

In its written comments, HHS concurred with our recommendation and stated that it will consider requiring states to report on lock-in programs for abusers of noncontrolled substances and pharmacy automatic refill policies. HHS also outlined the steps the agency has taken to improve data collection in Medicaid and address prescription-medication fraud since the fiscal year 2011 data used in our study. We incorporated these comments in our report as appropriate.

In its written comments, AHCCCS said that it takes exception to being included in a series of findings that offer no state-specific detail. As we noted in our meetings with all state agencies included in our study, we did not provide state-level detail for two primary reasons. First, because CMS was the audited agency for our work, conducting analysis at the state-level would be outside the scope of our work and would put the focus on a comparison between the states, rather than on CMS oversight. In addition, due to the age and limitations of the data, as noted in the report, we would not be referring specific cases for follow-up. Moreover, AHCCCS noted that the findings of our study represent less than one-tenth of Medicaid spending for the four states used in our study. As we stated previously in this report, all of the states in our study had MCO arrangements in place during our study period. As a result, the Medicaid paid amounts associated with managed care may not be reflected in the state claims that were submitted to CMS for medical services, and hence our estimate is likely understated.

AHCCCS also commented on specific sections of our analysis. First, AHCCCS stated that our report did not identify state practices that are able to leverage more-accurate data sources on a real-time basis. As mentioned above, the focus of our work was CMS oversight of the Medicaid program rather than an in-depth discussion of current, specific practices employed by the states. Second, AHCCCS incorrectly stated that we used the federal incarceration file in our analysis. As we note in appendix I, we used each state's department of corrections prisoner databases for individuals incarcerated for any period during fiscal year 2011. Specifically, for our work, we used the same Arizona Department of Corrections file to perform matches that AHCCCS outlined in its response letter. Third, AHCCCS provided an overview of the additional checks the state performs to identify incarcerated beneficiaries, as well as deceased providers and beneficiaries. This overview does not refute the findings in our report, and we did not incorporate these details in the report.

Regarding our analysis of prescription-drug medication claims data, AHCCCS stated that our report should have used more than a single year of claims data to identify diagnosis information. We acknowledge this limitation, and updated our report with the appropriate caveats. Specifically, we state that we identified beneficiaries who did not have indicators of HIV or diabetes in their outpatient Medicaid activity from fiscal 2011, and that the absence of such evidence does not prove that the beneficiary does not have HIV or diabetes or that there was inappropriate off-label use. Further we stated that the results of this analysis may also be caused by off-label use, record-keeping, or data-

coding issues. In addition, we noted that timing differences in the prior-authorization process could explain some of these observations. We also note that we cannot determine from data analysis alone which cases represent inappropriate prescriptions and which are permissible prescribing patterns.

Regarding our analysis of brand-name medications, AHCCCS stated that our findings represent 0.425 percent of prescribing clinicians. In the draft report provided to AHCCCS, we provided the number of individuals we found and the total study population to provide the appropriate context. AHCCCS also noted that our report did not take into consideration that states may continue to require brand-name coverage because it may be more costly to the state to purchase the generic product. As a result, we incorporated discussion of this limitation in our report. Similarly, AHCCCS stated that our report does not differentiate between retail pharmacies and specialty pharmacies, and that some specific specialty pharmacies are expected to have a high percentage of branded medications. We noted that we did not control for medications where there was not a generic version available. However, to address the specific concern of AHCCCS, we incorporated this caveat into our report. Again, as noted several times in our report, the results of our analysis are indicators of potential fraudulent or improper payments.

AHCCCS further stated that Arizona protocols already apply the recommendations in our report. In our report, we note that Arizona has a lock-in program that can incorporate noncontrolled medications and prohibits automatic refills in the Medicaid program. As noted in our report, the recommendation is addressed to CMS, and not the states used in our study. Specifically, we recommended that CMS collect information on what other states' practices are related to lock-ins of noncontrolled medications and prohibitions of automatic refills, and examine the results to determine whether additional guidance is appropriate.

Finally, AHCCCS stated that our report reaches sweeping conclusions without validating findings based on state-specific data. Again, as mentioned earlier, the focus of our report is CMS oversight of the Medicaid program. Our report provides the appropriate context for our findings, including limitations of our analysis to ensure that the results of our analysis were not taken in an inappropriate context.

In response to our draft report, the Florida Agency for Health Care Administration (AHCA) stated that the Florida Medicaid program currently does not allow pharmacy automatic refills. Further AHCA stated that it will

work with CMS's guidance and recommendations for the implementation of a lock-in program for abusers of noncontrolled substances
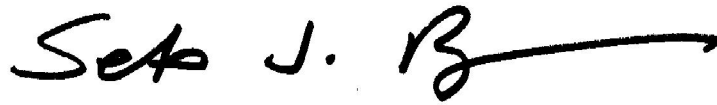
In its response to our draft report, the New Jersey Department of Human Services, Division of Medical Assistance and Health Services (DMAHS), stated that automatic prescription refills are a major concern for the State of New Jersey. According to DMAHS, although characterized by retail pharmacies as a "patient-friendly" service designed to improve the quality of prescription services, automatic prescription refills pose several concerns, such as the potential for stockpiling medications; continued filling of discontinued medications; unrecognized changes in drug therapies; and increases in fraud, waste, and abuse of prescription drugs. DMAHS stated that it looked forward to better understanding the audit practices used by CMS and certain states to audit this practice.

In addition, DMAHS outlined steps the New Jersey Medicaid program has taken to strengthen prescription-drug internal controls, including requiring MCO programs to implement a pharmacy lock-in program. DMAHS also provided comments to address additional actions the state has taken that would address the findings we outlined in our report, including a quality-management and utilization-review program that focuses on medical encounters and a quarterly doctor-shopper report that identifies recipients who may be engaged in fraudulent activities. While we did not make any specific recommendations to the states, we believe that such actions should enhance their oversight of prescription-drug controls.

Additionally, DMAHS provided comments on timely submission of MSIS data and stated that timely submission of MSIS data is related to the time required for CMS to validate New Jersey claims file submissions. We incorporated its comments in our report, as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Commissioner of Social Security, relevant state agencies, and interested congressional committees. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-6722 or bagdoyans@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff that made key contributions to this report are listed in appendix VII.

Seto J. Bagdoyan
Director, Audit Services
Forensic Audits and Investigative Service

List of Requesters

The Honorable Ron Johnson
Chairman
The Honorable Thomas R. Carper
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Claire McCaskill
Ranking Member
Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Sheldon Whitehouse
Ranking Member
Subcommittee on Crime and Terrorism
Committee on the Judiciary
United States Senate

Appendix I: Objectives, Scope, and Methodology

In this report, we (1) evaluated the reliability of Medicaid data from the Centers for Medicare & Medicaid (CMS) and selected states for the purpose of identifying indicators of potential fraud or abuse; (2) identified and analyzed indicators, if any, of potentially fraudulent or abusive activities related to prescription drugs in Medicaid; and (3) examined the extent to which federal and selected state oversight policies, controls, and processes are designed to prevent and detect indicators of prescription-drug fraud in Medicaid.

To evaluate the reliability of Medicaid data from CMS for our selected states that could be used to identify indicators of potential fraud or abuse, we took several steps. We vetted 11 states for possible inclusion in our study.[1] We selected states based on high Medicaid beneficiary enrollment, geographic diversity, and availability of data. In the selection process, we also considered whether drugs were paid under fee-for-service (FFS) or managed care, by including states that included these program types in our review. We performed electronic testing to determine the validity of specific data elements in the federal and selected state databases that we used to perform our work. We also reviewed related documentation, including data layouts and agency reports. Specifically, we used a January 2013 Mathematica Policy Research report that details Medicaid Statistical Information System (MSIS) state data characteristics and anomalies to further vet states selected for our audit work.[2] We also used published GAO and Department of Health and Human Services (HHS) Office of the Inspector General (OIG) reports that detailed the limitations of the MSIS data we used for our study.[3] Additionally, we interviewed officials responsible for their respective databases to discuss data-reliability considerations, and reviewed prior work related to the quality of the MSIS data used for our

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[1]The states vetted were: Arizona, California, Florida, Illinois, Maryland, Michigan, New Jersey, New York, Ohio, Pennsylvania, and Texas.

[2]Mathematica Policy Research, Inc., *MSIS State Data Characteristics/Anomalies Report* (Jan. 7, 2013).

[3]Department of Health and Human Services, Office of Inspector General, *Early Assessment of Review of Medicaid Integrity Contractors*, OEI-05-10-00200 (Washington, D.C.: February 2012); GAO, *National Medicaid Audit Program: CMS Should Improve Reporting and Focus on Audit Collaboration with States*, GAO-12-627 (Washington, D.C.: June 14, 2012); and *Medicaid: Data Sets Provide Inconsistent Picture of Expenditures*, GAO-13-47 (Washington, D.C.: Nov. 29, 2012).

study.[4] On the basis of our discussions with agency officials and our own
testing, we concluded that the data elements from the four states—
Arizona, Florida, Michigan and New Jersey—used for this report were
sufficiently reliable for the purpose of identifying indicators of potential
fraud or abuse. However, in assessing the reliability of the data, we
observed reportable shortcomings such as issues with timeliness,
completeness, and accuracy in the data that may affect Medicaid
administrators' ability to effectively oversee their program. We discuss
these shortcomings in greater detail earlier in this report.

To identify indicators of potentially fraudulent or abusive activities related
to prescription drugs in Medicaid, we obtained and analyzed Medicaid
claims paid in fiscal year 2011, the most-recent period from which we
could draw reliable data, for four states: Arizona, Florida, Michigan and
New Jersey. These states accounted for about 13 percent of the federal
share of fiscal year 2011 Medicaid expenditures. These states were
selected primarily because they had consistently comparable and reliable
data and were among the states with the highest Medicaid expenditures.
The results of our analysis of these states are not generalizable to other
states.

We obtained CMS MSIS beneficiary, provider, prescription-drug, and
other services claims data, as well as state Medicaid Management
Information Systems (MMIS) crosswalk data (with personal identifiers) to
perform our work. The crosswalk data we used contained specific
identifying information on prescribers, pharmacies, and beneficiaries that
were not collected in the MSIS data, such as name and address.
Additionally, managed-care organizations (MCO) receive a monthly
capitated payment.[5] As a result, the Medicaid paid amounts associated
with managed care may not be reflected in the state claims that were
submitted to CMS for medical services, and hence our estimate is likely
understated. All of the states included in our review—Arizona, Florida,
Michigan, and New Jersey—had MCO arrangements in place.

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[4]Mathematica Policy Research serves as CMS's contractor and performs reviews to
ensure and report on the quality of MSIS data. The organization publishes information on
unreconciled data in its anomalies report.

[5]Under managed-care arrangements, states contract with MCOs to deliver care through
networks. States typically pay the MCOs a fixed amount each month, called a capitation
payment. Approximately 70 percent of Medicaid enrollees are served through managed-
care delivery systems, where providers are paid at a monthly capitation payment rate.

We reviewed literature related to health-care fraud, including reports
discussing fraud, waste, and abuse related to prescription drugs. We
interviewed federal, state, and private-sector auditors, program
administrators, and other relevant officials who had published work that
investigated or researched prescription-drug fraud. On the basis of this
research, we identified areas at greater risk of fraud and abuse such as
drugs at high risk for diversion and types of prescribing patterns that
warranted additional review. We used this information to develop our
analytic approach to identify indicators of potential fraud and abuse
related to prescription drugs in Medicaid. To identify potential overuse, we
reviewed beneficiaries who received more than a 480-day supply of the
same medication in a single year based on the national drug code. To
identify potential doctor-shopping activities, we examined beneficiaries
who received prescriptions for drugs within one of two therapeutic classes
of drugs from five or more prescribers. We focused on beneficiaries who
received prescriptions for antipsychotics or respiratory medications from
five or more different prescribers over the course of 1 year. We selected
medications in these therapeutic classes because they had a large
number of individuals who received drugs from five or more prescribers
relative to other classes of noncontrolled substances we considered, have
a known diversion risk, and are relatively expensive.[6] We selected the
five-or-more prescribers threshold based on our review of drug-diversion
literature and prior GAO work. Since we did not focus on all noncontrolled
substances, our analysis understates the number of instances and dollar
amounts related to potential doctor-shopping activities. We also looked
for prescribers and pharmacies with a high proportion of prescribing or
dispensing activities for brand-name drugs (versus generics) compared to

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[6]Drugs and other substances that are considered controlled substances under the
Controlled Substances Act are divided into five schedules. An updated and complete list
of the schedules is published annually in 21 C.F.R. §§ 1308.11 – 1308.15. Substances
are placed in their respective schedules based on whether they have a currently accepted
medical use in treatment in the United States, their relative abuse potential, and likelihood
of causing dependence when abused. Drugs that are not considered controlled
substances are known as noncontrolled substances.

the average activity of other prescribers and pharmacies[7] and pharmacies
without any adjusted or voided claims.[8]

To identify potentially unnecessary prescription-drug activities, we
reviewed claims paid on behalf of beneficiaries who received human
immunodeficiency virus (HIV) and diabetes medications despite having
no HIV or diabetes-related indicators related to such ailments in their
fiscal year 2011 Medicaid outpatient claims listed in the MSIS "other
services" file. The absence of such evidence does not prove that the
beneficiary did not have HIV or diabetes or that there was inappropriate
off-label use: the claims files we used were for a limited period and did
not reflect the beneficiary's entire history, and our search may not have
included every possible diagnosis or service code related to HIV and
diabetes. We selected the HIV medications Atripla, Combivir, Norvir,
Reyataz, and Truvada based on their specific use as a treatment for HIV
as well as a preliminary examination of the MSIS data. We selected the
diabetes medications Actos, Humalog, Lantus, and Novolog based on
their primary use as a treatment for diabetes as well as a similar review of
the MSIS data. We selected these drugs and drug classes because they
were received by a relatively large number of beneficiaries and had a high
expense to Medicaid. In addition, when we examined the Food and Drug
Administration indications and usage labeling for each drug, we found
that each drug was only approved for treatment of HIV or diabetes.[9] For
each beneficiary who received one of these drugs, we reviewed the MSIS
"other services" file to determine whether the beneficiary (1) had an
International Classification of Diseases diagnosis code related to HIV or
diabetes, (2) had a Healthcare Common Procedure Coding System
service code related to HIV or diabetes, or (3) had claims associated with
the prescribing physician.[10] We removed beneficiaries from our analysis if
they exhibited one of these characteristics and reported on the remaining

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[7]Our analysis did not control for medications where there was not a generic version
available.

[8]When a change to a prescription is made or when a beneficiary fails to pick up the
prescribed drugs, the pharmacy must adjust the claim transaction. According to officials in
New Jersey, instances of pharmacies with too many or too few adjustments may be red
flags for concern.

[9]Our review did not include all drugs that may be used to treat HIV or diabetes.

[10]This analysis was based on diagnosis codes for HIV or diabetes. We did not account for
prescribing of these medications for other ailments.

population. We restricted our review to only include beneficiaries who
received at least one prescription written during fiscal year 2011.

We also matched the Medicaid data to other external sources to identify
potential fraud and improper payments. We compared the beneficiary and
prescriber identity information shown in the Medicaid claims data to the
Social Security Administration's (SSA) complete file of death information
from October 2012 to determine whether any individuals were reportedly
deceased before or when they purportedly prescribed, dispensed, or
received prescription drugs covered by Medicaid. To identify prescription-
drug claims that might have been improperly processed and paid by the
Medicaid program because either the prescribers or beneficiaries were
incarcerated, we matched our selected states' MMIS data to the states'
departments of corrections prisoner databases. Prisoner data included
individuals incarcerated for any period during fiscal year 2011. For
Arizona, Florida, and New Jersey, we identified provider and beneficiary
records for which the Medicaid Social Security number (SSN) and names
matched that of a person who was incarcerated in fiscal year 2011 in any
of the four states. Michigan did not provide SSNs in its incarceration data.
For Michigan, we identified provider and beneficiary records for which the
Medicaid name and birth day exactly matched that of a person who was
incarcerated in fiscal year 2011 in any of the four states. We then
identified Medicaid claims associated with the identified individuals by
matching to the MSIS data. We compared the beginning service date of
the claims to the individual's admittance and release date to identify all
claims that occurred while the associated beneficiary or provider identity
was incarcerated. Additionally, we reviewed these claims' type of service
to determine that none qualified for federal matching funds.

It is not possible to determine from data matching alone whether these
matches definitively identify recipients who were deceased or
incarcerated without reviewing the facts and circumstances of each case.
For example, it is possible that individuals can be erroneously listed in the
full Death Master File. Similarly, a provider or beneficiary may have an
SSN, name, and date of birth similar to an individual in state prison
records. Alternatively, our matches may also understate the number of
deceased or incarcerated individuals receiving assistance because
matching would not detect applicants whose identifying information in the
Medicaid data differed slightly from their identifying information in other
databases.

To identify Medicaid beneficiaries who received benefits in two or more
states concurrently, we identified all beneficiary SSNs that appeared in

two or more states' MMIS data in fiscal year 2011. We then found all
claims associated with the beneficiary identities. We conducted further
analysis to determine the states in which each beneficiary identity
appeared and the service ranges—first and last prescribed date—for
those states. We defined a concurrent claim as a claim that occurred
within the service range of a second state for the same beneficiary
identity. For each claim, we compared its prescription date to the service
ranges for the beneficiary identity to determine whether it was a
concurrent claim. It is not possible to definitely say through data matching
alone that a beneficiary was improperly receiving Medicaid benefits in two
or more states concurrently without looking into further information for
each claim and beneficiary. For example, a beneficiary could have been a
resident in one state and received services, then changed residency to a
second state and received benefits for a brief period, before finally
relocating again back to the original state and receiving additional
services. In this case, the claims could have been identified as a
concurrent claim even if the beneficiary did not receive any services from
the original state during his or her relocation period in the second state.

To identify claims that might have been improperly processed and paid by
the Medicaid program because the federal government had excluded
these providers from providing services to Medicaid beneficiaries, we
compared the Medicaid claims to the exclusion and debarment files from
the Department of Health and Human Services' (HHS) Office of Inspector
General (OIG) and the General Services Administration (GSA).
Specifically, we used the HHS List of Excluded Individuals and Entities
file from September 2012 and the GSA Excluded Parties List System
database extract from October 2011 to perform our match. We matched
MMIS and MSIS Medicaid data using SSN and individual name with both
the List of Excluded Individuals and Entities and the Excluded Parties List
System data extracts. We then identified unique individuals who had
Medicaid claims processed where the date of exclusion occurred before
the prescribed date in the Medicaid claims file.

To determine the extent to which federal and state oversight policies,
controls, and processes are designed to prevent and detect instances of
prescription-drug fraud in Medicaid, we reviewed CMS and state Medicaid
policies pertinent to program integrity over pharmaceuticals, met with
CMS officials, and visited state Medicaid offices that perform oversight
functions for the four states we selected. We used federal standards for

internal control,[11] GAO's Fraud Prevention Framework,[12] and Medicaid statutes and regulations addressing the administration of pharmacy benefits to evaluate these functions.

To determine the reliability of the data used in our analysis, we performed electronic testing to determine the validity of specific data elements in the federal and selected state databases that we used to perform our work. We also interviewed officials responsible for their respective databases, and reviewed documentation related to the databases and literature related to the quality of the data. On the basis of our discussions with agency officials and our own testing, we concluded that the data elements used for this report were sufficiently reliable for our purposes.

We identified criteria for Medicaid fraud controls by examining federal and state policies, laws, and guidance, including policy memos and manuals. We interviewed officials from CMS and the state governments of Arizona, Florida, Michigan, and New Jersey involved in Medicaid program administration, auditing, and Medicaid fraud response.

We conducted this performance audit from March 2014 to July 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our audit findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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[11]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

[12]GAO, *Individual Disaster Assistance Programs: Framework for Fraud Prevention, Detection, and Prosecution*, GAO-06-954T (Washington, D.C.: July 12, 2006).

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 0 9 2015

Seto Bagdoyan
Director, Forensic Audits
  and Investigative Service
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Bagdoyan:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Additional Reporting May Help CMS Oversee Prescription Drug Fraud Controls*" *(GAO-15-390)*.

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO)
DRAFT REPORT ENTITLED: MEDICAID: ADDITIONAL REPORTING MAY HELP
CMS OVERSEE PRESCRIPTION DRUG FRAUD CONTROLS (GAO-15-390)**

The Department of Health and Human Services (HHS) appreciates the opportunity to review and
comment on the Government Accountability Office's (GAO) draft report. HHS is strongly
committed to program integrity and data collection efforts in Medicaid.

In February 2011, HHS finalized regulations under which states must implement categorical
risk-based screening of newly enrolling Medicaid providers and revalidate all current Medicaid
providers under new requirements established by the Affordable Care Act. Providers are
assigned to categorical screening levels based on factors such as the type of service provided and
history of previous adverse actions. Providers in the limited risk category are subject to
verification of licensure, verification of compliance with federal regulations and state
requirements, and various database checks. Providers in the moderate and high risk categories
undergo additional screening, including unannounced site visits. Additionally, as a condition of
enrollment, providers in the high risk category and persons with five percent or greater
ownership interest in such providers must consent to criminal background checks including
fingerprinting.

HHS has been proactive about assisting states with provider enrollment and revalidation
screening. In April 2012, we provided states with direct access to Medicare's enrollment
database—the Provider Enrollment, Chain, and Ownership System (PECOS). In October 2013,
in response to input from states, HHS began providing access to monthly PECOS data extracts
that states could use to systematically compare state enrollment records against available PECOS
information. We have also provided states with training and technical assistance on using
PECOS.

In 2012, HHS issued regulations to require states to use the Data Services Hub (Hub) to verify
applicant eligibility upon enrollment and at least annually thereafter. States are able to use this to
identify applicants and beneficiaries who may be incarcerated, deceased, or do not meet
Medicaid eligibility requirements. States can also validate applicants' Social Security Numbers
(SSNs) using the Hub. In 2012, HHS required every state to submit a verification plan describing
their verification policies and procedures for certain Medicaid populations including the fact that
the state verifies SSNs.

As part of our ongoing program integrity efforts, HHS has put programs in place to prevent
"doctor shopping," and other methods of obtaining drugs in order to divert them for financial
gain or abuse. HHS has provided education and training to state Medicaid agencies on strategies
for reducing prescription drug diversion and improving prescription drug program integrity
oversight in Medicaid. Prospective Drug Utilization Review (DUR) works to identify
inappropriate prescribing before the prescription is dispensed by giving the pharmacist
information about the patient's complete medication profile to identify any potential drug related
issues. Through Retrospective DUR screening and educational interventions, state Medicaid
agencies identify aberrant prescribing patterns, including patterns that could be indicative of
doctor shopping, and perform outreach to prescribers to encourage appropriate prescribing. In
February 2011, HHS finalized regulations to require all providers prescribing medication under
the state plan or under a waiver of the plan to be enrolled as participating Medicaid providers.
This enrollment requirement is expected to have mitigating effects on doctor shopping.

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<u>**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO)
DRAFT REPORT ENTITLED: MEDICAID: ADDITIONAL REPORTING MAY HELP
CMS OVERSEE PRESCRIPTION DRUG FRAUD CONTROLS (GAO-15-390)**</u>

HHS is also taking steps to improve data collection in Medicaid. We are currently implementing
the Transformed Medicaid and Statistical Information System (T-MSIS), which will allow HHS
to collect and analyze Medicaid claims and encounter data. T-MSIS will provide HHS with more
robust, accurate, and timely data than our current data collection system. HHS will have
enhanced ability to examine claims and encounter data that may be anomalous and to follow-up
with states for further investigation. HHS went live with its federal T-MSIS platform in May
2015. We expect that state T-MSIS data will be submitted for more than half the Medicaid
population by the end of 2015.

Lock-in programs can be a key control feature within the Drug Utilization Review program and
allow states to maintain program integrity while ensuring access to controlled substances for
beneficiaries. If a state Medicaid agency finds that a beneficiary has utilized Medicaid services at
a frequency or amount that is not medically necessary, as determined in accordance with
utilization guidelines established by the state, it may require that beneficiary to obtain some
services only from designated providers. Some states require high users of certain drugs to use
only one pharmacy and get prescriptions for controlled substances from only one medical office.
Although there is no federal requirement for states to implement a lock-in program, forty-nine
states currently operate lock-in programs.

Some pharmacies choose to automatically refill prescriptions for patients and hold them for pick-
up or, in the case of mail-service pharmacies, mail them directly to patients. If prescriptions are
automatically refilled and not picked up by the beneficiary, the pharmacy is required to reverse
the claim and does not receive reimbursement from Medicaid. Pharmacy automatic refill
programs can help ensure beneficiary access to medications and help improve adherence to
treatment regimens. State Medicaid agencies may set policies on automatic refill programs or
prohibit the practice.

<u>**GAO Recommendation**</u>
To enhance monitoring of potentially wasteful or abusive practices in the Medicaid program,
GAO recommends that the Administrator of CMS require states to report to CMS whether their
state has lock-in programs for abusers of non-controlled substances and prohibitions on
pharmacy auto refills and examine the results to determine if additional guidance is appropriate.

<u>**HHS Response**</u>
HHS concurs with this recommendation. HHS currently requires states to report on lock-in
programs. HHS will consider requiring states to report on lock-in programs for abusers of non-
controlled substances and pharmacy auto refill policies.

HHS thanks GAO for their efforts on this issue and looks forward to working with GAO on this and
other issues in the future.

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Appendix III: Comments from the Social Security Administration

SOCIAL SECURITY
Office of the Commissioner

June 02, 2015

Mr. Seto Bagdoyan, Director
Forensic Audits and Investigative Service
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Bagdoyan:

Thank you for the opportunity to review the draft report, "MEDICAID: Additional Reporting May Help CMS Oversee Prescription Drug Fraud Controls" (GAO-15-390). We have no comments.

If you have any questions, please contact me at (410) 965-4991. Your staff may contact Gary S. Hatcher, Senior Advisor for Records Management and Audit Liaison Staff, at (410) 965-0680.

Sincerely,

Frank Cristaudo
Executive Counselor to the Commissioner

SOCIAL SECURITY ADMINISTRATION   BALTIMORE, MD 21235-0001

Appendix IV: Comments from the Arizona Health Care Cost Containment System

AHCCCS
Arizona Health Care Cost Containment System

Douglas A. Ducey, Governor
Thomas J. Betlach, Director

June 3, 2015

Seto J. Bagdoyan
Director, Forensic Audits and Investigative Services
U.S. Government Accountability Office
441 G. Street, NW
Washington, DC 20548

Re: U.S. GAO Report to Congressional Requesters, *MEDICAID: Additional Reporting May Help CMS Oversee Prescription Drug Fraud Controls*; **GAO-15-390**

Dear Mr. Bagdoyan:

The Arizona Health Care Cost Containment System ("AHCCCS") is Arizona's single state Medicaid agency. AHCCCS has reviewed the U.S. GAO Report to Congressional Requesters, entitled *MEDICAID: Additional Reporting May Help CMS Oversee Prescription Drug Fraud Controls*, GAO-15-390, (hereinafter "GAO Report") and takes exception to being included in a series of findings that offer no state-specific detail, particularly when there is state-specific detail for Arizona that exists to refute many of the global conclusions the GAO reached. AHCCCS is particularly concerned regarding the methodology (aggregated data and the time period) and the audit objectives. The findings are limited in that they cannot be attributed to any of the states reviewed for the lack of specificity. Additionally, states continually look to improve Program Integrity processes, but those efforts are minimized when GAO findings, such as this Report, are not placed into context. For instance, the findings identified within this GAO Report represent less than one-tenth of one percent of Medicaid spending for these four states.

Data Match Findings

Similar to other reviews, the GAO Report focuses on several potential vulnerabilities that may exist within state Medicaid programs with regards to prescription drugs. The GAO Report looks at exposures around incarcerated members, excluded providers, multiple state enrollment and deceased members and providers, with a focus on federal data matching. The GAO Report fails to identify state practices that are able to leverage more accurate data sources on a real-time basis that serve to better protect limited taxpayer resources.

For example, the GAO Report looks at data matches with the federal incarceration file. The primary challenge Arizona has experienced is this federal file is routinely out of date. In addition, the federal file does not capture the majority of Arizonans who are incarcerated because they are in state and local facilities. To combat these limitations, Arizona has conducted electronic matches with the Arizona Department of Corrections and the Arizona Department of Juvenile Corrections for several years. In addition, the State receives daily files electronically from several counties, including the two largest – Maricopa and Pima – as well as rural counties,

such as Yuma, Coconino, Cochise, Pinal, Yavapai and Mohave. This allows the State to obtain incarceration status from county jails and suspend enrollment of beneficiaries until the State is notified of their release. The State also has manual notification processes in place to identify juveniles in detention in eight out of the fifteen counties.

It is also important to note state efforts around identifying deceased providers and members. Arizona uses SSA's Wire Third Party Query (WTPY) to obtain date of death information at initial application and renewal. In addition to the WTPY, Arizona uses SSA's real-time SOLQI to obtain date of death information at initial application and renewal. Additionally, the SSA notifies the State of the date of death for SSI Cash recipients on the daily SDX file. CMS also notifies the State of the date of death for individuals receiving Medicare.

Arizona also matches with the Arizona Office of Vital Records death file monthly. Through past experience, the State has found the SSA death file to be inaccurate. By relying on the information from the State's own Office of Vital Records, accuracy in date of death matches is extremely high.

With regards to the data matches specific to HIV and diabetes, Arizona believes the GAO should have gathered more than just a single year of claims data to identify if a diagnosis existed in the system. For instance, it is common to have a drug claim for a member but not a corresponding medical claim for a diagnosis relating to the condition, because the medical claim for that diagnosis could have been incurred from the previous year. Unfortunately, Arizona had insufficient time to run a similar analysis over a longer time-frame, but believes an analysis like this is critical to validate the GAO findings. Ultimately, however, for purposes of assigning findings to this degree, a chart review is the best way to obtain completely accurate information as to what transpired between the member and provider at that appointment.

GAO Findings

Specifically the GAO Report recommended "that CMS require states to report to the agency whether their state uses lock-ins for non-controlled substances and prohibitions on auto-refills, and examine the results to determine if additional guidance is appropriate."

Arizona Protocols Already Apply GAO Recommendations

Arizona has already taken several steps to address and prevent fraud, waste or abuse of non-controlled medications. Some of these steps include:

1. Establishing a Minimum Required Prescription Drug List;
2. Applying Concurrent Utilization Review processes, such as having point-of-sale edits used by PBMs to adjudicate prescription claims to prevent adverse events, waste and abuse, including edits related to dispensing limits, quantity limits, refill too soon, age, gender, generic substitution, maximum daily dose, ineffective daily dose, drug interactions, duplicate therapy, drug disease, drug pregnancy, high dollar, date of death, and others;

3. <u>Requiring Prospective Utilization Review protocols</u>, such as prior authorization on various HIV medications, diabetes medications, respiratory medications, and antipsychotic medications, as well as evaluating respiratory medication utilization during claims adjudication processes for appropriate utilization and to eliminate stockpiling;
4. <u>Utilizing Retrospective Drug Utilization Review strategies</u>, such as member utilization reports, prescribing clinician reports and pharmacy reports to identify aberrant utilization or prescribing patterns, as well as contractor comparison reports to identify outliers, and PBM desk and onsite audit reports, among others; and
5. <u>Prohibiting automatic refills</u>.

In addition, Arizona already has a lock-in program for controlled medications and is currently standardizing a statewide policy for lock-ins related to non-controlled medications.

GAO Findings Do Not Address Specific Issues Related to Specialty Care

Questionable prescribing and dispensing patterns were also discussed in the GAO Report. Per the GAO Report, 119 out of 28,000 prescribers had at least 500 claims for which at least 75% of the prescriptions were for brand name drugs. It should be noted that the 119 prescribers represent 0.425% of the 28,000 prescribing clinicians. The GAO report did not evaluate the 119 prescribers to determine their specialty and compare their utilization to that of their peers. The report also did not take into consideration that there are some states that continue to require specific brand name medication coverage because it is more costly to the state to purchase the generic product.

The GAO Report also indicates 301 pharmacies filled half of all prescriptions for brand name drugs and 37 pharmacies with at least 500 claims that only dispensed brand name drugs. The GAO Report does not differentiate retail pharmacies from specialty pharmacies. Biologics and medications that are required to have a REMS program are typically branded drugs and dispensed by specialty pharmacies. These pharmacies are expected to have a high percentage of branded medications.

Arizona's Emphasis on Program Integrity Allows Broad Authority to its Office of the Inspector General

Arizona also has a centralized Office of the Inspector General (OIG) that has broad authority. The AHCCCS OIG oversees all provider registration requirements, as well as provider and member fraud investigations. Provider Registration has a systematic monthly practice in which the entire provider network is compared against all the required and available databases, such as the Social Security Death Master File, the LEIE and SAM, among others. The OIG Member Compliance Section addresses referrals alleging doctor shopping and other irregular behaviors and derives patterns and trend analysis. The OIG is also enhancing its data mining approaches utilizing the intelligent investigator software to include pharmacy fraud for both beneficiaries and providers. From those results, investigations and program integrity audits will be conducted periodically.

Conclusion

Reaching such sweeping conclusions without properly validating findings based on state-specific data has the potential for adverse consequences. AHCCCS respectfully requests the GAO Report Team release the state specific findings, to the respective states, regarding questionable prescribing and dispensing patterns so that Arizona can investigate the findings properly.

Sincerely,

Monica Higuera Coury
Assistant Director
Office of Intergovernmental Relations

Appendix V: Comments from the State of Florida Agency for Health Care Administration

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

May 21, 2015

Mr. Seto Bagdoyan
Director, Forensic Audits and Investigative Service
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Bagdoyan:

Thank you for providing the Agency for Health Care Administration, the state agency which administers the Florida Medicaid Program, with an opportunity to review and comment on the draft report entitled *Medicaid: Additional Reporting May Help CMS Oversee Prescription Drug Fraud Controls (GAO-15-390)*.

In October of 2014, the Agency finalized implementation of the Managed Medical Assistance component of the Statewide Medicaid Managed Care Program. The Agency has procured contracts with health plans to manage primary care, acute care and behavioral health services for Florida's Medicaid recipients. Most of Florida's Medicaid recipients are enrolled in a health plan.

Medicaid health plans must adhere to Florida Statutes requirements regarding prior authorization procedures for covering medically necessary services, including prescribed drug services. The Agency also requires Medicaid health plans to design and implement drug utilization review (DUR) programs to encourage coordination between the enrollee's primary care provider and the prescriber of prescription medications. The DUR program also identifies medications for serious medical conditions posing significant risk to the enrollee by potential drug interactions. When potential risks are identified the plan must notify all related prescribers that certain drugs may be contra-indicated, encouraging prescribers to coordinate their care.

We are happy to report that Florida Medicaid does not allow pharmacy auto refills. Additionally, we are willing to work with CMS' guidance and recommendations for the implementation of a lock-in program for abusers of non-controlled substances.

Again, we support the Government Accountability Office's (GAO) efforts to evaluate Florida's Medicaid program and the fraud controls currently in place for prescription drugs, and appreciate the opportunity to provide comments on your draft report. Should you have any questions about our comments or require further information, please contact me at (850) 412-3603.

Sincerely,

Elizabeth Dudek
Secretary

ED/cs

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Tallahassee, FL 32308
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SlideShare.net/AHCAFlorida

State of New Jersey

DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

CHRIS CHRISTIE
Governor

P.O. Box 712
Trenton, NJ 08625-0712

ELIZABETH CONNOLLY
Acting Commissioner

KIM GUADAGNO
Lt. Governor

VALERIE HARR
Director

June 1, 2015

Seto J. Bagdoyan
United States Government Accountability Office
441 G. Street NW
Washington, DC 20548

Dear Mr. Bagdoyan:

This is in response to a request by the United States Government Accountability Office (GAO) to review the findings from a draft report, entitled *Additional Reporting May Help CMS Oversee Prescription Drug Fraud Controls (GAO-15-390)*, dated July 2015.

The GAO identified two potential controls that are not included in the Centers for Medicare and Medicaid Services' (CMS') current reporting requirements, **including lock-in programs for non-controlled substances; and the prohibition of automatic refills.**

DMAHS contractually requires managed care organizations (MCOs) that serve NJ FamilyCare (NJFC) members to implement a pharmacy lock-in program. MCOs are required to report back to DMAHS the member's ID, name, lock-in effective date, lock-in termination date, restricted pharmacy ID, pharmacy NPI and reason(s) for locking-in a member to a pharmacy. The Division standardized the reason(s) for a member being locked into a pharmacy. These reasons include:

✓ Questionable coordinated care (multiple prescribers/misappropriation of benefits) – historical only;
✓ Multiple prescriptions filled out-of-state;
✓ Multiple pharmacies;
✓ Duplication of analgesic therapy;
✓ Multiple controlled substances;
✓ Multiple prescribers;
✓ Misappropriation of benefits;
✓ Duplication of non-controlled substances; and
✓ Other.

DMAHS is also working on a web-based solution that will provide MCOs access to standardized lock-in data, *whether provided by other MCOs or by DMAHS*. MCO access would be limited to members newly enrolled in a plan. MCOs using a User ID and password would gain

Seto J. Bagdoyan
June 1, 2015
Page 2

access to a NJ Medicaid Management Information (NJMMIS) webpage to query lock-in information for newly enrolled members. The information would include the data elements indicated above, including most importantly standardized reasons for a member being locked in to a pharmacy.

Automatic prescription refills are a major concern for the State of New Jersey. Although characterized by retail pharmacy as a 'patient-friendly' service, designed to improve the quality of prescription services, the State has the same concerns as those expressed in GAO report. These concerns include the potential for stockpiling medications; the continued filling of discontinued medications; unrecognized changes in drug therapies; and increases in fraud, waste and the abuse of prescription drugs.

Detection of automatic prescription refills by a point-of-sale system is very difficult and is best accomplished by on-site pharmacy audits. In addition, proof of delivering prescriptions is a written or electronic signature which is subject to its own fraud and abuse concerns.

DMAHS was pleased to learn that CMS banned automatic prescription refills in the Medicare Part D prescription drug benefit program in 2013 and was also pleased to learn that the states of Florida and Arizona did the same. The Division has explored ways to identify automatic refills, such as looking at a certain percentage of dispense that would consistently 'trigger' an automatic refill when exhausting the day's supply for a prescription, but have been less than successful. DMAHS looks forward to better understanding the audit practices used by CMS and these states to audit this banned pharmacy practice.

The following comments address additional findings not identified by the GAO as potential controls.

> **Medicaid Statistical Information System (MSIS)**

  The decision to use New Jersey in this report was based, in part, on the conclusion that data elements received from New Jersey were '*sufficiently reliable*' for the purpose of identifying indicators of potential fraud, waste and abuse. However, the report also identified what were referred to as '*observed reportable shortcomings, such as issues with timeliness, completeness, and accuracy in the data that may affect the Medicaid administrator's ability to effectively oversee their program.*'

  Page 9 of the report discusses issues with timely access to verified data by States indicating that '*the most recent, validated data available from CMS for Arizona, Florida, Michigan and New Jersey were more than 3 years past the date when they should have been validated [by CMS].*' The report also concludes that MSIS submissions were not timely because states failed to submit data timely and/or CMS was failing to review and validate data timely.

Seto J. Bagdoyan
June 1, 2015
Page 3

For New Jersey, the concern regarding the timely submission of MSIS data is related solely to the time required for CMS to validate New Jersey claims file submissions. CMS was still validating our quarterly claims file submissions for Calendar Years 2012 and 2013 in Calendar Year 2014.

New Jersey is working to exchange Transformed Medicaid Statistical Information System (T-MSIS) Data with CMS. There is however a concern. Both MSIS and T-MSIS do not provide for any indication that a drug was paid only after prior authorization (PA) was issued. The absence of PA information on the record to MSIS or T-MSIS limits the ability of CMS to determine if a service was medically necessary *even without a medical claim to support a particular diagnosis, such HIV.* It is suggested that any study conducted to assess medical necessity for prescription drugs be conducted using the date the prescription was written and comparing this date to the dates of service for medical claims no sooner than three months after the prescription dispense date.

➢ **New Jersey Quality Management and Utilization Review Program**

Over ninety-five percent of NJFC beneficiaries are now enrolled in managed care and the State has been routinely processing encounter claims for services provided to MCO members. As part of Phase 1 of this Program, the State's point-of-sale system (POS) was enhanced creating a 'Media 9' adjudication process to adjudicate pharmacy encounters, applying the same POS edit logic used for fee-for-service (FFS) claims. These edits include prospective and retrospective drug utilization review edits which may be found in New Jersey's Drug Utilization Review Board Annual Report at: http://nj.gov/humanservices/dmahs/boards/durb/reports/index.html.

Phase II of this same Program will focus on medical encounters. The NJMMIS was also modified to introduce medical encounters to McKesson ClaimCheck®. McKesson ClaimCheck® is a comprehensive claims auditing software system that automatically audits and adjusts FFS professional claims for billing errors and detects common code manipulations to avoid costly overpayments. ClaimCheck® will be used as an informational tool to determine whether medical encounters are being appropriately reported to DMAHS.

The approach in Phase II will also identify targeted disease states to be subjected to retrospective utilization reviews. This approach will rely heavily on disease state protocols already established by CMS in addition to peer-reviewed and accepted medical protocols for disease state treatment. This approach will compare service utilization to CMS-approved protocols to determine the extent to which (1) medically necessary services are or are not being received based on diagnosis; (2) whether opportunities for medical interventions are being lost; or (3) whether services are being over or under-utilized and not contributing to positive or resulting in negative health outcomes. The intent is to improve the quality of services provided and reported for MCO members.
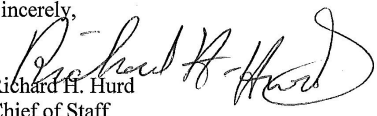
Seto J. Bagdoyan
June 1, 2015
Page 4

Office of the State Comptroller, Medicaid Fraud Division

Currently, the Medicaid Fraud Division (MFD) runs a quarterly Dr. Shopper report that identifies recipients with higher than average number of multiple doctors, pharmacies and prescriptions for antipsychotics, controlled substances, and HIV drugs. The MFD also regularly compares diagnosis and procedure codes to prescription claims to verify that Medicaid is paying for medication which is medically necessary. MFD is in the process of developing a report to identify prescribers who have claims for prescriptions after cancelation effective dates as well as a process to verify providers are not on the Exclusion List.

DMAHS appreciates the opportunity to review and comment on the GAO report findings. We are hopeful that these comments will be found helpful. If you have any questions regarding our response, please do not hesitate to contact Eugene Azoia, R. Ph., Chief, Pharmaceutical Services, at 609-631-4685.

Sincerely,

Richard H. Hurd
Chief of Staff

RH:EJV:v
c: Eugene Azoia, R.Ph.
   File

Appendix VII: GAO Contact and Staff Acknowledgments

Appendix VII: Accessible Data

Agency Comment Letters

Text of Appendix II: Department of Health and Human Services Comment Letter

Page 1

June 9, 2015

Seto Bagdoyan

Director, Forensic Audits and Investigative Service

U.S. Government Accountability Office 441 G Street NW

Washington , DC 20548 Dear Mr. Bagdoyan:

Attached are comments on the U .S. Government Accountability Office's (GAO) report entitled,

"Additional Reporting May Help CMS Oversee Prescription Drug Fraud Controls " (GA0-15-390).

The Department appreciates the opportunity to review this report prior to publication .

Sincerely,

Jim R. Esquea

Assistant Secretary for Legislation

Attachment

Page 2

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO)

DRAFT REPORT ENTITLED: MEDICAID: ADDITIONAL REPORTING MAY HELP CMS OVERSEE PRESCRIPTION DRUG FRAUD CONTROLS (GA0-15-390)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. HHS is strongly committed to program integrity and data collection efforts in Medicaid.

In February 2011, HHS finalized regulations under which states must implement categorical risk-based screening of newly enrolling Medicaid providers and revalidate all current Medicaid providers under new requirements established by the Affordable Care Act. Providers are assigned to categorical screening levels based on factors such as the type of service provided and history of previous adverse actions. Providers in the limited risk category are subject to verification of licensure, verification of compliance with federal regulations and state requirements, and various database checks. Providers in the moderate and high risk categories undergo additional screening, including unannounced site visits. Additionally , as a condition of enrollment, providers in the high risk category and persons with five percent or greater ownership interest in such providers must consent to criminal background checks including fingerprinting.

HHS has been proactive about assisting states with provider enrollment and revalidation screening. In April 2012, we provided states with direct access to Medicare's enrollment database-the Provider Enrollment, Chain, and Ownership System (PECOS). In October 2013, in response to input from states, HHS began providing access to monthly PECOS data extracts that states could use to systematically compare state enrollment records against available PECOS information. We have also provided states with training and technical assistance on using PECOS.

In 2012, HHS issued regulations to require states to use the Data Services Hub (Hub) to verify applicant eligibility upon enrollment and at least annually thereafter. States are able to use this to identify applicants and beneficiaries who may be incarcerated, deceased, or do not meet Medicaid eligibility requirements. States can also validate applicants' Social Security Numbers (SSNs) using the Hub. In 2012, HHS required

every state to submit a verification plan describing their verification policies and procedures for certain Medicaid populations including the fact that the state verifies SSNs.

As part of our ongoing program integrity efforts, HHS has put programs in place to prevent "doctor shopping," and other methods of obtaining drugs in order to divert them for financial gain or abuse. HHS has provided education and training to state Medicaid agencies on strategies for reducing prescription drug diversion and improving prescription drug program integrity oversight in Medicaid. Prospective Drug Utilization Review (DUR) works to identify inappropriate prescribing before the prescription is dispensed by giving the pharmacist information about the patient's complete medication profile to identify any potential drug related issues. Through Retrospective DUR screening and educational interventions, state Medicaid agencies identify aberrant prescribing patterns, including patterns that could be indicative of doctor shopping, and perform outreach to prescribers to encourage appropriate prescribing. In February 2011, HHS finalized regulations to require all providers prescribing medication under the state plan or under a waiver of the plan to be enrolled as participating Medicaid providers. This enrollment requirement is expected to have mitigating effects on doctor shopping

Page 3

DRAFT REPORT ENTITLED: MEDICAID: ADDITIONAL REPORTING MAY HELP CMS OVERSEE PRESCRIPTION DRUG FRAUD CONTROLS (GA0-15-390)

HHS is also taking steps to improve data collection in Medicaid. We are currently implementing the Transformed Medicaid and Statistical Information System (T-MSIS), which will allow HHS to collect and analyze Medicaid claims and encounter data. T-MSIS will provide HHS with more robust, accurate, and timely data than our current data collection system. HHS will have enhanced ability to examine claims and encounter data that may be anomalous and to follow-up with states for further investigation. HHS went live with its federal T-MSIS platform in May 2015. We expect that state T-MSIS data will be submitted for more than half the Medicaid population by the end of 2015.

Lock-in programs can be a key control feature within the Drug Utilization Review program and allow states to maintain program integrity while ensuring access to controlled substances for beneficiaries. If a state Medicaid agency finds that a beneficiary has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in

accordance with utilization guidelines established by the state, it may require that beneficiary to obtain some services only from designated providers. Some states require high users of certain drugs to use only one pharmacy and get prescription s for controlled substances from only one medical office. Although there is no federal requirement for states to implement a lock-in program , forty-nine states currently operate lock-in programs.

Some pharmacies choose to automatically refill prescriptions for patients and hold them for pick- up or, in the case of mail-service pharmacies , mail them directly to patients. If prescriptions are automatically refilled and not picked up by the beneficiary , the pharmacy is required to reverse the claim and does not receive reimbursement from Medicaid. Pharmacy automatic refill

program s can help ensure beneficiary access to medications and help improve adherence to treatment regimens. State Medicaid agencies may set policies on automatic refill program s or prohibit the practice.

GAO Recommendation

To enhance monitoring of potentially wasteful or abusive practices in the Medicaid program, GAO recommends that the Administrator of CMS require states to report to CMS whether their state has lock-in programs for abusers of non-controlled substances and prohibitions on pharmacy auto refills and examine the results to determine if additional guidance is appropriate.

HHS Response

HHS concurs with this recommend ation. HHS currently requires states to report on lock-in programs. HHS will consider requiring states to report on lock-in programs for abusers of non- controlled substances and pharmacy auto refill policies.

HHS thanks GAO for their efforts on this issue and looks forward to working with GAO on this and other issues in the future.

Text of Appendix III:
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Security Administration

Page 1   June 02 ,2015

Mr. Seto Bagdoyan. Director

Forensic Audits and Investigat ve Service

United States Government Accountability Office 441 G Street , NW

Washington. DC 20548 Dear Mr. Bagdoyan:

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I r you have any quest ions. please contact me at (4 10) 965-499 1 . Your staff may contact Gary S. Hatcher, Senior Advisor for Records Management and Audit Liaison Staff. at

(4 10) 965-0680.

Sincerely,

Frank Cristaudo

Executive Counselor to the Commissioner

Text of Appendix IV: Comments from the Arizona Health Care Cost Containment System

Page 1

June 3, 2015

Seto J. Bagdoyan

Director, Forensic Audits and Investigative Services

U.S. Government Accountability Office

441 G. Street, NW

Washington, DC 20548

Re: U.S. GAO Report to Congressional Requesters, MEDICAID: Additional Reporting May

Help CMS Oversee Prescription Drug Fraud Controls; GAO-15-390

Dear Mr. Bagdoyan:

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Page 3

such as Yuma, Coconino, Cochise, Pinal, Yavapai and Mohave. This allows the State to obtain incarceration status from county jails and suspend enrollment of beneficiaries until the State is notified of their release. The State also has manual notification processes in place to identify juveniles in detention in eight out of the fifteen counties.

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GAO Findings

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Arizona Protocols Already Apply GAO Recommendations

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1. Establishing a Minimum Required Prescription Drug List;

2. Applying Concurrent Utilization Review processes, such as having point-of-sale edits used by PBMs to adjudicate prescription claims to prevent adverse events, waste and abuse, including edits related to dispensing limits, quantity limits, refill too soon, age, gender, generic substitution, maximum daily dose, ineffective daily dose, drug interactions, duplicate therapy, drug disease, drug pregnancy, high dollar, date of death, and others;

Page 4

3. Requiring Prospective Utilization Review protocols, such as prior authorization on various HIV medications, diabetes medications, respiratory medications, and antipsychotic medications, as well as evaluating respiratory medication utilization during claims adjudication processes for appropriate utilization and to eliminate stockpiling;

4. Utilizing Retrospective Drug Utilization Review strategies, such as member utilization reports, prescribing clinician reports and pharmacy reports to identify aberrant utilization or prescribing patterns, as well as contractor comparison reports to identify outliers, and PBM desk and onsite audit reports, among others; and

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GAO Findings Do Not Address Specific Issues Related to Specialty Care

Questionable prescribing and dispensing patterns were also discussed in the GAO Report. Per the GAO Report, 119 out of 28,000 prescribers had at least 500 claims for which at least 75% of the prescriptions were for brand name drugs. It should be noted that the 119 prescribers represent 0.425% of the 28,000 prescribing clinicians. The GAO report did not evaluate the 119 prescribers to determine their specialty and compare their utilization to that of their peers. The report also did not take into consideration that there are some states that continue to require specific

brand name medication coverage because it is more costly to the state to purchase the generic product.

The GAO Report also indicates 301 pharmacies filled half of all prescriptions for brand name drugs and 37 pharmacies with at least 500 claims that only dispensed brand name drugs. The GAO Report does not differentiate retail pharmacies from specialty pharmacies. Biologics and medications that are required to have a REMS program are typically branded drugs and dispensed by specialty pharmacies. These pharmacies are expected to have a high percentage of branded medications.

Arizona's Emphasis on Program Integrity Allows Broad Authority to its Office of the Inspector General

Arizona also has a centralized Office of the Inspector General (OIG) that has broad authority. The AHCCCS OIG oversees all provider registration requirements, as well as provider and member fraud investigations. Provider Registration has a systematic monthly practice in which the entire provider network is compared against all the required and available databases, such as the Social Security Death Master File, the LEIE and SAM, among others. The OIG Member Compliance Section addresses referrals alleging doctor shopping and other irregular behaviors and derives patterns and trend analysis. The OIG is also enhancing its data mining approaches utilizing the intelligent investigator software to include pharmacy fraud for both beneficiaries and providers. From those results, investigations and program integrity audits will be conducted periodically.

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Conclusion

Reaching such sweeping conclusions without properly validating findings based on state-specific data has the potential for adverse consequences. AHCCCS respectfully requests the GAO Report Team release the state specific findings, to the respective states, regarding questionable prescribing and dispensing patterns so that Arizona can investigate the findings properly.

Sincerely,

Monica Higuera Coury

Assistant Director

Office of Intergovernmental Relations

Text of Appendix V: Comments from the State of Florida Agency for Health Care Administration

Page 1

Mr. Seto Bagdoyan

Director, Forensic Audits and Investigative Service United States Government Accountability Office 441 G Street, NW

Washington, DC 20548 Dear Mr. Bagdoyan:

Thank you for providing the Agency for Health Care Administration, the state agency which administers the Florida Medicaid Program, with an opportunity to review and comment on the draft report entitled Medicaid: Additional Reporting May Help CMS Oversee Prescription Drug Fraud Controls (GA0-15- 390).

In October of 2014 , the Agency finalized implementation of the Managed Medical Assistance component of the Statewide Medicaid Managed Care Program. The Agency has procured contracts with health plans to manage primary care, acute care and behavioral health services for Florida's Medicaid recipients. Most of Florida's Medicaid recipients are enrolled in a health plan.

Medicaid health plans must adhere to Florida Statutes requirements regarding prior authorization procedures for covering medically necessary services, including prescribed drug services. The Agency also requires Medicaid health plans to design and implement drug utilization review (DUR) programs to encourage coordination between the enrollee's primary care provider and the prescriber of prescription medications. The DUR program also identifies medications for serious medical conditions posing significant risk to the enrollee by potential drug interactions. When potential risks are identified the plan must notify all related prescribers that certain drugs may be contra-indicated, encouraging prescribers to coordinate their care.

We are happy to report that Florida Medicaid does not allow pharmacy auto refills. Additionally, we are willing to work with CMS' guidance and

recommendations for the implementation of a lock-in program for abusers of non-controlled substances .

Again , we support the Government Accountability Office's (GAO) efforts to evaluate Florida's Medicaid program and the fraud controls currently in place for prescription drugs, and appreciate the opportunity to provide comments on your draft report. Should you have any questions about our comments or require further information, please contact me at (850) 412-3603.

Sincerely,

Elizabeth Dudek

Secretary

Text of Appendix VI: Comments from the New Jersey Department of Human Services

Page 1

Seto J. Bagdoyan

United States Government Accountability Office 441 G. Street NW

Washington, DC 20548 Dear Mr. Bagdoyan:

This is in response to a request by the United States Government Accountability Office (GAO) to review the findings from a draft report, entitled Additional Reporting May Help CMS Oversee Prescription Drug Fraud Controls (GA0-15-390), dated July 2015.

The GAO identified two potential controls that are not included in the Centers for Medicare and Medicaid Services (CMS) current reporting requirements, including lock-in programs for non-controlled. substances; and ;the prohibition of automatic refills.

DMAHS contractually requires managed care organizations (MCOs) that serve NJ Family Care (NJFC) members to implement' a pharmacy lock-in program. MCOs are required to report back to DMAHS the member's Id, name lock-in effective date, lock-in termination date, restricted pharmacy ID, pharmacy NPI and reason(s) for locking-in a member to a pharmacy.

The Division standardized the reason(s) for a member being locked into a pharmacy. These reasons include:

Questionable coordinated care (multiple prescribers/misappropriation of benefits) - historical only;

- Multiple prescriptions filled out-of-state;
- Multiple pharmacies;
- Duplication of analgesic therapy;
- Multiple controlled substances;
- Multiple prescribers;
- Misappropriation of benefits;
- Duplication of non-controlled substances; and
- Other

DMAHS is also working on a web-based solution that will provide MCOs access to standardized lock-in data,' whether provided by other MCOs or by DMAHS. MCO access would be limited to members newly enrolled in a plan. MCOs using a User ID and password would gain

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access to a NJ Medicaid Management Information (NJMMIS) webpage to query lock-in information for newly enrolled members. The information would include the data elements indicated above, including most importantly standardized reasons for a member being locked in to a pharmacy.

Automatic prescription refills are a major concern for the State of New Jersey. Although characterized by retail pharmacy as a 'patient-friendly' service, designed to improve the quality of prescription services, the State has the same concerns as those expressed in GAO report. These concerns include the potential for stockpiling medications; the continued filling of discontinued medications; unrecognized changes in drug therapies; and increases in fraud, waste and the abuse of prescription drugs.

Detection of automatic prescription refills by a point-of-sale system is very difficult and is best accomplished by on-site pharmacy audits. In addition, proof of delivering prescriptions is a written or electronic signature which is subject to its own fraud and abuse concerns.

DMAHS was pleased to learn that CMS banned automatic prescription refills in the Medicare Part D prescription drug benefit program in 2013 and was also pleased to learn that the states of Florida and Arizona did

the same. The Division has explored ways to identify automatic refills, such as looking at a certain percentage of dispense that would consistently 'trigger' an automatic refill when exhausting the day's supply for a prescription, but have been less than successful. DMAHS looks forward to better understanding the audit practices used by CMS and these states to audit this banned pharmacy practice.

The following comments address additional findings not identified by the GAO as potential controls.

Medicaid Statistical Information System (MSIS)

The decision to use New Jersey in this report was based, in part, on the conclusion that data elements received from New Jersey were 'sufficiently reliable ' for the purpose of identifying indicators of potential fraud, waste and abuse. However, the report also identified what were referred to as 'observed reportable shortcomings, such as issues with timeliness, completeness, and accuracy in the data that may affect the Medicaid administrator 's ability to effectively oversee their program. '

Page 9 of the report discusses issues with timely access to verified data by States indicating that 'the most recent, validated data available from CMS for Arizona, Florida, Michigan and New Jersey were more than 3 years past the date when they should have been validated [by CMS].' The report also concludes that MSIS submissions were not timely because states failed to submit data timely and/or CMS was failing to review and validate data timely.

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For New Jersey, the concern regarding the timely submission of MSIS data is related solely to the time required for CMS to validate New Jersey claims file submissions. CMS was still validating our quarterly claims file submissions for Calendar Years 2012 and 2013 in Calendar Year 2014.

New Jersey is working to exchange Transformed Medicaid Statistical Information System (T-MSIS) Data with CMS. There is however a concern. Both MSIS and T-MSIS do not provide for any indication that a drug was paid only after prior authorization (PA) was issued. The absence of PA information on the record to MSIS or T-MSIS limits the ability of CMS to determine if a service was medically necessary even without a medical claim to support a particular diagnosis, such HIV.It is suggested that any study conducted to assess medical necessity for prescription drugs be conducted using the date the prescription was

written and comparing this date to the dates of service for medical . claims no sooner than three months after the prescription dispense date.

New Jersey Quality Management and Utilization Review Program

Over ninety-five percent of NJFC beneficiaries are now enrolled in managed care and the State has been routinely processing encounter claims for services provided to MCO members. As part of Phase 1 of this Program, the State's point-of-sale system (POS) was enhanced creating a 'Media 9' adjudication process to adjudicate pharmacy encounters, 1 applying the same POS edit logic used for fee-for-service (FFS) claims. These edits include prospective and retrospective drug utilization review edits which may be found in New Jersey's Drug Utilization Review Board Annual Report at:
http://nj.gov/humanservices/dmahs/boards/durb/reports/index.html.

Phase II of this same Program will focus on medical encounters. The NJMMIS was also modified to introduce medical encounters to McKesson ClaimCheck®. McKesson ClaimCheck® is a comprehensive claims auditing software system that automatically audits and adjusts FFS professional claims for billing errors and detects common code manipulations to avoid costly overpayments. ClaimCheck® will be used as an informational tool to determine whether medical encounters are being appropriately reported to DMAHS.

The approach in Phase II will also identify targeted disease states to be subjected to retrospective utilization reviews. This approach will rely heavily on disease state protocols already established by CMS in addition to peer-reviewed and accepted medical protocols for disease state treatment. This approach will compare service utilization to CMS-approved protocols to determine the extent to which (1) medically necessary services are or are not being received based on diagnosis; (2) whether opportunities for medical interventions are being lost; or (3) whether services are being over or under- utilized and not contributing to positive or resulting in negative health outcomes. The intent is to improve the quality of services provided and reported for MCO members.

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Office of the State Comptroller, Medicaid Fraud Division

Currently, the Medicaid Fraud Division (MFD) runs a quarterly Dr. Shopper report that identifies recipients with higher than average number of multiple doctors, pharmacies and prescriptions for antipsychotics, controlled substances, and HIV drugs. The MFD also regularly compares

diagnosis and procedure codes to prescription claims to verify that Medicaid is paying for medication which is medically necessary. MFD is in the process of developing a report to identify prescribers who have claims for prescriptions after cancelation effective dates as well as a process to verify providers are not on the Exclusion List.

DMAHS appreciates the opportunity to review and comment on the GAO report findings. We are hopeful that these comments will be found helpful. If you have any questions regarding our response, please do not hesitate to contact Eugene Azoia, R. Ph., Chief, Pharmaceutical Services, at 609-631-4685.

Sincerely,

Richard H. Hurd

Chief of Staff

cc: Eugene Azoia, R.Ph.

File