Healthcare Audit and Enforcement Risk Analysis

HHS OIG Work
Plan Summary
Report Payer
Focus

Active Work Plan Items





To our Compliance Colleagues and Partners:

SunHawk's review of OIG Audit statistics in 2020 found that compliance professionals and business risk owners experienced a 58% increase in HHS OIG audit activity over the prior year. In an effort to promote the value of shared learnings, as well as give our colleagues and clients organized summaries of the over 250 active HHS OIG Work Plan items, SunHawk Consulting, LLC, has gathered, organized, and summarized the HHS OIG Work Plan for the Payer and Provider Industries.

HHS OIG Office of Audit Services and Office of Evaluation and Inspections issues approximately 300 audits and evaluations a year. The OIG Work Plan sets forth various projects, including OIG audits and evaluations, that are underway or planned to be addressed during the fiscal year and beyond. The Work Plan item summaries provided herein are referenced by their respective Work Plan numbers at the end of each abstract. SunHawk's report summarizes currently active Work Plan items and sorts relevant Work Plans items into Provider and Payer categories. The electronic version of this report includes hyperlinks to the original Work Plan item summaries.

After your review, we would appreciate any feedback that would make this report more valuable to you or others. Should you find you would like to proactively conduct a review of activity within your organization to avoid future adverse findings, SunHawk's team of experts are always available to offertheir assistance. Visit us at SunHawkConsulting.com and Connect with us on LinkedIn for updates on our Healthcare Audit and Enforcement Risk Analysis. SunHawk looks forward to working with you and your organization.

*HHS OIG's Semi-annual reports to Congress for the April 1, 2019 to March 31, 2020 periods reported 304 new Audits and Evaluations which was an increase of 111 more issued reports during the same prior year period.



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Medicaid

Status of State Medicaid Provider Enrollment and Screening Activities

Expected Issue Date: 2026 Announced: December 2024

Provider enrollment screening is a key program integrity tool for protecting Medicaid against fraudulent and abusive providers. Federal law requires State Medicaid agencies to screen providers as part of the Medicaid enrollment process. For high-risk provider types, including durable medical equipment, prosthetics, and orthotics suppliers and home health agencies, required screening activities include site visits and fingerprint-based criminal background checks. Prior OIG work has identified issues with States' implementation of provider enrollment and screening requirements for both fee-for-service Medicaid and Medicaid managed care. During the COVID-19 public health emergency, CMS suspended certain screening requirements, which may have exacerbated the issues previously identified and presented new challenges. This study will determine the status of States' required Medicaid provider enrollment and screening and will assess States' standards and processes for screening.

Work Plan #: OEI-05-24-00400

Government Program: Office of Evaluation and Inspections

Access to Hepatitis C Treatment in Medicaid

Expected Issue Date: 2026 Announced: November 2024

Hepatitis C is a liver disease caused by the highly infectious hepatitis C virus. If untreated, hepatitis C can result in serious liver disease. In the past decade, direct-acting antiviral drugs that can cure hepatitis C within 12 weeks have revolutionized treatment. Despite their improved tolerability over previous treatments and recommended use by prominent medical associations, these hepatitis C drugs are underutilized, and the virus continues to spread. In recent years, Federal and State policymakers have attempted to improve access to hepatitis C treatment while simultaneously addressing its high cost. In Medicaid-which serves a high proportion of people with hepatitis C-some States have arranged alternative payment structures for hepatitis C drugs and removed related coverage restrictions. This study will examine the extent to which Medicaid enrollees diagnosed with chronic hepatitis C receive drug treatment in Medicaid and identify potential disparities in treatment rates.

Work Plan #: OEI-BL-24-00450

Government Program: Office of Evaluation and Inspections





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Audit of Medicaid Reimbursement for Clinical Laboratory Services

Expected Issue Date: 2026 **Announced:** October 2024

Outpatient clinical diagnostic laboratory tests encompass tests performed in a physician's office, by an independent laboratory, or by a hospital laboratory, and provide information for the diagnosis, prevention, or treatment of disease or for the assessment of a medical condition. Medicaid reimbursement for outpatient clinical diagnostic laboratory services performed in a physician's office, by an independent laboratory, or by a hospital laboratory, generally may not exceed the amount set in the Medicare clinical laboratory fee schedule. OIG's objective is to determine whether selected States claimed Federal Medicaid reimbursement for outpatient clinical diagnostic laboratory services in accordance with the payment limits set in Federal and State requirements.

Work Plan #: OAS-25-01-004

Government Program: Office of Audit Services

Medicaid Managed Care Organizations in States With Remittance Requirements

Expected Issue Date: 2025 **Announced:** September 2024

CMS established medical loss ratios (MLRs) in Medicaid managed care as a tool to ensure that managed care plans spend most of their revenue on services related to the health of their enrollees, thereby limiting the amount that plans can spend on administration and keep as profit. As part of the capitation rate setting process, Federal regulations require States to set their plans' capitation rates so that plans will reasonably achieve MLRs of at least 85 percent. Further, States also have the option to require their managed care plans to pay remittances if the plan fails to meet the minimum MLR set by the State. OIG will review States and managed care plans with contract provisions that require remittances from managed care plans if a minimum MLR is not met. OIG will determine whether the remittances the MCOs reported to States were correctly calculated and whether the Federal share of remittances that States received was returned to the Federal Government.

Work Plan #: WA-24-0067 (W-00-24-31582)
Government Program: Office of Audit Services

Medicaid Managed Care Capitation Payments on Behalf of Incarcerated Enrollees

Expected Issue Date: 2025 **Announced:** July 2024

States contract with Medicaid managed care organizations to provide specific services to Medicaid enrollees, usually in return for a predetermined periodic payment known as a capitation payment. Section 1905 of Title XIX of the Social Security Act, 42 CFR § 435.1009, and guidance from CMS state that Federal financial participation is generally not available for services provided to adult inmates of public institutions except when the individual is not in a prison setting and becomes an inpatient in a medical institution. OIG will determine whether select States made unallowable capitation





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payments to Medicaid managed care organizations on behalf of individuals incarcerated in State prisons.

Work Plan #: WA-24-0057 (W-00-24-31581)
Government Program: Office of Audit Services

State Directed Payments in Medicaid Managed Care

Expected Issue Date: 2025 **Announced:** July 2024

As the HHS agency overseeing Medicaid, CMS issued regulations establishing certain circumstances under which States may direct managed-care payments to providers. These payments are referred to as State directed payments. While working within Federal parameters, States determine criteria for providers to receive these directed payments. For selected State directed payments in Medicaid managed care, OIG's objective is to determine whether the State: (1) obtained CMS approval for the directed payment proposal, (2) complied with CMS-approved requirements and outcomes in the approved proposal, and (3) ensured that directed payments were made according to the approved proposal.

Work Plan #: WA-24-0056 (W-00-24-31580)
Government Program: Office of Audit Services

Medicaid Managed Care: CMS's Oversight of Whether States Return the Required Federal Share of Medical Loss Ratio Remittances

Expected Issue Date: 2025 Announced: June 2024

With its 2016 Medicaid managed care regulations, CMS established medical loss ratios (MLRs) as a policy tool to ensure appropriate stewardship of managed care funds. The Federal MLR is the percentage of premium revenue that a managed care plan spent on covered health care services and quality improvement activities during a 12 month period. Federal MLR regulations allow States to require Medicaid managed care plans to meet a minimum MLR of at least 85 percent. States that set minimum MLRs with remittance requirements for their managed care plans could receive MLR remittance payments if plans fail to achieve at least the State-set minimum MLR. A minimum MLR with a remittance requirement limits financial risks for State and Federal governments. CMS is responsible for ensuring that States return to CMS the required Federal share of any MLR remittance payments that States receive from their plans. OIG's evaluation will determine whether and how CMS tracked that States returned to CMS the required Federal share of MLR remittances for the 2017-2018 and 2018-2019 MLR reporting periods.

Work Plan #: OEI-03-23-00041

Government Program: Office of Evaluation and Inspections



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Use of Electronic Visit Verification Data for Medicaid Personal Care Services

Expected Issue Date: 2026 **Announced:** June 2024

Section 12006 of the 21st Century Cures Act (Cures Act) requires that States implement and use an Electronic Visit Verification (EVV) system to verify the delivery of Medicaid personal care services. EVV requirements were included in the Cures Act in response to longstanding fraud, waste, and abuse concerns associated with Medicaid personal care services. This evaluation will assess the availability and completeness of EVV data and examine how State Medicaid agencies and others use these data for program integrity purposes.

Work Plan #: OEI-09-24-00290

Government Program: Office of Evaluation and Inspections

OIG Oversight of Medicaid Fraud Control Units

Expected Issue Date: Completed (partial)

Announced: April 2024

The 53 Medicaid Fraud Control Units (MFCUs)-located in the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands-investigate and prosecute Medicaid provider fraud as well as complaints of abuse or neglect in health care facilities, board and care facilities, and of Medicaid beneficiaries in noninstitutional or other settings. OIG provides oversight for MFCUs and administers a Federal grant award to fund a portion of each MFCU's operational costs. OIG, in exercising oversight for MFCUs, annually recertifies each MFCU and assesses each MFCU's performance and compliance with Federal requirements. OIG also provides technical assistance and training, and identifies effective practices in MFCU management and operations. OIG will perform onsite reviews of a sample of MFCUs. OIG will also issue an annual report that will analyze the statistical information that was reported by MFCUs, describing in the aggregate the outcomes of MFCU criminal and civil cases. The report will also identify trends in MFCU case results.

Work Plan #: OEI-06-23-0045; OEI-07-24-00220; OEI-06-24-00300; OEI-07-24-00340; OEI-09-24-00410;

OEI-09-25-00090

Government Program: Office of Evaluation and Inspections

Audit of Medicaid Select Diabetes and Weight Loss Drugs

Expected Issue Date: Completed (partial)

Announced: March 2024

Medicaid utilization of and gross spending on select diabetes and weight loss drugs have rapidly increased in recent years. The select diabetes drugs were approved to help control blood sugar levels for individuals with type 2 diabetes; however, these drugs are known to be used for weight loss. Most States cover these drugs to treat Medicaid enrollees with diabetes. Additionally, some States cover similar types of drugs that were approved for weight loss. OIG will identify national Medicaid utilization for select diabetes and weight loss drugs and select one or more States to review.



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Work Plan #: WA-24-0036 (W-00-24-35911); A-05-24-00016

Government Program: Office of Audit Services

Evaluating the Accuracy of Medicaid Managed Care Provider Directories for Maternal Health Care Providersgit

Expected Issue Date: 2026 **Announced:** January 2024

Pregnant women in the United States experience worse pregnancy outcomes than women in any other high-income country. Maternal health care can improve pregnancy outcomes; however, many pregnant women in the United States lack access to maternal health care. Medicaid is the Nation's largest maternal health care payor, financing more than 40 percent of all U.S. births, and many pregnant women enrolled in Medicaid are enrolled in managed care plans. This study will review Medicaid managed care provider directories to evaluate the accuracy of information listed for maternal health care providers.

Work Plan #: OEI-05-24-00090

Government Program: Office of Evaluation and Inspections

<u>Audit of Emergency Preparedness, Infection Prevention and Control, and Life</u> <u>Safety at Intermediate Care Facilities for Individuals With Intellectual Disabilities</u>

Expected Issue Date: Completed (Partial)

Announced: November 2023

An Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) is an institution that provides health and/or rehabilitation services to individuals with intellectual disabilities under the Medicaid program. ICF/IID services are covered by Medicaid when they are provided in a residential facility licensed and certified by a State survey agency as an ICF/IID. Medicaid covers ICF/IID services for more than 100,000 individuals with intellectual disabilities and other related conditions. ICF/IIDs face significant challenges in the event of emergencies such as fires, emerging infectious disease outbreaks, and natural disasters. Previous OIG audits on infection prevention and control, emergency preparedness, and life safety at nursing homes identified multiple issues that put Medicaid enrollees at increased risk. OIG's objective is to determine whether selected States' ICF/IIDs complied with Federal requirements for infection prevention and control, emergency preparedness, and life safety.

Work Plan #: WA-24-0010 (W-00-24-31574); A-01-24-00001



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<u>Timeliness of Mental Health Care Following a Suicide Attempt or Intentional</u> Self-Harm Incident for Children Enrolled in Medicaid

Expected Issue Date: 2026 **Announced:** October 2023

Rates of suicide attempts and intentional self-harm among youth are on the rise. A previous suicide attempt is the most important predictor of death by suicide, and the risk of death by suicide is highest in the period immediately after a hospitalization or emergency department visit for a suicide attempt or intentional self-harm incident. As such, providing timely mental health followup care is critical to decreasing the likelihood of rehospitalization and preventing suicide. OIG will conduct an evaluation to assess whether children enrolled in Medicaid and the Children's Health Insurance Program (CHIP) who had an emergency department visit or hospitalization for a suicide attempt or intentional self-harm incident received mental health followup care within established timeframes. OIG will also examine whether certain groups of children in the population were less likely to receive timely mental health followup care after a hospitalization or emergency department visit. Finally, OIG will interview subject matter experts to identify the challenges and best practices that States encountered when working to ensure that youth enrolled in Medicaid and CHIP receive timely mental health followup care.

Work Plan #: OEI-07-23-00510

Government Program: Office of Evaluation and Inspections

CMS Oversight of States' Preparation of the CMS-64 Report

Expected Issue Date: 2025 Announced: July 2023

The Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State governments jointly fund and administer the Medicaid program. At the Federal level, CMS administers the program. The Federal Government pays its share of a State's Medicaid expenditures based on the Federal Medical Assistance Percentage, which varies depending on the State's relative per capita income. Within 30 days after the end of each quarter, States report expenditures and the associated Federal share on the CMS-64 report. The amounts that States report must represent actual expenditures. CMS is responsible for reviewing the CMS-64 report to ensure that the expenditures reported are consistent with Medicaid requirements and matched with the correct amount of Federal funds. CMS works with States to resolve any questionable expenditures. OIG will determine the effectiveness of CMS's oversight of Medicaid State expenditures reported on CMS-64 reports for the quarter ended September 30, 2022.

Work Plan #: WA-23-0030 (W-00-23-31572)
Government Program: Office of Audit Services



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<u>State Medicaid Agencies' Perspectives of Managed Care Plans' Referral of</u> Fraud

Expected Issue Date: 2026 **Announced:** June 2023

For Medicaid managed care, States contract with and oversee private health insurance companies, known as managed care plans, which have the primary responsibility for processing, paying, and monitoring claims from providers in their networks. As such, States play a critical role in safeguarding the Medicaid program's integrity. For example, States are required to: (1) monitor plans' compliance with the program integrity provisions of their contracts (including the provisions related to fraud referrals), (2) determine whether potential fraud reflects a credible allegation of fraud, and (3) take action against providers upon the identification of a credible allegation of fraud. According to Federal regulations, States' contracts with managed care plans must require the plans to promptly refer any potential fraud, waste, or abuse to State Medicaid agencies or Medicaid Fraud Control Units. However, both OIG and CMS have ongoing concerns about States' and plans' efforts to combat fraud, including a lack of fraud referrals. This evaluation will determine whether State contractual requirements support managed care plans' submission of fraud referrals, determine how States evaluate the volume and quality of the fraud referrals made by managed care plans, identify the factors that States believe incentivize managed care plans to refer fraud, and determine the challenges States face regarding fraud referrals from managed care plans. This work may also identify ways to increase the total number of managed care plans' fraud referrals and ensure the quality and timeliness of these referrals.

Work Plan #: OEI-03-23-00340

Government Program: Office of Evaluation and Inspections

CMS's Oversight of Federal Medical Loss Ratio Requirements in Medicaid Managed Care

Expected Issue Date: 2026 Announced: December 2022

With its 2016 Medicaid managed care regulations, CMS chose medical loss ratios (MLRs) as a policy tool to ensure appropriate stewardship of managed care funds. The Federal MLR is the percentage of premium revenue that a managed care plan spent on covered health care services and quality improvement activities during a 12-month period. Federal MLR requirements help ensure that managed care plans spend most of their revenue on services related to the health of their enrollees, thereby limiting the amount that plans can spend on administration and keep as profit. As part of the process for setting capitation rates, Federal regulations require States to set their plans' capitation rates so that plans will reasonably achieve MLRs of at least 85 percent-the Federal MLR standard. States must take into account their plans' reported MLRs when setting future capitation rates. OIG has previously found weaknesses in States' oversight of the completeness and accuracy of their plans' MLR reporting. CMS plays a vital role in overseeing States' implementation of Federal MLR requirements, as it is responsible for the review and approval of States' capitation rates for their managed care plans, including review of State-submitted MLR data. OIG's evaluation will determine: (1) how CMS has incorporated MLR data in its review of States' capitation rate certifications; (2) the oversight activities that CMS conducts to ensure that States submit to CMS complete and accurate MLR data; and (3) whether CMS has ensured that States have used MLR data, as required, to set accuratilly sound capitation rates.



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Work Plan #: OEI-03-23-00040

Government Program: Office of Evaluation and Inspections

Medicaid Managed Care Plans' Focus on Fraud Referrals

Expected Issue Date: 2025 **Announced:** September 2022

For Medicaid managed care, States contract with private health insurance companies, or managed care plans, that have the primary responsibility for processing, paying, and monitoring the claims of providers in their networks. As such, managed care plans play a critical role in safeguarding Medicaid program integrity. According to Federal regulations, State contracts with managed care plans must require that plans promptly refer any potential fraud, waste, or abuse to State Medicaid agencies or Medicaid Fraud Control Units (MFCUs). However, both OIG and CMS have ongoing concerns about managed care plans' efforts to combat fraud, including concerns about a lack of fraud referrals. This evaluation will determine the number of potential fraud referrals managed care plans made to States, MFCUs, and other entities; determine whether managed care plan processes support the referral of potential fraud; and identify the factors that influence whether managed care plans make referrals. This work may identify ways to increase the total number of managed care plan referrals and ensure the quality and timeliness of referrals.

Work Plan #: OEI-03-22-00410

Government Program: Office of Evaluation and Inspections

States' Medicaid Eligibility and Enrollment Actions Concluding the COVID-19 Public Health Emergency

Expected Issue Date: Completed

Announced: August 2022

In response to the COVID-19 pandemic, section 6008 of the Families First Coronavirus Response Act (FFCRA) provides a temporary increase of 6.2 percentage points to each qualifying State's and Territory's Federal Medical Assistance Percentage (FMAP), effective January 1, 2020. To receive the increased FMAP, FFCRA requires States to provide benefits to individuals who were enrolled in Medicaid at the start of the COVID-19 public health emergency (PHE) or become enrolled in Medicaid during the emergency period. These individuals should remain eligible for Medicaid through the last day of the month in which the COVID-19 PHE ends (continuous enrollment period), unless the individual requests a voluntary termination of eligibility, or the individual ceases to be a resident of the State. Within the 12-month period in which the COVID-19 PHE ends, States must initiate all renewals, post-enrollment verifications, and redeterminations for all individuals enrolled when the continuous enrollment expires. At the conclusion of the COVID-19 PHE, OIG will review the States' required Medicaid eligibility and enrollment actions. OIG will determine whether States completed pending Medicaid eligibility and enrollment actions in accordance with CMS requirements that take effect after the COVID-19 PHE.



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Work Plan #: WA-22-0012 (W-00-22-31567); A-02-24-01001; A-07-24-07013

Government Program: Office of Audit Services

States' and MCOs' Compliance With Mental Health Parity Requirements

Expected Issue Date: Completed (partial)

Announced: June 2022

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) promotes equal access to treatment for mental health and substance use disorder (MH/SUD) by prohibiting coverage limitations that apply more restrictively to MH/SUD benefits than medical or surgical benefits. Such limitations could include higher copayments, separate deductibles, and stricter preauthorization or medical necessity reviews, as compared to other covered medical treatments. Federal regulations require managed care organizations (MCOs) with plans that provide services to Medicaid enrollees to comply with the parity provisions of MHPAEA. Federal regulations require that States or their MCOs, as applicable, conduct analyses to demonstrate compliance with parity requirements. CMS reviews States' parity analyses as part of its review of States' MCO contracts. OIG will audit CMS's oversight of States' compliance with Federal parity requirements, including whether States and their MCOs conducted the required parity analyses and whether States ensured that their MCOs complied with certain parity requirements for MH/SUD benefits.

Work Plan #: WA-22-0003 (W-00-22-31565); A-02-22-01016

Government Program: Office of Audit Services

Electronic Visit Verification System for Medicaid In-Home Services

Expected Issue Date: Completed (Partial)

Announced: April 2022

All States were required to implement an electronic visit verification (EVV) system for personal care services (PCS) by January 1, 2020, and for home health services by January 1, 2023. CMS granted the vast majority of States a 1-year extension (to January 1, 2021) for meeting EVV requirements for PCS. EVV was developed to address weaknesses in PCS that contribute to improper payments, questionable quality of care, and significant fraud. OIG's objectives will be to determine whether selected States: (1) implemented an EVV system according to Federal and State requirements, and (2) complied with Federal and State requirements when claiming Medicaid in home PCS.

Work Plan #: W-00-22-31564; A-07-23-03255 Government Program: Office of Audit Services



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Achieved Savings Rebate Program-Offset of Rebates on CMS-64

Expected Issue Date: Completed (partial)

Announced: March 2022

The Social Security Act (the Act) Section 1115 gives CMS authority to approve experimental, pilot or demonstration projects that it considers likely to assist in promoting the objectives of the Medicaid program. States may then use CMS-approved waivers to have Managed Care Organizations (MCOs) provide care to Medicaid beneficiaries. Under these arrangements, States make capitation payments to the MCOs in return for the MCOs providing the patient care for the Medicaid beneficiaries. Some States place limitations on MCOs' earnings, for example, limiting the profits they may earn or requiring a certain percentage of their revenues to be spent on medical expenses. States with such limitations may require the MCOs to return a portion of the capitation payments when the MCOs exceed those limitations. According to the Act, § 1903(d)(3)(A) States are required to refund to the Federal Government the Federal share of any amounts recovered during any fiscal quarter. Additionally, 45 CFR § 75.406(a) requires recipients of Federal awards (which includes State Medicaid agencies) to credit to the Federal award the Federal share of reduction-of-expenditure type transactions, such as rebates, purchase discounts, or allowances when those transactions relate to allowable costs. For selected States, OIG will determine whether the States properly offset against CMS-64 expenditures refunds of capitation payments received from MCOs.

Work Plan #: W-00-22-31562; A-04-22-04089 Government Program: Office of Audit Services

Medicaid Managed Care Organizations' Denials

Expected Issue Date: Completed (partial)

Announced: February 2022

The State Medicaid agency and the Federal Government are responsible for the financial risk for the costs of Medicaid services. State Medicaid agencies contract with managed care organizations (MCOs) to ensure that beneficiaries receive covered Medicaid services. The contractual arrangement shifts the financial risk from the State Medicaid agency and the Federal Government to MCOs, which can create an incentive for MCOs to deny beneficiaries' access to covered services. OIG's audits will determine whether Medicaid MCOs complied with Federal requirements when denying access to requested medical and dental services, behavioral health services, and associated drug prescriptions that required prior authorization.

Work Plan #: W-00-19-31535; W-00-20-31535; A-03-20-00201; W-00-21-31535; W-00-22-31535; W-00-24-31535;

A-02-21-01016; A-07-22-07007



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States' Use of Local Provider Participation Funds as the State Share of Medicaid Payments

Expected Issue Date: 2024 **Announced:** November 2021

Local units or jurisdictions of government have the option to use Local Provider Participation Funds (LPPFs) to generate and collect local funding to finance the State share of Medicaid supplemental and directed payment programs. In the past several years, some States and local units of governments have increasingly used LPPFs to fund the State share of Medicaid payments. As such, OIG will determine whether the LPPFs the State agency used as the State share of Medicaid payments were permissible and in accordance with applicable Federal and State requirements.

Work Plan #: W-00-22-31557

Government Program: Office of Audit Services

<u>Audit of Medicaid Applied Behavior Analysis for Children Diagnosed With</u> Autism

Expected Issue Date: Completed (partial)

Announced: June 2021

Autism can cause significant social, communication, and behavioral challenges for children. According to the Centers for Disease Control and Prevention, research has shown that early intervention and therapy can improve social and behavioral development in children diagnosed with autism. A common therapy for autism is Applied Behavior Analysis (ABA). ABA can help an autistic child improve social interaction, learn new skills, maintain positive behaviors, and minimize negative behaviors. In the past few years, some Federal and State agencies have identified questionable billing patterns by some ABA providers as well as Federal and State payments to providers for unallowable services. OIG will audit Medicaid claims for ABA services provided to children diagnosed with autism to determine whether a State Medicaid agency's ABA payments complied with Federal and State requirements.

Work Plan #: W-00-24-31555; A-09-22-02002 Government Program: Office of Audit Services

Risk Assessment at a State Medicaid Agency

Expected Issue Date: 2025 **Announced:** December 2020

One goal of the President's Management Agenda is to maximize grant funding by applying a risk-based, data-driven framework that balances compliance requirements with demonstrating successful results to the American taxpayer. Enterprise Risk Management-based risk assessments can help organizations quickly understand and prioritize critical, enterprisewide risks, and develop plans to maximize as well as mitigate and manage risk. OIG will perform an Enterprise Risk Management-based risk assessment at one State Medicaid agency to identify internal control weaknesses and process risks.



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Work Plan #: W-00-21-31552

Government Program: Office of Audit Services

Risk Assessment of Puerto Rico Medicaid Program

Expected Issue Date: Completed (partial)

Announced: October 2020

The Puerto Rico Medicaid program is a 100-percent managed care program that provides health services to more than 1 million beneficiaries. In December 2019, Congress provided Puerto Rico additional funding under the Further Consolidated Appropriations Act of 2020 (P.L. 116-94). P.L. 116-94 also contains anticorruption measures including requirements for OIG to develop and submit to Congress a report identifying payments made under Puerto Rico's Medicaid program to managed care organizations that are at high risk for waste, fraud, or abuse, and a plan for auditing such payments.

Work Plan #: W-00-20-31544; W-00-21-31544; W-00-23-31544; W-00-24-31544; A-02-21-01004; A-02-21-01005

Government Program: Office of Audit Services

Nationwide Review of the Administration and Oversight of Physician-Administered Drugs

Expected Issue Date: 2024 **Announced:** October 2020

States are required to collect rebates on covered outpatient drugs administered by physicians in order to be eligible for Federal matching funds (SSA § 1927(a)). Previous OIG work identified significant concerns with States' efforts in obtaining rebates for these physician-administered drugs. OIG will summarize the results and issues identified in these audits and examine CMS's policies and procedures to ensure States appropriately collect Medicaid rebates on physician-administered drugs.

Work Plan #: W-00-20-35860

Government Program: Office of Audit Services

Joint Work With State Agencies

Expected Issue Date: Completed (Partial)

Announced: October 2020

To strengthen program integrity and efficiently use audit resources, OIG will enhance its efforts to provide broader oversight of the Medicaid program by partnering with State auditors, State comptrollers general, and State inspectors general. Federal-State partnerships will provide effective methods that address improper payments in fee-for-service programs such as home health, hospice, and durable medical equipment, and in managed care. OIG will partner with States to: (1) address known vulnerabilities that it has identified in both Medicare and Medicaid to curb such vulnerabilities in Medicaid nationwide; and (2) identify new areas that put the integrity of the Medicaid program at risk.



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Work Plan #: W-00-21-40002; A-09-23-02004 Government Program: Office of Audit Services

<u>Penetration Tests of State Medicaid Management Information Systems and Eligibility & Enrollment Systems</u>

Expected Issue Date: Completed (partial)

Announced: June 2020

State Medicaid agencies use the Medicaid Management Information System (MMIS) for administrating the Medicaid program; processing beneficiary and provider inquiries and services; operating claims control and computer capabilities; and managing reporting for planning and control. State Medicaid Eligibility & Enrollment (E&E;) systems support processes related to a determination of Medicaid coverage and required procedures necessary for registration. State agencies are responsible for the security of MMIS and E&E; systems. HHS OIG will perform a series of penetration tests in select State MMIS or Medicaid E&E; environments to identify cybersecurity vulnerabilities on high-risk information systems and networks.

Work Plan #: W-00-20-42028; W-00-21-42028; <u>A-18-20-08005</u>; <u>A-18-20-08004</u>; <u>A-18-20-08003</u>; <u>A-18-21-09003</u>;

<u>A-18-21-09004</u>; <u>A-18-21-09001</u>; <u>A-18-22-09005</u>; <u>A-18-22-09010</u>; <u>A-18-22-09009</u>

Government Program: Office of Audit Services

Medicaid—Telehealth Expansion During COVID-19 Emergency

Expected Issue Date: Completed

Announced: June 2020

As a result of the coronavirus disease 2019 (COVID-19) pandemic, State Medicaid programs have expanded options for telehealth services. Rapid expansion of telehealth may pose challenges for State agencies and providers, including State oversight of these services. OIG's objective is to determine whether State agencies and providers complied with Federal and State requirements for telehealth services under the national emergency declaration, and whether the States gave providers adequate guidance on telehealth requirements.

Work Plan #: A-05-21-00035; A-07-21-03250 Government Program: Office of Audit Services

Medicaid MCO PBM Pricing

Expected Issue Date: Completed (partial)

Announced: February 2020

The State Medicaid agency and the Federal Government are responsible for financial risk for the costs of Medicaid services. Managed care organizations (MCOs) contract with State Medicaid agencies to ensure that beneficiaries receive covered Medicaid services including prescription drugs. MCOs may contract with pharmacy benefit managers



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(PBMs) to manage or administer the prescription drug benefits on their behalf. Spread pricing is a practice where a PBM charges an MCO more for a drug than the amount a PBM pays a pharmacy. OIG's audit will determine whether States provide adequate oversight of Medicaid MCOs to ensure accountability over amounts paid for prescription drug benefits to its PBMs.

Work Plan #: W-00-20-31542; A-03-20-00200 Government Program: Office of Audit Services

Medicaid Concurrent Eligibility

Expected Issue Date: Completed (partial)

Announced: November 2019

State Medicaid agencies contract with managed care organizations (MCOs) to make services available to enrolled Medicaid beneficiaries. The contractual arrangement shifts financial risk for the cost of care to the MCO. State Medicaid agencies pay MCOs on a per-beneficiary per-month basis, and MCOs are at financial risk if the costs of care exceed those payments. If a beneficiary who resides in one State subsequently establishes residency in another State, the beneficiary's Medicaid eligibility in the previous State should end and the MCO should not receive payments for that beneficiary. OIG's review will determine whether States made capitation payments on behalf of beneficiaries who established residency in another State.

Work Plan #: <u>A-05-19-00023</u>; <u>A-05-19-00031</u>; <u>A-05-19-00032</u>; W-00-19-31539; W-00-21-31539; W-00-21-35726; <u>A-05-20-00025</u>; <u>A-05-21-00028</u>; W-00-22-31539; W-00-23-31539; W-00-24-31539; <u>A-05-22-00018</u>; <u>A-05-23-00008</u>

Government Program: Office of Audit Services

Review of State Uncompensated Care Pools

Expected Issue Date: Completed (partial)

Announced: April 2019

Some State Medicaid agencies operate uncompensated care pools (UCPs) under waivers approved by CMS. Section 1115 of Title XIX of the Social Security Act gives CMS authority to approve experimental, pilot, or demonstration projects that it considers likely to help promote the objectives of the Medicaid program. The purpose of these projects, which give States additional flexibility to design and improve their programs, is to demonstrate and evaluate State-specific policy approaches to better serve Medicaid populations. To implement a State demonstration project, States must comply with the special terms and conditions (STCs) of the agreement between CMS and the State. The purpose of the UCPs is to pay providers for uncompensated cost incurred in caring for low-income (Medicaid and uninsured) patients. Through UCPs, States pay out hundreds of millions of dollars to providers and receive Federal financial participation. However, in some States there has previously been little oversight of the payments. OIG will determine whether selected States' Medicaid agencies made payments to hospitals under the UCPs that were in accordance with the STCs of the waiver and with applicable Federal regulations.

Work Plan #: W-00-19-31537; A-04-19-04070 Government Program: Office of Audit Services



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Medicaid School-Based Costs Claimed Based on Contingency Fee Contractor Coding

Expected Issue Date: 2025 Announced: March 2018

There is no text provided to edit. Please provide the text you would like to be changed from OIG's first person perspective to a third person perspective.

Work Plan #: A-04-18-07075; W-00-18-31529; A-02-20-01012; A-02-18-01019

Government Program: Office of Audit Services

States' Collection of Rebates for Drugs Dispensed to Medicaid MCO Enrollees

Expected Issue Date: Completed (partial)

Announced: October 2017

Medicaid MCOs are required to report enrollees' drug utilization to the State for the purpose of collecting rebates from manufacturers. Section 2501(c) of the Patient Protection and Affordable Care Act expanded the rebate requirement to include drugs dispensed to MCO enrollees. OIG will determine whether States are collecting prescription drug rebates from pharmaceutical manufacturers for Medicaid MCOs. Drugs dispensed by Medicaid MCOs were excluded from this requirement until March 23, 2010.

Work Plan #: A-06-16-00004; A-07-16-06065; A-09-16-02027; A-09-16-02028; A-09-16-02029; A-02-16-01011;

<u>A-09-16-02031</u>; <u>A-06-16-00001</u>; W-00-16-31483; various reviews

Government Program: Office of Audit Services

States' Collection of Rebates on Physician-Administered Drugs

Expected Issue Date: Completed (partial)

Announced: October 2017

States are required to collect rebates on covered outpatient drugs administered by physicians in order to be eligible for Federal matching funds (SSA § 1927(a)). Previous OIG work identified concerns with States' collection and submission of data to Centers for Medicare & Medicaid Services, including national drug codes that identify drug manufacturers, thus allowing States to invoice the manufacturers responsible for paying rebates (Deficit Reduction Act of 2005). OIG will determine whether States have established adequate accountability and internal controls for collecting Medicaid rebates on physician-administered drugs. OIG will assess States' processes for collecting national drug code information on claims for physician-administered drugs and subsequent processes for billing and collecting rebates.

Work Plan #: <u>A-02-16-01012</u>; <u>A-06-16-00018</u>; <u>A-05-16-00013</u>; <u>A-05-16-00014</u>; W-00-16-31400; W-00-21-31400; W-00-22-31400; <u>A-07-21-07003</u>; <u>A-07-21-06096</u>; <u>A-07-21-06101</u>; <u>A-07-21-07002</u>; <u>A-04-21-08089</u>; <u>A-04-21-07098</u>;

<u>A-04-21-08090</u>; <u>A-04-22-07102</u>; <u>A-07-21-06103</u>; <u>A-07-22-07010</u>; various reviews



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Recovery of Federal Funds Through Judgments/Settlements

Expected Issue Date: Completed (partial)

Announced: July 2017

Any State action taken as a result of harm to a State's Medicaid program must seek to recover damages sustained by the Medicaid program as a whole, including both Federal and State shares. On October 28, 2008, CMS issued a letter (SHO #08-004) to State health officials that clarified language from Section 1903(d) of the Social Security Act, stating that the Federal Government is entitled to the Federal Medical Assistance Percentages (FMAP) proportionate share of a States entire settlement or final judgment amount. OIG will determine whether selected States reported and returned the applicable FMAP share of the settlement and judgment amounts to the Federal Government.

Work Plan #: A-05-17-00041; A-03-17-00203; A-07-18-02814; A-07-21-02834; W-00-17-31522; A-05-17-00000;

W-00-23-31522; A-06-20-04004; A-07-19-02816; A-06-23-04004

Government Program: Office of Audit Services

<u>Duplicate Payments for Beneficiaries with Multiple Medicaid Identification</u> **Numbers**

Expected Issue Date: Completed (partial)

Announced: November 2016

During a preliminary data match, OIG identified a significant number of individuals who were assigned more than one Medicaid identification number and for whom multiple Medicaid payments were made for the same period. OIG will review duplicate payments made by States on behalf of Medicaid beneficiaries with multiple Medicaid identification numbers and identify States' procedures or other controls for preventing such payments.

Work Plan #: A-04-16-07061; A-02-20-01007; A-04-20-07094; W-00-20-31374; W-00-16-31374; W-00-21-31374;

<u>A-04-21-07097</u>; various reviews

Government Program: Office of Audit Services

Third-Party Liability Payment Collections in Medicaid

Expected Issue Date: Completed (partial)

Announced: November 2016

Medicaid beneficiaries may have additional health insurance through third-party sources. Previous OIG work described problems that State Medicaid agencies had in identifying and collecting third-party payments. States are to take all reasonable measures to ascertain the legal liabilities of third parties with respect to health care items and services (SSA § 1902(a)(25)). Medicaid is the payer of last resort and providers are to identify and refund overpayments received. OIG will determine if States have taken action to ensure that Medicaid is the payer of last resort by identifying whether a third-party payer exists and if the State correctly reports the third-party liability to Centers for Medicare & Medicaid Services.



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Work Plan #: <u>A-05-21-00013</u>

Government Program: Office of Audit Services

MCO Payments for Services After Beneficiaries' Deaths

Expected Issue Date: Completed (partial)

Announced: November 2016

Previous OIG reports found that Medicare paid for services that purportedly started or continued after beneficiaries' dates of death. OIG will identify Medicaid managed care payments made on behalf of deceased beneficiaries. OIG will also identify trends in Medicaid claims with service dates after beneficiaries' dates of death.

Work Plan #: <u>A-06-16-05004</u>; <u>A-05-19-00007</u>; <u>A-04-19-06223</u>; <u>A-07-20-05125</u>; A-04-15-06190; W-00-20-31497; W-00-19-31497; W-00-21-31497; W-00-22-31497; W-00-23-31497; <u>A-03-22-00203</u>; <u>A-04-19-07082</u>; <u>A-04-21-09005</u>;

A-03-22-00205

Government Program: Office of Audit Services

Managed Long-Term-Care Reimbursements

Expected Issue Date: 2024 **Announced:** November 2016

Medicaid managed care plans are subject to Federal requirements (42 CFR Part 438). Some States contract with MCOs to provide long-term services. OIG will review States' reimbursements made to managed long-term-care plans to determine whether those reimbursements complied with certain Federal and State requirements.

Work Plan #: W-00-17-31510



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Medicare Advantage Health Risk Assessments - Continuity of Care

Expected Issue Date: 2026 Announced: November 2024

CMS makes monthly risk-adjusted payments to Medicare Advantage (MA) organizations based in part on the health characteristics of the enrollees being covered (Social Security Act § 1853(a)). Federal regulations at 42 CFR § 422.310(b) require that MA organizations submit risk adjustment data, which includes diagnosis codes, to CMS in accordance with CMS instructions. Inaccurate diagnoses may cause CMS to pay MA organizations improper amounts. MA organizations use health risk assessments (HRAs) to gather information, including diagnoses, about enrollees. MA organizations can use HRAs for early identification of health risks to improve enrollees' care and health outcomes. However, prior OIG work found that MA organizations may have inappropriately leveraged HRAs to maximize risk-adjusted payments. These audits focused on enrollees whose diagnoses, reported first on HRAs, mapped to hierarchical condition categories and resulted in increased risk-adjusted payments from CMS to MA organizations. OIG will determine whether MA organizations complied with Federal requirements when: (1) submitting diagnoses reported on HRAs to CMS for use in CMS's risk-adjustment program and (2) taking any needed steps to ensure continuity of care and integration of services for enrollees who had received HRAs.

Work Plan #: OAS-24-07-015; SRS-A-25-019 Government Program: Office of Audit Services

Audits of Medicare Part C Supplemental Benefits

Expected Issue Date: 2025 Announced: June 2024

Under the Medicare Advantage (MA) program, an MA organization can offer supplemental benefits, which are items or services that are not covered by traditional Medicare, to its enrollees. MA organizations must design the supplemental benefits to improve enrollees' health, allow enrollees to manage their chronic conditions, or support enrollees' access to care. Over the past 5 years, the types of supplemental benefits-and payments for them-have grown considerably, and per-person payments from CMS to MA organizations for these benefits have more than doubled. For this series of audits, OIG will determine whether MA organizations complied with Federal requirements for the supplemental benefits offered to their enrollees.

Work Plan #: W-00-24-35917 (WA-24-0052); SRS-A-25-022



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<u>Audit To Determine Whether CMS Oversight of Its Preclusion List Ensured That Certain Revoked Providers Did Not Receive Payment for Medicare Part C and Part D Services</u>

Expected Issue Date: 2025 **Announced:** June 2024

CMS contracts with Medicare Advantage plans and private prescription drug plans (collectively known as sponsors) to offer Part C and Part D managed care benefits to eligible enrollees. CMS maintains a list known as the Preclusion List that includes excluded providers and other providers who have been or could have been revoked from the Medicare program for conduct that CMS determines is detrimental to the best interest of the Medicare program. Federal regulations prohibit sponsors from making payments for services provided or prescriptions written by providers on the Preclusion List. OIG will analyze CMS data to identify any revoked providers not included on the Preclusion List; report on why they were not included, as determined by CMS; and point out potential vulnerabilities in not including revoked providers on the Preclusion List.

Work Plan #: WA-24-0051 (W-00-24-35916)
Government Program: Office of Audit Services

Medicare Part C Audits of Documentation Supporting Specific Diagnosis Codes

Expected Issue Date: 2026 Announced: November 2023

Payments to Medicare Advantage (MA) organizations are risk-adjusted based on each enrollee's health status (SSA § 1853(a)). MA organizations are required to submit risk-adjustment data to CMS in accordance with CMS instructions (42 CFR § 422.310(b)), and inaccurate diagnoses may cause CMS to pay MA organizations improper amounts. In general, MA organizations receive higher payments for enrollees with more complex diagnoses. CMS estimates that 9.5 percent of payments to MA organizations are improper, mainly due to unsupported diagnoses submitted by MA organizations. Prior OIG reviews have shown that some diagnoses are more at risk than others to be unsupported by medical record documentation. OIG will perform a targeted review of these diagnoses and will review the medical record documentation to ensure that it supports the diagnoses that MA organizations submitted to CMS for use in CMS's risk score calculations and to determine whether the diagnoses submitted complied with Federal requirements.

Work Plan #: WA-24-0004 (W-00-24-35906); SRS-A-25-017



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Audits of Medicare Part C Health Risk Assessment Diagnosis Codes

Expected Issue Date: 2025 Announced: November 2023

Payments to Medicare Advantage (MA) organizations are risk-adjusted based on each enrollee's health status (SSA § 1853(a)). One tool that MA organizations use to collect risk-adjusted data is the health risk assessment (HRA), which gathers information about enrollees, including health status and health risks. MA organizations are required to submit risk-adjustment data to CMS in accordance with CMS instructions (42 CFR § 422.310(b)), and inaccurate diagnoses may cause CMS to pay MA organizations improper amounts. For these audits, the focus is on enrollees whose diagnoses, reported only on HRAs, mapped to a hierarchical condition category and resulted in increased risk-adjusted payments from CMS to MA organizations. OIG will determine whether these diagnosis codes, as submitted by MA organizations to CMS for use in CMS's risk-adjustment program, complied with Federal requirements.

Work Plan #: WA-24-0003 (W-00-24-35905); SRS-A-25-020

Government Program: Office of Audit Services

Audits of Medicare Part C Unlinked Chart Review Diagnosis Codes

Expected Issue Date: 2026 Announced: September 2023

Payments to Medicare Advantage (MA) organizations are risk-adjusted on the basis of each enrollee's health status (SSA § 1853(a)). MA organizations are required to submit risk adjustment data to CMS according to CMS instructions (42 CFR § 422.310(b)). CMS allows MA organizations to conduct chart reviews of enrollee medical record documentation to identify diagnosis codes that providers either: (1) did not originally provide the MA organization or (2) provided the MA organization in error. For some chart reviews known as unlinked chart reviews, CMS does not require that the MA organization identify the specific date of service for previously unidentified diagnosis codes. CMS also allows MA organizations to submit chart review results to CMS for inclusion in calculating each enrollee's risk score. Miscoded diagnoses may cause CMS to pay MA organizations improper amounts. For these audits, OIG will focus on enrollees who had diagnoses identified from unlinked chart reviews that resulted in increased risk-adjusted payments from CMS to MA organizations. For these enrollees, OIG will determine whether all of the diagnosis codes that the MA organizations submitted to CMS for use in CMS's risk adjustment program, including the diagnosis codes submitted via unlinked chart reviews, complied with Federal requirements.

Work Plan #: WA-23-0037 (W-00-23-35903); SRS-A-25-020



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Medicare Part C High-Risk Diagnosis Codes Tool Kit

Expected Issue Date: Completed

Announced: July 2023

Payments to Medicare Advantage (MA) organizations are risk adjusted on the basis of each enrollee's health status (SSA § 1853(a)). MA organizations are required to submit risk adjustment data to CMS according to CMS instructions (42 CFR § 422.310(b)). Miscoded diagnoses may cause CMS to pay MA organizations improper amounts. For this toolkit, OIG will develop a resource that will provide highly technical information to assist MA organizations with analyzing the accuracy of the risk adjustment data that they receive from their providers and submit to CMS. OIG will provide this information as a starting point to allow MA organizations to research enrollees who receive diagnoses that are at high risk for being miscoded and to take appropriate action if needed.

Work Plan #: <u>A-07-23-01213</u>

Government Program: Office of Audit Services

CMS May Make Increased Payments to MA Organizations for Diagnoses That Were Reported on Physicians' Claims But Were Not Confirmed on a Concurrent Inpatient Stay

Expected Issue Date: 2025 Announced: July 2023

Payments to Medicare Advantage (MA) organizations are risk adjusted on the basis of each enrollee's health status (SSA § 1853(a)). MA organizations are required to submit risk adjustment data to CMS in accordance with CMS instructions (42 CFR § 422.310(b)), and inaccurate diagnoses may cause CMS to pay MA organizations improper amounts. For this review, OIG will focus on enrollees who had a diagnosis on a physician or outpatient claim that did not appear on a concurrent inpatient claim. In these instances, the diagnosis codes from the physician or outpatient claim—ostensibly, potentially unconfirmed diagnosis codes that misrepresented the health status of the enrollee—were submitted to CMS and resulted in increased payments to MA organizations. If these occurrences were reviewed as part of a Risk Adjustment Data Validation (RADV) audit (or during a subsequent RADV appeals process), CMS could potentially review the claims collectively, instead of separately, in order to ensure the accuracy of the enrollee's health status. OIG will identify the increased payments to MA organizations that were based on any unconfirmed and inaccurate diagnoses.

Work Plan #: WA-23-0032 (W-00-23-35900)
Government Program: Office of Audit Services





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Nationwide Audits of Medicare Part C High-Risk Diagnosis Codes

Expected Issue Date: 2025 **Announced:** June 2023

Payments to Medicare Advantage (MA) organizations are risk-adjusted on the basis of the health status of each enrollee. MA organizations are required to submit risk-adjustment data to CMS according to CMS instructions (42 CFR § 422.310(b)). Miscoded diagnoses may cause CMS to pay MA organizations improper amounts (The Act §§ 1853(a)). For these audits, OIG will focus on enrollees who received diagnoses that are at high risk for being miscoded and resulted in increased risk-adjusted payments from CMS to MA organizations. OIG will determine whether these diagnosis codes, as submitted by MA organizations to CMS for use in CMS's risk-adjustment program, complied with Federal requirements.

Work Plan #: WA-23-0019 (W-00-23-35896); SRS-A-25-021

Government Program: Office of Audit Services

<u>Medicare Advantage Risk-Adjustment Data - Targeted Review of Documentation</u> Supporting Specific Diagnosis Codes

Expected Issue Date: Completed (partial)

Announced: November 2019

Payments to Medicare Advantage (MA) organizations are risk-adjusted on the basis of the health status of each beneficiary. MA organizations are required to submit risk-adjustment data to CMS in accordance with CMS instructions (42 CFR § 422.310(b)), and inaccurate diagnoses may cause CMS to pay MA organizations improper amounts (SSA §§ 1853(a)(1)(C) and (a)(3)). In general, MA organizations receive higher payments for sicker patients. CMS estimates that 9.5 percent of payments to MA organizations are improper, mainly due to unsupported diagnoses submitted by MA organizations. Prior OIG reviews have shown that some diagnoses are more at risk than others to be unsupported by medical record documentation. OIG will perform a targeted review of these diagnoses and will review the medical record documentation to ensure that it supports the diagnoses that MA organizations submitted to CMS for use in CMS's risk score calculations and determine whether the diagnoses submitted complied with Federal requirements.

<u>A-04-21-07095</u>; <u>A-06-20-02000</u>; <u>A-07-22-01209</u> **Government Program:** Office of Audit Services

Risk Adjustment Data - Sufficiency of Documentation Supporting Diagnoses

Expected Issue Date: Completed (partial)

Announced: October 2017

Payments to Medicare Advantage organizations are risk adjusted on the basis of the health status of each beneficiary. Medicare Advantage organizations are required to submit risk adjustment data to Centers for Medicare & Medicaid Services in accordance with Centers for Medicare & Medicaid Services instructions (42 CFR § 422.310(b)), and inaccurate diagnoses may cause Centers for Medicare & Medicaid Services to pay Medicare Advantage organizations

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improper amounts (SSA §§ 1853(a)(1)(C) and (a)(3)). In general, Medicare Advantage organizations receive higher payments for sicker patients. Centers for Medicare & Medicaid Services estimates that 9.5 percent of payments to Medicare Advantage organizations are improper, mainly due to unsupported diagnoses submitted by Medicare Advantage organizations. Prior OIG reviews have shown that medical record documentation does not always support the diagnoses submitted to Centers for Medicare & Medicaid Services by Medicare Advantage organizations. OIG will review the medical record documentation to ensure that it supports the diagnoses that Medicare Advantage organizations submitted to Centers for Medicare & Medicaid Services for use in Centers for Medicare & Medicaid Services's risk score calculations and determine whether the diagnoses submitted complied with Federal requirements.

Work Plan #: <u>A-07-16-01165</u>; W-00-16-35078; various reviews; <u>A-07-17-01169</u>; <u>A-03-18-00002</u>; <u>A-05-18-00020</u>; <u>A-04-18-03085</u>; <u>A-04-20-07090</u>; <u>A-06-18-02001</u>; W-00-18-35078; <u>A-09-18-03007</u>; <u>A-04-19-07082</u>; W-00-19-35078 **Government Program:** Office of Audit Services



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[NEW] Ensuring Dual-Eligible Enrollees' Access to Drugs Under Part D: Mandatory Review

Expected Issue Date: 2025 **Announced:** February 2025

Dual-eligible enrollees are enrolled in both Medicaid and Medicare, and they receive prescription drug coverage under Medicare Part D. As long as Part D plans abide by certain limitations outlined in 42 CFR § 423.120, Part D sponsors have discretion to include different Part D drugs in their formularies. As required under section 3313 of the Patient Protection and Affordable Care Act, OIG will conduct an annual study of the extent to which formularies used by Medicare Part D plans include drugs commonly used by dual-eligible enrollees. This study will focus on Part D plans' 2025 formularies.

Work Plan #: OEI-05-25-00120

Government Program: Office of Evaluation and Inspections

Audit of Medicare Part D Over-the-Counter Drugs

Expected Issue Date: 2026 **Announced:** October 2024

Over-the-counter (OTC) drugs may be purchased without a prescription. Medicare Part D does not cover OTC drugs under their basic prescription drug benefit or as a supplemental benefit under enhanced alternative coverage. Subject to approval by the Food and Drug Administration (FDA), companies may convert a brand-name prescription-only (Rx-only) drug to an OTC drug. After FDA approves a brand-name drug's conversion to OTC status, which includes requiring changes to its labeling, the drug is no longer considered an Rx-only drug. Because the labeling of brand-name drugs and generic equivalents must be identical, makers of the generic equivalents must make corresponding revisions to their labeling or cease marketing their generic equivalents. OIG will conduct a nationwide audit of Medicare Part D prescription drug event data to identify payments for OTC drugs sold under obsolete Rx-only labeling. OIG will determine whether CMS oversight of Medicare Part D sponsors ensured compliance with Federal requirements for preventing payments for OTC drugs.

Work Plan #: OAS-24-02-004

Government Program: Office of Audit Services<

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Medicaid Medicare Part C

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Audit of Vertically Integrated Medicare Part D Sponsors

Expected Issue Date: 2026 Announced: April 2024

CMS oversees prescription drug coverage for Medicare Part D enrollees. CMS contracts with health insurers, known as plan sponsors, who are responsible for delivering the benefit through a network of pharmacy providers. Under Part D, sponsors often contract with pharmacy benefit managers (PBMs) to manage or administer the drug benefit on a sponsor's behalf. PBM services may include contracting with pharmacies to establish pharmacy networks and negotiate pharmacy reimbursement rates. In recent years, the pharmaceutical market has experienced a wave of vertical integration between PBMs, health insurers, and pharmacies. Concern has been raised about the vertically integrated model. One such concern is that, by owning many links in the chain, a vertically integrated Medicare Part D sponsor may inflate drug prices. OIG will determine the impact of related entity transactions within select vertically integrated entities on the prices for covered Part D drugs.

Work Plan #: WA-24-0037 (W-00-24-35912)
Government Program: Office of Audit Services

Audit of Diabetes Drugs Under Medicare Part D

Expected Issue Date: 2025 **Announced:** March 2024

In 2022, six type 2 diabetes drugs accounted for more than half of all Medicare Part D payments for diabetes drugs. Diabetes drugs are meant to lower blood sugar levels and often result in weight loss. Part D spending for one of these six drugs, Ozempic, more than tripled between 2020 and 2022, with expenditures jumping from \$1.5 billion to \$4.6 billion. Other diabetes drugs are experiencing similar growth and could overshadow Ozempic. Part D payments for a type 2 diabetes drug, such as Ozempic, for a use that Medicare does not cover as a medically accepted indication is not in compliance with Medicare requirements and presents an opportunity for fraudulent, excessive, or unnecessary Part D payments. Furthermore, drugs that are used for weight loss are specifically excluded from Medicare Part D coverage. OIG will obtain Part D data for prescribed diabetes drugs and any related Part B service claims. OIG will determine whether they were billed according to Medicare requirements.

Work Plan #: WA-24-0035 (W-00-24-35910)
Government Program: Office of Audit Services

Effects of Vertical Integration on Medicare Part D

Expected Issue Date: 2026 **Announced:** March 2024

Approximately three-quarters of Medicare Part D enrollees receive their prescription drug benefits through plans offered by five large companies. These large plan sponsors are vertically integrated operations affiliated with their own pharmacy benefit managers and, in many cases, their own mail-order and specialty pharmacies. Congress, the Medicare Payment Advisory Commission, and the media have raised concerns that vertical integration leads to higher



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prescription drug costs. This study will use existing pricing, payment, and rebate data to provide broader insight into the effect of vertical integration on Part D costs for both the Medicare program and its enrollees.

Work Plan #: OEI-BL-24-00240

Government Program: Office of Evaluation and Inspections

Audits of Pharmacy Support for Prescription Drug Event Data

Expected Issue Date: 2025 **Announced:** December 2023

Medicare Part D plan sponsors must submit prescription drug event (PDE) records, which are summary records of pharmacy drug claims, for the Secretary of Health and Human Services to determine payments to the plans (SSA § 1860D-15(f)(1)). For selected pharmacies, OIG will determine whether PDE records were adequately supported by inventory purchases and complied with applicable Federal requirements.

Work Plan #: WA-24-0014 (W-00-24-35907)
Government Program: Office of Audit Services

Medicare Part D Formulary Coverage of Humira Biosimilars

Expected Issue Date: Completed **Announced:** November 2023

Humira-one of the best selling prescription drugs in the world and one of the most costly drugs for the Medicare Part D program-faced its first competition in the United States in 2023, ending nearly 20 years of market exclusivity. Launches of multiple biosimilars for Humira in 2023, including one interchangeable version, have presented an opportunity to increase access to lower cost drugs and, ultimately, significantly reduce Part D drug spending. However, a lack of Part D formulary coverage for Humira's biosimilars, or preferential formulary placement for Humira, could limit the wider use of these biosimilars, as well as limit any potential spending reductions for the Part D program and its enrollees. OIG's study will determine how often Part D formularies covered Humira biosimilars after they became available and describe differences in cost-sharing or utilization management requirements, as well as list prices, for Humira.

Work Plan #: OEI-05-23-00520

Government Program: Office of Evaluation and Inspections

Medicare Part D Compounded Drugs

Expected Issue Date: 2025 **Announced:** November 2020

In 2016, OIG called attention to significant growth in spending for compounded drugs. Specifically, OIG found that Medicare Part D spending for compounded topical drugs grew by 625 percent during 2006—2015. OIG has been involved in an increasing number of fraud investigations related to compounded drugs. OIG will conduct a risk assessment of CMS's oversight of pharmacies compounding drugs for beneficiaries to determine whether systemic



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vulnerabilities affecting the integrity of Medicare Part D; specifically, OIG will assess the risk that pharmacies did not meet Federal and State requirements.

Work Plan #: W-00-21-35415

Government Program: Office of Audit Services

Nationwide Audit of Medicare Part D Eligibility Verification Transactions

Expected Issue Date: Completed **Announced:** February 2020

An E1 transaction is a Medicare Part D eligibility verification transaction that the pharmacy submits to the Part D transaction facilitator to bill for a prescription or determine drug coverage billing order. The Part D transaction facilitator returns information to the pharmacy that is needed to submit the prescription drug event. E1 transactions are part of the real-time process of the Coordination of Benefits and calculating the true out-of-pocket costs (CMS, Medicare Prescription Drug Benefit Manual, Pub. No. 100-18, chapter 14, 30.4). OIG will review CMS's oversight of E1 transactions processed by contractors and determine whether the E1 transactions were created and used for intended purposes.

Work Plan #: W-00-20-35751; A-05-22-00022 Government Program: Office of Audit Services

Part D Sponsors Reporting of Direct and Indirect Remunerations

Expected Issue Date: Completed (partial)

Announced: September 2017

Medicare calculates certain payments to sponsors on the basis of amounts actually paid by the Part D sponsors, net of direct and indirect remuneration (DIR). (42 CFR pt. 423, subpart G.) DIR includes all rebates, subsidies, and other price concessions from sources (including, but not limited to, manufacturers and pharmacies) that decrease the costs incurred by Part D sponsors for Part D drugs. CMS requires that Part D sponsors submit DIR reports for use in the payment reconciliation process. OIG will determine whether Part D sponsors complied with Medicare requirements for reporting DIR.

Work Plan #: <u>A-03-18-00006</u>; <u>A-03-18-00007</u>; W-00-18-35514; <u>A-03-19-00002</u>

Government Program: Office of Audit Services

Medicare Part D Payments During Covered Part A SNF Stay

Expected Issue Date: Completed (Partial)

Announced: Revised

Medicare Part A prospective payments to skilled nursing facilities (SNFs) cover most services, including drugs and biologicals furnished by the SNF for use in the facility for the care and treatment of beneficiaries. Accordingly, Medicare Part D drug plans should not pay for prescription drugs related to posthospital SNF care because these drugs are

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already included in the consolidated payment for Part A SNF stays. OIG will determine whether Medicare Part D paid for drugs that should have been paid under Part A SNF stays.

Work Plan #: W-00-21-35866; A-09-21-03008
Government Program: Office of Audit Services