Healthcare Audit and Enforcement Risk Analysis

HHS OIG Work Plan Summary Report Payer Focus

March 2022

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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.[1] 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.

We review all OIG Work Plan items that we believe may have value for our partners. As a result, in addition to Payer and Provider-Focused Work Plan items, SunHawk has identified other audit items which we determined relevant to a limited number of Providers and Payers. We plan to publish a summary of these items in January 2021.

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.

[1] 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

Medicaid Partial Care Program

Expected Issue Date: 2023
Announced or Revised: December 2021

Prior audit work identified a State agency's Medicaid adult partial care program as at high risk for improper payments. The purpose of the adult partial care program is to provide Medicaid beneficiaries with serious mental illnesses individualized outpatient clinic services to reduce unnecessary hospitalizations. OIG's prior audit made a financial recommendation and procedural recommendations to the State agency to improve its guidance and monitoring. This audit work will determine whether the State agency adequately implemented OIG's prior recommendations. OIG will also review claims for compliance with Federal and State requirements, including the State agency's implementation of telehealth services due to the COVID-19 pandemic.

Work Plan #: W-00-22-31559
Government Program: Medicaid

Survey of Potential Drug Rebates Associated with Drugs Administered to Enrollees in Separate Children's Health Insurance Programs

Expected Issue Date: 2022
Announced or Revised: December 2021

Under current Federal requirements, States are required to obtain drug rebates from manufacturers for Medicaid-covered outpatient prescription drugs that are provided through Medicaid expansion-under either: (1) Medicaid expansion only or (2) the Medicaid expansion portion if the State chooses a combination of Medicaid expansion and a separate Children's Health Insurance Program (CHIP). However, for prescription drugs that are funded through a separate CHIP, the Federal Medicaid Drug Rebate Program (MDRP) requirements currently do not apply. OIG will determine the total drug rebates that States could potentially have collected under separate CHIPs if those rebates had been part of the MDRP requirements and OIG will identify State policy differences.

Work Plan #: W-00-22-35880
Government Program: Medicaid

Race and Ethnicity Data for Medicaid Beneficiaries

Expected Issue Date: 2023
Announced or Revised: December 2021

Complete and consistent race and ethnicity data for Medicaid beneficiaries are critical to identifying and addressing health disparities. As the COVID-19 pandemic has highlighted disparities among racial and ethnic groups, the availability and quality of data on race and ethnicity warrants a closer look in order to accurately and appropriately mitigate health disparities within the Medicaid population. This study will evaluate the extent to which Medicaid's race and ethnicity data for

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beneficiaries as reported to T-MSIS are complete and consistent across States. OIG will also determine the extent to which the data align with Federal data collection standards for race and ethnicity.

Work Plan #: OEI-02-22-00130
Government Program: Medicaid

OIG Oversight of State Medicaid Fraud Control Units

Expected Issue Date: 2023
Announced or Revised: October 2021

The 50 State Medicaid Fraud Control Units (MFCUs), located in 49 States and the District of Columbia, investigate and prosecute Medicaid provider fraud as well as complaints of patient abuse or neglect in Medicaid-funded facilities and board and care facilities. OIG provides oversight for the MFCUs and administers a Federal grant award that provides 75 percent of each MFCU's funding. As part of OIG's oversight, they provide guidance to the MFCUs; assess their adherence to Federal regulations, policy, and performance standards; and collect and analyse performance data. OIG will also provide technical assistance and training and identify effective practices in MFCU management and operations. OIG will perform onsite reviews of a sample of MFCUs.

Work Plan #: OEI-12-19-00170; OEI-07-21-00340; OEI-06-21-00360; OEI-09-22-00020
Government Program: Medicaid

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

Expected Issue Date: 2023
Announced or Revised: 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: Medicaid

States' Oversight of Medicaid Managed Care Medical Loss Ratios

Expected Issue Date: 2022
Announced or Revised: August 2021

The Federal Government pays its share of a State's Medicaid expenditures based on the Federal Medical Assistance Percentages (FMAPs), which vary depending on the State's per capita income. Although FMAPs are adjusted annually for economic changes in the States, Congress may increase FMAPs at any time. On March 18, 2020, the then President signed

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into law the Families First Coronavirus Response Act (FFCRA), which provided a temporary 6.2-percentage-point increase to each qualifying State's and territory's FMAP under section 1905(b) of the Act effective January 1, 2020. States must meet the requirements of section 6008(b) and (c) of the FFCRA to qualify to receive the temporary 6.2-percentage-point increase. OIG plans to perform audit work at selected States to determine whether those States met the requirements to receive the temporary COVID-19 FMAP increase.

Work Plan #: W-00-21-31556
Government Program: Medicaid

States' Oversight of Medicaid Managed Care Medical Loss Ratios

Expected Issue Date: 2022
Announced or Revised: July 2021

Medical loss ratio (MLR) requirements in Medicaid managed care provide a method for addressing State and Federal concerns about growth in Medicaid spending. Federal MLR requirements are intended to ensure that Medicaid managed care plans spend most of the Medicaid capitation payments received from States on beneficiaries' medical care, which limits the amount plans can spend on administration and keep as profit. Pursuant to the May 2016 Medicaid managed care final rule, States must include requirements in managed care plan contracts for plans to calculate MLR percentages and report percentages and related, underlying data to the States. States' collections of complete and accurate MLR data from their managed care plans provide a critical first step for determining Medicaid managed care MLR performance nationwide. Complete and accurate MLR data also enable States to set appropriate managed care payment rates to control Medicaid costs. This work will: (1) determine whether States receive all required MLR data from their plans and (2) examine States' oversight of Medicaid managed care plans' compliance with MLR requirements.

Work Plan #: OEI-03-20-00231
Government Program: Medicaid

Audit of Medicaid Applied Behavior Analysis for Children Diagnosed with Autism

Expected Issue Date: 2022
Announced or Revised: June 2021

Autism spectrum disorder (autism) is a developmental disability that can cause significant social, communication, and behavioral challenges for children. According to the Centers for Disease Control and Prevention, there is currently no cure for autism; however, research has shown that early intervention and treatment can improve a child's development. A common treatment 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-00-21-31555
Government Program: Medicaid

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Medicaid Claims for Federal Reimbursement Using Managed-Care Proxy Methodology

Expected Issue Date: 2023
Announced or Revised: January 2021

Federal health care benefits are generally allowable when provided to a beneficiary who is a U.S. citizen, U.S. national, or qualified alien. Generally, a qualified alien is ineligible for full-scope Medicaid services before 5 years have passed from the date he or she enters the United States with qualifying status (5-year bar). Medicaid eligibility for most qualified aliens who are subject to the 5-year bar is generally limited to emergency services (restricted-scope services). States may choose to provide full-scope services to qualified aliens who are subject to the 5-year bar using their own State funds. Furthermore, States may choose to cover full-scope services to aliens permanently residing in the United States under color of law and to children under the age of 19 regardless of immigration status. However, the costs related to nonemergency services provided to non-citizens in these groups without satisfactory immigration status are not eligible for Federal reimbursement. OIG will review whether States properly claimed Federal Medicaid reimbursement related to services provided to non-citizens who lacked satisfactory immigration status.

Work Plan #: W-00-21-31554
Government Program: Medicaid

Comparison of T-MSIS Prescription Drug Payment Data to Actual Pharmacy Reimbursements for Medicaid Managed Care

Expected Issue Date: 2023
Announced or Revised: December 2020

Effective oversight of growing prescription drug costs in Medicaid requires accurate and consistent data. Managed Care Organizations (MCOs) are responsible for the majority of Medicaid enrollment and prescription drug reimbursements. The Centers for Medicare and Medicaid Services (CMS) established the Transformed Medicaid Statistical Information System (T-MSIS) to provide CMS, states, and other stakeholders with accurate and reliable Medicaid claims and encounter data to safeguard the Medicaid program. However, states' Managed Care drug claims data reported in T-MSIS may not uniformly represent drug payments across the Medicaid program. The data may contain the amounts MCOs or their pharmacy benefit managers (PBMs) paid to pharmacies or the amounts MCOs paid to their PBMs, which could include certain PBM fees known as "spread." CMS and states have expressed concerns that the use of spread pricing by PBMs lacks transparency and may inflate Medicaid drug costs. This evaluation will identify how states report managed care drug payment data to T-MSIS and determine the extent to which the data represents pharmacy reimbursements. Furthermore, OIG will identify how states ensure the accuracy of their T-MSIS managed care drug claims data and use these data to oversee managed care prescription drug expenditures and the PBMs' spread 'pricing practices.

Work Plan #: OEI-03-20-00560
Government Program: Medicaid

State Medicaid Agency Risk Assessments

Risk Assessment at a State Medicaid Agency (W-00-21-31552)

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Expected Issue Date: 2022
Announced or Revised: 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, enterprise-wide 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.

Risk Assessment of Puerto Rico Medicaid Program (W-00-20-31544)

Expected Issue Date: 2022
Announced or Revised: 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-00-21-31552
Government Program: Medicaid

Audit of Medicaid Components for States in Cycle 1 of CMS's PERM Review

Expected Issue Date: 2022
Announced or Revised: November 2020

The Improper Payments Information Act of 2002 requires the heads of Federal agencies to annually review programs they administer to identify programs that may be susceptible to significant improper payments and estimate the amount of improper payments. The Medicaid program has been identified as a program at risk for significant improper payments. CMS developed the Payment Error Rate Measurement (PERM) program to measure improper payments in the Medicaid program. PERM produces an improper payment rate based on reviews of the fee-for-service, managed care, and eligibility components of Medicaid. In 2017, CMS published a new, final rule implementing substantive changes to the PERM program that, among other things, were aimed at improving program integrity and promoting State accountability through policy and operational improvements. OIG will assess the adequacy of the PERM program by determining the accuracy of determinations for the eligibility, fee-for-service, and managed care components of the PERM error rate.

Work Plan #: W-00-20-31540
Government Program: Medicaid

Medicaid and ACA Enrollment Processes During the COVID-19 Pandemic

Expected Issue Date: 2022
Announced or Revised: November 2020

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Economic and health impacts caused by the COVID-19 pandemic have left States facing increases in new applications for health insurance through the Medicaid and ACA Marketplace programs. Responding to the pandemic, including meeting the new enrollment and oversight demands, has taxed State health care systems. This evaluation will assess efforts by the States and CMS to effectively enroll residents impacted by the COVID-19 pandemic in Medicaid and ACA Marketplace plans. By identifying effective practices or any breakdowns in enrollment and oversight systems, this review would help improve the efficiency of State health insurance enrollment processes under both emergency and more typical conditions.

Work Plan #: OEI-09-20-00590
Government Program: Medicaid

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

Expected Issue Date: 2022
Announced or Revised: 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: Medicaid

Joint Work with State Agencies

Expected Issue Date: 2022
Announced or Revised: October 2020

To strengthen program integrity and efficiently use audit resources, OIG will enhance their efforts to provide broader oversight of the Medicaid program by partnering with State auditors, State comptroller's 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.

Work Plan #: W-00-21-40002
Government Program: Medicaid

Medicaid: Expedited Provider Enrollment During COVID-19 Emergency

Expected Issue Date: 2022

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As a result of the coronavirus disease 2019 (COVID-19) pandemic, Medicaid provider enrollment through State Medicaid agencies has been expedited under the SSA §1135 Authority to Waive Requirements during National Emergencies. Rapid loosening of established provider screening and background check requirements may limit a State's ability to identify providers who are not eligible to participate in Medicaid. OIG's objective is to determine whether the State agency and providers complied with Federal and State requirements for newly enrolled providers under the national emergency declaration and if the State established tracking controls for these providers as well as giving providers adequate guidance on waived enrollment requirements.

Work Plan #: W-00-20-31547; W-00-21-31547; A-07-21-03248 (November 2021)
Government Program: Medicaid

Penetration Tests of State Medicaid Management Information Systems and Eligibility & Enrollment Systems

Expected Issue Date: 2022
Announced or Revised: 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
Government Program: Medicaid

Blood Lead Screening

There is no safe level of lead exposure for children. In the absence of timely screening, follow-up services, and treatment, children remain vulnerable to cognitive deficiencies associated with lead exposure. Medicaid-enrolled children are required to receive blood lead screenings. Under the Early and Periodic Screening, Diagnostic, and Treatment program, children are also entitled to receive follow up services and treatment for conditions identified through screenings (e.g., elevated blood lead levels (EBLLs). Although previous OIG reports identified low rates of lead screenings, an evaluation of follow up services for Medicaid-enrolled children with EBLLs has not been done.

Blood Lead Screening Tests, Follow up Services, and Treatment for Medicaid-Enrolled Children (OEI-07-18-00370)

Expected Issue Date: 2022
Announced or Revised: May 2020

OIG will identify the percentage of children under 26 months of age who (1) received required blood lead screenings, (2) had EBLLs, and (3) received needed follow up services and treatment. Additionally, OIG will determine why children with EBLLs did not receive screening, follow up services, and treatment and the extent to which the Centers for Medicare & Medicaid Services provided guidance and technical assistance to States.

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Blood Lead Screening Tests for Medicaid-Enrolled Children (OEI-07-18-00371)

Expected Issue Date: 2022
Announced or Revised: May 2020

This work expands on previous OIG work in EPSDT screenings and will incorporate State health department data to supplement screening rates for Medicaid-enrolled children who may receive lead screenings in other settings. Additionally, this work will identify barriers to and opportunities for improving required lead screenings and boosting education and outreach for practitioners, parents, and caregivers.

Work Plan #: OEI-07-18-00370, OEI-07-18-00371
Government Program: Medicaid

States' Oversight of Medicaid Managed Care Medical Loss Ratios

Expected Issue Date: 2021
Announced or Revised: April 2020

Medical loss ratio (MLR) requirements in Medicaid managed care are a method to address State and Federal concerns about the growth in Medicaid spending. Federal MLR requirements are intended to ensure that Medicaid managed care plans spend the majority of the Medicaid capitation payments that they receive from the State on beneficiaries' medical care rather than on administration and profit. Pursuant to the May 2016 Medicaid managed care final rule, States must include requirements in managed care plan contracts for plans to collect MLR data, calculate an MLR percentage, and report that percentage and related, underlying data to the State. States' collection of complete and accurate MLR data from their managed care plans is a critical first step for determining Medicaid managed care MLR performance nation-wide. Complete and accurate MLR data will also enable States to set appropriate managed care payment rates to control Medicaid costs. This work will provide timely, nation-wide data on MLR performance in Medicaid managed care and identify the actions that States have taken to ensure the completeness and accuracy of their managed care plans' MLR data.

Work Plan #: OEI-03-20-00230
Government Program: Medicaid

Medicaid MCO PBM Pricing

Expected Issue Date: 2022
Announced or Revised: 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 (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
Government Program: Medicaid

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MCO Payments for Services After Beneficiaries' Deaths

Expected Issue Date: 2023

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

Work Plan #: A-04-19-06223 (July 2020); A-05-19-00007 (January 2020); A-04-15-06190 (December 2017); A-06-16-05004 (November 2017); W-00-19-31497; W-00-20-31497; A-07-20-05125 (September 2021)
Government Program: Medicaid

Medicaid Concurrent Eligibility

Expected Issue Date: 2023

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 #: A-05-19-00032 (May 2021); A-05-19-00031 (February 2021); A-05-19-00023 (November 2020); W-00-19-31539
Government Program: Medicaid

Specialty Drug Coverage and Reimbursement in Medicaid

Expected Issue Date: 2021
Announced or Revised: September 2019

Medicaid spending on specialty drugs has rapidly increased. There is no standard definition for specialty drugs. They may be expensive, difficult to handle, monitor or administer; or treat rare, complex or chronic conditions. OIG will describe States' definitions of, and payment methodologies for, Medicaid specialty drugs and determine how much States paid for specialty drugs. OIG will also review strategies that States use to manage specialty drug costs, such as formularies, cost sharing, step therapy, and prior authorization.

Work Plan #: OEI-03-17-00430
Government Program: Medicaid

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Medicaid Eligibility Determinations in Selected States

Expected Issue Date: 2022

The Patient Protection and Affordable Care Act, § 2001, required significant changes affecting State processes for Medicaid enrollment, modified criteria for Medicaid eligibility, and authorized the use of an enhanced Federal Medical Assistance Percentages (FMAP) of 100 percent for newly eligible individuals. OIG will determine the extent to which selected States made inaccurate Medicaid eligibility determinations. OIG will examine eligibility inaccuracy for Medicaid beneficiaries in selected States that expanded their Medicaid programs pursuant to the Patient Protection and Affordable Care Act and in States that did not. OIG will also assess whether and how the selected States addressed issues that contributed to inaccurate determinations. For some States, OIG will calculate a Medicaid eligibility error rate and determine the amount of payments associated with beneficiaries who received incorrect eligibility determinations.

Work Plan #: A-07-16-04228 (August 2019); A-02-16-01005 (July 2019); A-09-16-02023 (February 2018); A-04-16-08047 (August 2017); W-00-16-31140; various reviews
Government Program: Medicaid

Opioids in Medicaid: Review of Extreme Use and Overprescribing in the Appalachian Region

Expected Issue Date: 2021
Announced or Revised: August 2019

Opioid abuse and overdose deaths remain at crisis levels in the United States and the Appalachian region. In 2017, opioids were involved in nearly 48,000 overdose deaths nation-wide, and the opioid overdose death rate was 72 percent higher in Appalachian counties than non-Appalachian counties. These issues are of particular concern for Medicaid beneficiaries, who are more likely to have chronic conditions and comorbidities that require pain relief, especially those beneficiaries who qualify through a disability. Consistent with previous OIG work in Medicaid and Medicare Part D, OIG will identify beneficiaries who received extreme amounts of opioids through Medicaid, beneficiaries who appear to be doctor or pharmacy shopping, and prescribers associated with these beneficiaries.

Work Plan #: OEI-05-19-00410
Government Program: Medicaid

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

Expected Issue Date: 2022

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.

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Work Plan #: A-02-16-01011 (August 2019); A-09-16-02031 (February 2018); A-06-16-00004 (December 2017); A-09-16-02028 (September 2017); A-09-16-02029 (September 2017); A-09-16-02027 (September 2017); A-07-16-06065 (May 2017); W-00-16-31483; various reviews
Government Program: Medicaid

Oversight and Effectiveness of Medicaid Waivers

Expected Issue Date: 2022

More States are using waivers to alter their Medicaid program in significant ways. Oversight of State waiver programs present challenges to ensure that payments made under the waivers are consistent with regards to efficiency, economy, and quality of care and do not inflate Federal costs. OIG will determine the extent to which selected States made use of Medicaid waivers and if costs associated with the waivers are efficient, economic, and do not inflate Federal costs. OIG will also look at Centers for Medicare & Medicaid Services oversight of State Medicaid waivers.

Work Plan #: A-05-19-00022 (June 2021); A-04-17-04058 (August 2019); A-02-17-01005 (July 2019); A-03-17-00200 (June 2018); W-00-17-31513
Government Program: Medicaid

States' Medicaid Agency Claims for Indian Health Service Expenditures

Expected Issue Date: 2022
Announced or Revised: August 2019

The Federal government pays its share of a State's Medicaid expenditures based on the Federal Medical Assistance Percentage (FMAP), which varies depending on the State's relative per capita income. States' regular FMAPs range from a low of 50 percent to a high of 83 percent; however, States receive a 100-percent FMAP for expenditures related to services received through Indian Health Service (IHS) facilities. In Federal fiscal years 2016 through 2018, States claimed $6.6 billion in expenditures at the IHS services FMAP, all of which was Federally funded. OIG will analyse selected States' methodologies for identifying expenditures claimed at the IHS services FMAP and determine whether the States claimed these expenditures in accordance with Federal requirements.

Work Plan #: W-00-19-31538
Government Program: Medicaid

Recovery of Federal Funds Through Judgments/Settlements

Expected Issue Date: 2022

Any State action taken because 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.

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Work Plan #: A-07-18-02814 (June 2021);A-03-17-00203 (June 2019); A-05-17-00041 (December 2018); W-00-17-31522; A-05-17-00000
Government Program: Medicaid

Overturned Denials in Medicaid Managed Care

Expected Issue Date: 2022
Announced or Revised: June 2019

Managed care organizations (MCOs) contract with State Medicaid agencies to provide beneficiaries with Medicaid services. MCOs must cover services in at least the same amount, duration, and scope that would be covered under Medicaid fee-for-service. However, capitated payment models in managed care may create an incentive for MCOs to inappropriately limit or deny access to covered services to increase profits. OIG will review the extent to which selected MCOs' denied services and payments were overturned upon appeal. OIG will also review any concerns about the selected MCOs' performance related to denials and appeals that were identified through State oversight and monitoring efforts.

Work Plan #: OEI: 09-19-00350
Government Program: Medicaid

States' Collection of Rebates on Physician-Administered Drugs

Expected Issue Date: 2022

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 #: A-02-16-01012 (May 2019); A-06-16-00018 (February 2018); A-05-16-00013 (November 2017); A-05-16-00014 (March 2019); W-00-16-31400; various reviews
Government Program: Medicaid

Review of State Uncompensated Care Pools

Expected Issue Date: 2022

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

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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 (October 2021)
Government Program: Medicaid

Medicaid Managed Care Organization Denials

Expected Issue Date: 2023
Announced or Revised: April 2019

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. The contractual arrangement shifts financial risk for the costs of Medicaid services from the State Medicaid agency and the Federal Government to the MCO, which can create an incentive to deny beneficiaries' access to covered services. OIG's review will determine whether Medicaid MCOs complied with Federal requirements when denying access to requested medical and dental services and drug prescriptions that required prior authorization.

Work Plan #: W-00-19-31535
Government Program: Medicaid

Delivery System Reform Incentive Payments

Expected Issue Date: 2022

Delivery System Reform Incentive Payments are incentive payments made under Section 1115 waivers to hospitals and other providers that develop programs or strategies to enhance access to health care, increase the quality and cost-effectiveness of care, and increase the health of patients and families served. States must be able to demonstrate outcomes and ensure accountability for allocated funding. These incentive payments have significantly increased funding to providers for their efforts related to the quality of services. For example, one State made incentive payments totaling more than $6 billion in a 5-year period. OIG will ensure that select States adhered to applicable Federal and State requirements when they made incentive payments to providers.

Work Plan #: A-06-17-09002 (August 2020); A-02-17-01007 (March 2019); W-00-17-31516; various reviews
Government Program: Medicaid

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Medical Loss Ratio - Recoveries of MCO Remittances from Profit-Limiting Arrangements

Expected Issue Date: 2022

When a State recovers a prior expenditure, it must refund the Federal share by reporting the recovery to Centers for Medicare & Medicaid Services at the FMAP used to calculate the amount it had originally received (SSA § 1903(d)(2); Centers for Medicare & Medicaid Services State Medicaid Manual, § 2500.6(B)). In its final rule (81 Fed. Reg. 27498 (May 6, 2016)), Centers for Medicare & Medicaid Services encouraged States to adopt provisions in contracts with managed care plans that would require remittances from the MCOs if a minimum medical loss ratio is not met. A medical loss ratio is a tool that can help ensure that the majority of capitated payments are used to deliver services to beneficiaries. Prior OIG reviews found that some States have adopted such remittance provisions. OIG will review States and managed care plans with contract provisions that require remittances from managed care plans if a minimum percentage of total costs to be expended for medical services (medical loss ratio) is not met. OIG will determine whether the Federal share of recoveries of MCO payments that States received through profit-limiting methodologies is returned to the Federal Government. Centers for Medicare & Medicaid Services reimburses each State at the FMAP for the quarter in which the expenditure was made (SSA § 1903(a)(1)).

Work Plan #: A-06-18-09001 (February 2019); W-00-18-31508

Government Program: Medicaid Duplicate Payments for Home Health Services Covered Under Medicare and Medicaid

Expected Issue Date: 2020
Announced or Revised: January 2019

Medicare Home Health Agency (HHA) coverage requirements state that an HHA is responsible for providing all services either directly or under arrangement while a beneficiary is under a home health plan of care authorized by a physician. Consequently, Medicare pays a single HHA overseeing that plan. "Dual eligible beneficiaries" generally describes beneficiaries eligible for both Medicare and Medicaid. Medicare pays covered medical services first for dual eligible beneficiaries because Medicaid is generally the payer of last resort. OIG will determine whether States made Medicaid payments for home health services for dual eligible beneficiaries who are also covered under Medicare.

Work Plan #: W-00-19-31141
Government Program: Medicaid

Medicaid Capitation Payments Made on Behalf of Incarcerated Individuals

Expected Issue Date: 2022
Announced or Revised: October 2018

States contract with Medicaid managed care organizations to provide specific services to enrolled Medicaid beneficiaries, 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, and guidance from the Centers for Medicare & Medicaid Services state that Federal financial participation is not available for services provided to inmates of public institutions, except when the inmate is not

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in a prison setting and becomes an inpatient in a medical institution. OIG will determine whether select States made unallowable capitation payments to Medicaid managed care organizations on behalf of individuals who were incarcerated.

Work Plan #: W-00-18-31534; various reviews
Government Program: Medicaid

Potential Abuse and Neglect of Children Receiving Medicaid Benefits

Expected Issue Date: 2022
Announced or Revised: August 2018

Medicaid beneficiaries, including children, are treated at inpatient and outpatient medical facilities for conditions that may be the result of abuse or neglect. Although all States have laws mandating reporting of suspected child abuse, these laws vary considerably in their definitions, scope, and procedures. Prior OIG reviews have highlighted problems with the quality of care and the reporting and investigation of potential abuse or neglect of vulnerable beneficiary populations at group homes, nursing homes, and skilled nursing facilities. Based on diagnoses from medical facilities treating conditions potentially related to abuse or neglect, OIG will determine the prevalence of Medicaid claims indicating potential abuse or neglect of children receiving Medicaid benefits.

Work Plan #: W-00-18-31533
Government Program: Medicaid

ACF Child Care Development Fund: Program Integrity

Expected Issue Date: 2020
Announced or Revised: August 2018

The Child Care and Development Fund (CCDF) program provides subsidized childcare to low-income families, families receiving temporary public assistance, and families transitioning from public assistance so family members can work or attend training or education. Each State must develop, and submit to the Administration for Children and Families (ACF) for approval, a plan that identifies the purposes for which CCDF funds will be spent for a 3-year grant period and designates a lead agency responsible for administering childcare programs. States receive block grants and other Federal funds (approximately $5.77 billion annually) to operate their childcare programs. Prior OIG work identified vulnerabilities in States' internal controls for the CCDF program and a national CCDF payment error rate of 5.74 percent. OIG will determine whether State agencies complied with Federal and State requirements when making payments to licensed providers under these childcare programs for Federal fiscal years 2016 through 2018.

Work Plan #: W-00-18-20019
Government Program: Medicaid

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

Expected Issue Date: 2022

Several State Medicaid agencies retain consultants to assist with preparing Medicaid claims for school-based activities. Consultants often are paid a contingency fee based on the percentage of Federal funds reimbursed to the State. During a prior review, OIG found that one consultant developed unsupported time studies that it used to develop payment rates for school-based health services. Based on those rates, the State claimed unallowable Federal funds. Consultants developed time studies using a similar methodology in many other States. OIG will initiate a multiple State review with a roll-up report to CMS to determine whether consultants developed school-based Medicaid rates based on unsupported time studies and unallowable costs in these States.

Work Plan #: A-04-18-07075 (November 2020); W-00-18-31529
Government Program: Medicaid

Duplicate Payments for Beneficiaries with Multiple Medicaid Identification Numbers

Expected Issue Date: 2022

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-04-20-07094 (December 2021); A-06-20-10003 (July 2021); A-02-20-01007 (May 2021); A-04-16-07061 (December 2017); W-00-16-31374; various reviews
Government Program: Medicaid

Use of Funds by Medicaid Managed Care Organizations

Expected Issue Date: 2022

Managed care is a health care delivery system organized to manage cost, utilization, and quality. In 2015, Federal Medicaid managed care payments were approximately $161.8 billion, which was more than 40 percent of the $349.8 billion in total Federal expenditures for Medicaid. States continue to expand their use of managed care. To deliver services to Medicaid managed care enrollees, States contract with managed care organizations (MCOs) and make monthly payments, called a capitation payment, to those plans to provide enrollees with Medicaid-covered services. Appropriately set capitation rates help to ensure that adequate payments are made to provide services to beneficiaries. OIG will examine how Medicaid funds received by MCOs are used to provide services to enrollees.

Work Plan #: A-05-18-00018 (September 2021); W-00-18-31526
Government Program: Medicaid

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Medicaid Managed Care Reimbursement

Expected Issue Date: 2022
Announced or Revised: November 2016

States contract with MCOs to provide coverage for specific services to enrolled Medicaid beneficiaries. In return for covering those services, MCOs are paid a set monthly capitation payment. Previous work by GAO found that Centers for Medicare & Medicaid Services' oversight of States' rate-setting required improvement and that States may not audit or independently verify the MCO-reported data used to set rates (GAO-10-810). OIG will review States' managed care plan reimbursements to determine whether MCOs are appropriately and correctly reimbursed for services provided. OIG will ensure that the data used to set rates are reliable and include only costs for services covered under the State plan or costs of services authorized by Centers for Medicare & Medicaid Services (42 CFR § 438.6(e)). OIG will also verify that payments made under a risk-sharing mechanism and incentive payments made to MCOs are within the limits set forth in Federal regulations.

Work Plan #: W-00-17-31471; various reviews
Government Program: Medicaid

Third-Party Liability Payment Collections in Medicaid

Expected Issue Date: 2022

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.

Work Plan #: A-05-21-00013 (October 2021); W-00-17-31517; A-05-17-00000
Government Program: Medicaid

Accountable Care in Medicaid

Expected Issue Date: 2020
Announced or Revised: November 2016

The Medicaid program is experiencing a shift toward new models that promote accountability for the cost and quality of care delivered to patients and focus on better, more efficient coordination of care. Several delivery system reform initiatives in Medicaid, including, for example, medical homes and accountable care organizations, focus on accountable care and include elements such as implementing value-based payment structures, measuring quality improvement, and collecting and analysing data. OIG will review selected accountable care models in Medicaid for compliance with relevant State and Federal requirements.

Work Plan #: W-00-17-31518; various reviews
Government Program: Medicaid

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Identifying Denied Claims in Medicare Advantage Encounter Data

Expected Issue Date: 2022
Announced or Revised: November 2021

CMS requires Medicare Advantage organizations (MAOs) to submit records of all services provided to beneficiaries to CMS's Medicare Advantage (MA) Encounter Data System. These records often (although not always) begin as claims for payments that health care providers submit to MAOs. MAOs must submit all records of services to CMS, including records of denied claims-i.e., claims for which an MAO determines it had no responsibility to pay the health care provider. CMS does not require MAOs to differentiate between paid and denied claims when submitting encounter records. In the absence of requiring a denied claims indicator, CMS requires each MAO to submit claim adjustment reason codes that contain information about how the MAO processed the claim and may be a helpful, but not definitive, method for identifying denied claims. The lack of a definitive method to identify denied claims in the MA encounter data may limit the use of these data to ensure MA program integrity and quality of care. This work will: (1) determine the extent to which the MA encounter data contained potentially denied claims and (2) identify any challenges to MA program oversight that result from the lack of a denied claim indicator on services in the MA encounter data.

Work Plan #: OEI-03-21-00380
Government Program: Medicare Part C – Advantage

Ineligible Providers in Medicare Part C and Part D

Expected Issue Date: 2022
Announced or Revised: October 2020

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 beneficiaries. Federal law prohibits Medicare payments for services provided or prescriptions written by individuals or entities who are excluded from Federal health care programs (excluded providers) when the sponsor knows or has reason to know of the exclusion. Federal regulations also prohibit Medicare payments to ineligible providers whose billing privileges have been deactivated, denied, or revoked. OIG will conduct a nationwide audit of Medicare Part C and Part D managed care data for calendar years 2018 and 2019 to identify ineligible providers that had been excluded, precluded, or deactivated as Medicare providers but provided services through Part C and D sponsors. OIG's audit will determine whether Part C and Part D sponsors complied with Federal requirements on preventing ineligible providers from rendering services to Medicare beneficiaries.

Work Plan #: W-00-20-35859
Government Program: Medicare Part C – Advantage

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Rates of Estimated Payments from Chart Reviews and Health Risk Assessments Across Medicare Advantage Organizations

Expected Issue Date: 2021
Announced or Revised: August 2020

The Medicare Advantage (MA) program provided coverage to 23 million beneficiaries in 2019 at a cost of $264 billion. CMS risk-adjusts these payments by using beneficiaries' diagnoses to pay higher capitated payments to MA organizations (MAOs) for beneficiaries expected to have greater health care needs. This payment policy may create financial incentives for MAOs to misrepresent beneficiaries' health status and make them appear to have additional illnesses and other conditions that would command higher payment. A previous OIG evaluation identified $6.7 billion in estimated 2017 risk-adjusted payments resulting from diagnoses that MAOs reported only on chart reviews, and not on any records of services provided to beneficiaries in 2016. Findings from this evaluation raise concerns about the completeness of payment data that MAOs submit to CMS, the validity of diagnoses on chart reviews, and the quality of care provided to beneficiaries. A current OIG evaluation examines the extent to which diagnoses solely generated by health risk assessments (HRAs) were associated with higher risk scores and higher MA payments. OIG will combine data from these evaluations to perform new analyses that will determine whether certain MAOs and parent organizations had higher or lower amounts of risk-adjusted payments from both chart reviews and HRAs relative to their peers.

Work Plan #: OEI-03-17-00474
Government Program: Medicare Part C – Advantage

Medicare Advantage Risk-Adjustment Data - Targeted Review of Documentation Supporting Specific Diagnosis Codes

Expected Issue Date: 2022

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.

Work Plan #: A-07-19-01187 (May 2021); W-00-20-35079; A-07-19-01188 (November 2021); A-07-17-01173 (October 2021)
Government Program: Medicare Part C – Advantage

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Inappropriate Denial of Services and Payment in Medicare Advantage

Expected Issue Date: 2022
Announced or Revised: June 2019

Capitated payment models are based on payment per person rather than payment per service provided. A central concern about the capitated payment model used in Medicare Advantage is the incentive to inappropriately deny access to, or reimbursement for, health care services to increase profits for managed care plans. OIG will conduct medical record reviews to determine the extent to which beneficiaries and providers were denied preauthorization or payment for medically necessary services covered by Medicare. To the extent possible, OIG will determine the reasons for any inappropriate denials and the types of services involved.

Work Plan #: OEI-09-18-00260
Government Program: Medicare Part C – Advantage

Review of CMS Systems Used to Pay Medicare Advantage Organizations

Expected Issue Date: 2021
Announced or Revised: December 2017

Medicare Advantage (MA) organizations submit to CMS diagnoses on their beneficiaries; in turn, CMS categorizes certain diagnoses into groups of clinically related diseases called hierarchical condition categories (HCC). For instances in which a diagnosis maps to a HCC, CMS increases the risk-adjusted payment. CMS has designed its Medicare Part C systems to capture the necessary data in order to make these increased payments to MA organizations. As CMS transitions to a new data system to make these payments, OIG will conduct analysis to inform both use of current systems and the transition to a new system. OIG will review the continuity of data maintained on current Medicare Part C systems. Specifically, OIG will review instances in which CMS made an increased payment to an MA organization for an HCC and determine whether CMS's systems properly contained a requisite diagnosis code that mapped to that HCC.

Work Plan #: W-00-18-35804
Government Program: Medicare Part C – Advantage

Risk Adjustment Data - Sufficiency of Documentation Supporting Diagnoses

Expected Issue Date: 2022

Payments to Medicare Advantage organizations are risk adjusted based on 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 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

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that it supports the diagnoses that Medicare Advantage organizations submitted to Centers for Medicare & Medicaid Services for use in Centers for Medicare & Medicaid Services' risk score calculations and determine whether the diagnoses submitted complied with Federal requirements.

Work Plan #: A-07-16-01165 (April 2021); W-00-16-35078; various reviews
Government Program: Medicare Part C – Advantage

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Medicare Part D - Prescription Drug Program

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

Expected Issue Date: 2022
Announced or Revised: February 2022

Dual-eligible beneficiaries are enrolled in Medicaid but qualify for prescription drug coverage under Medicare Part D. As long as Part D plans meet certain limitations outlined in 42 CFR § 423.120, Part D plan sponsors have discretion to include different Part D drugs and drug utilization tools in their formularies. OIG will review the extent to which drug formularies developed by Part D plan sponsors include drugs commonly used by dual-eligible beneficiaries as required. The Affordable Care Act, § 3313, requires OIG to conduct this review annually.

Work Plan #: OEI-05-22-00230
Government Program: Medicare Part D - Prescription Drug Program

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How Part D Plans' Preference for Higher Cost Hepatitis C Drugs Affects Medicare Beneficiaries

Expected Issue Date: 2022
Announced or Revised: April 2021

In 2019, Medicare Part D spent approximately $2.5 billion for hepatitis C drugs to treat 50,000 beneficiaries with the disease. Three drugs—Harvoni, Epclusa, and Mavyret—accounted for 93 percent of expenditures, with annual Medicare costs ranging from $28,000 to $77,000 per beneficiary. A portion of these totals was shared by Medicare beneficiaries who faced thousands of dollars in out-of-pocket costs for hepatitis C drugs under Part D. In early 2019, Gilead—the manufacturer of Harvoni and Epclusa—launched authorized generic versions of both drugs with the expressed goal of reducing patients' out-of-pocket costs. The retail price of authorized generic versions is $24,000, which is significantly less than the prices of Harvoni and Epclusa, and even less than Mavyret. These lower list prices should in turn lead to lower out-of-pocket costs, as authorized generics are as effective as branded versions but sell for only a fraction of the cost. However, a preliminary analysis indicates that Medicare utilization has not shifted from brand name versions of Harvoni and Epclusa to their significantly cheaper, authorized generic versions or to Mavyret. This study will examine the utilization of hepatitis C drugs under Part D and the financial impact on Medicare Part D and beneficiaries.

Work Plan #: OEI-BL-21-00200
Government Program: Medicare Part D - Prescription Drug Program

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Medicare Part D Payments During Covered Part A SNF Stay

Expected Issue Date: 2022

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Announced or Revised: January 2021

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 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
Government Program: Medicare Part D - Prescription Drug Program

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Medicare Part D Compounded Drugs

Expected Issue Date: 2022
Announced or Revised: 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 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: Medicare Part D - Prescription Drug Program

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Medicare Part D Payments for Transmucosal Immediate-Release Fentanyl Drugs

Expected Issue Date: 2022
Announced or Revised: May 2020

Transmucosal Immediate-Release Fentanyl (TIRF) drugs are a Schedule II controlled substance. Medicare Part D covers TIRF drugs only for managing breakthrough pain in adult cancer patients who are already receiving and are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. OIG will determine whether TIRF drugs were appropriately dispensed in Medicare Part D in accordance with Medicare requirements.

Work Plan #: W-00-20-35846
Government Program: Medicare Part D - Prescription Drug Program

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Nationwide Audit of Medicare Part D Eligibility Verification Transactions

Expected Issue Date: 2022
Announced or Revised: February 2020

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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, Â§ 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
Government Program: Medicare Part D - Prescription Drug Program

Part D Sponsors Reporting of Direct and Indirect Remunerations

Expected Issue Date: 2022

Medicare calculates certain payments to sponsors based on 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 #: A-03-18-00007 (September 2020)**;** A-03-18-00006 (October 2019); W-00-18-35514
Government Program: Medicare Part D - Prescription Drug Program

Documentation of Pharmacies' Prescription Drug Event Data

Expected Issue Date: 2022

Drug plan sponsors must submit prescription drug event records, which is a summary record of individual drug claim transactions at the pharmacy, for the HHS Secretary to determine payments to the plans (SSA § 1860D-15(f)(1)). OIG will determine whether Medicare Part D prescription drug event records submitted by the selected pharmacies were adequately supported and complied with applicable Federal requirements. OIG will also conduct additional reviews of selected retail pharmacies identified in a prior OIG report as having questionable Part D billing.

Work Plan #: A-07-16-06068 (November 2018); W-00-17-35411; various reviews
Government Program: Medicare Part D - Prescription Drug Program

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