2021

OIG's Top Unimplemented Recommendations:

Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs



U.S. Department of Health and Human Services
Office of Inspector General

About the 2021 Edition

OlG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs is an annual publication of the Department of Health and Human Services (HHS), Office of Inspector General (OlG). In this edition, we focus on the top 25 unimplemented recommendations that, in OlG's view, would most positively affect HHS programs in terms of cost savings, public health and safety, and program effectiveness and efficiency, if implemented. These recommendations come from OlG audits and evaluations performed pursuant to the Inspector General Act of 1978, as amended. This publication is responsive to requirements of the Inspector General Act.¹

The top 25 unimplemented recommendations in this edition derive from audits and evaluations issued through December 31, 2020. As such, many of these recommendations predate the COVID-19 public health emergency. We recognize that COVID-19 response and recovery efforts continue to be a top priority for HHS, including OIG. As of September 21, 2021, OIG had 58 audits and evaluations underway related to COVID-19 response and recovery, which may result in recommendations that appear in future editions. OIG's completed and ongoing work related to COVID-19 is available via the COVID-19 Portal on our website.

This edition begins with a list of the top 25 unimplemented recommendations, grouped by the cognizant HHS operating division (OpDiv). For each of the top 25 recommendations, we outline key OIG findings and the OpDiv's reported progress toward implementation. In Appendix A, we include a list of all unimplemented OIG recommendations that require legislative action. In Appendix B, we include a broader list of OIG's significant unimplemented recommendations issued through June 1, 2021.

Additionally, in Appendix C we include a list of 95 significant recommendations reported in the 2020 edition of this publication that have since been implemented or closed.² This list includes several top 25 recommendations from the 2020 edition that were implemented by OpDivs in critical areas, such as followup care for children treated for attention deficit hyperactivity disorder and oversight of information technology systems.

In addition to this publication, OIG reports annually on the top management and performance challenges facing HHS.³ These challenges arise across HHS programs and cover critical HHS responsibilities that include delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity. We highlight management and performance challenges facing each OpDiv throughout this document.

For more information

More information on OIG's work, including the reports mentioned in this publication, appears on our website at https://oig.hhs.gov/. For questions about OIG's Top Unimplemented Recommendations and

¹ P.L. No. 113-235 (Dec. 16, 2014). The Inspector General Act requires Federal inspectors general to identify significant recommendations described in previous *Semiannual Report(s)* to *Congress* with respect to problems, abuses, or deficiencies for which corrective action has not been completed.

² OIG, 2020 OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs, Aug. 2020. Available at https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2020.pdf.

³ OIG, 2020 Top Management and Performance Challenges Facing HHS, Nov. 2020. Available at https://oig.hhs.gov/reports-and-publications/top-challenges/2020/2020-tmc.pdf.

the lists of legislative and significant unimplemented recommendations, please contact Public Affairs a <u>Public.Affairs@oig.hhs.gov</u> .

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Top 25 Unimplemented Recommendations

Details for each of the following recommendations are in the section of this document that follows. We note that the numbering of the recommendations does not necessarily signal prioritization.

Centers for Medicare & Medicaid Services (CMS)—Protecting Patients (Cross-Cutting)

- 1. To ensure that nursing homes are implementing actions to prevent the spread of COVID-19 and that they are protecting residents, CMS should assess the results of infection control surveys of nursing homes and revise surveys as appropriate, and clarify expectations for States to complete backlogs of standard surveys and high priority complaint surveys that were suspended in the early months of the pandemic.*
- 2. CMS should take actions to ensure that incidents of potential abuse or neglect of Medicare and Medicaid beneficiaries are identified and reported. *

CMS—Medicare Parts A and B

- 3. CMS should take steps to tie Medicare hospice payments to beneficiary care needs and quality of care to ensure that services rendered adequately serve beneficiaries' needs.*
- 4. CMS should reevaluate the inpatient rehabilitation facility (IRF) payment system, which could include seeking legislative authority to make any changes necessary to more closely align IRF payment rates and costs.
- 5. CMS should seek legislative authority to comprehensively reform the hospital wage index system.
- 6. CMS should recover overpayments of \$1 billion resulting from incorrectly assigning severe malnutrition diagnosis codes to inpatient hospital claims, ensure that hospitals bill appropriately moving forward, and conduct targeted reviews of claims at the highest severity level that are vulnerable to upcoding.*
- 7. CMS should analyze the potential impacts of counting time spent as an outpatient toward the 3-night requirement for skilled nursing facility (SNF) services so that beneficiaries receiving similar hospital care have similar access to these services.
- 8. CMS should consider seeking legislative authority to implement least costly alternative policies for Part B drugs under appropriate circumstances.

CMS—Medicare Parts C and D

- 9. CMS should pursue strategies to educate beneficiaries and providers about access to medication-assisted treatment drugs and naloxone (a drug that reverses opioid overdoses).*
- 10. CMS should provide targeted oversight for Medicare Advantage organizations that received a disproportionate share of risk-adjusted payments for diagnoses identified through in-home health risk assessments (HRA) with no other service records.*
- 11. CMS should require Medicare Advantage organizations to submit an ordering provider's national provider identifier (NPI) on encounter records for durable medical equipment, prosthetics, orthotics, and supplies, and for laboratory, imaging, and home health services.

12. CMS should develop and execute a strategy to ensure that Part D does not pay for drugs that should be covered by the Part A hospice benefit.

CMS—Medicaid

- 13. CMS should ensure that States' reporting of national Medicaid data is complete, accurate, and timely.
- 14. CMS should develop policies and procedures to improve the timeliness of and recover uncollected amounts identified by OIG's audits.
- 15. CMS should improve Medicaid managed care organizations' identifications and referrals of cases of suspected fraud or abuse.*
- 16. CMS should identify States with limited availability of behavioral health services and develop strategies and share information to ensure that Medicaid managed-care enrollees have timely access to these services.

Administration for Children and Families (ACF)

- 17. ACF and HHS should improve their operational, management, and communication systems to better address the safety, security, and mental health needs of unaccompanied children.*
- 18. ACF should develop a comprehensive strategy to improve States' compliance with requirements related to treatment planning and medication monitoring for children who are prescribed psychotropic medication.

Indian Health Service (IHS)

19. As a management priority, IHS should develop and implement a staffing program for recruiting, retaining, and transitioning staff and leadership to remote hospitals.

National Institutes of Health (NIH)

20. NIH should continue to build on its efforts to identify and mitigate potential foreign threats to research integrity.

Food and Drug Administration (FDA)

21. FDA should improve its use of Risk Evaluation and Mitigation Strategies (REMS) by enhancing the assessment review process, ensuring that assessment reviews are timely, and strengthening REMS to better address the opioid crisis.*

General Departmental

- 22. HHS should ensure it has effective response plans and provide necessary guidance to effectively respond to domestic and international public health emergences.
- 23. HHS should improve administration and management of contracts related to inherently government functions and personal services. HHS should also provide training to political appointees and senior leaders related to contract administration.*

- 24. HHS should ensure that all future web application developments incorporate security requirements from an industry-recognized web application security standard.
- 25. HHS should address gaps in cybersecurity incident response capabilities across the department.*
- * These recommendations appear on OIG's Top 25 list for the first time in this edition.

CMS—Protecting Patients (Cross-Cutting)

CMS oversees the two largest Federal health care programs, Medicare and Medicaid, as well as the Children's Health Insurance Program and Health Insurance Marketplace programs. More than 145 million beneficiaries—or more than 43 percent of Americans—rely on these programs for their health insurance including senior citizens, individuals with disabilities, low-income families and individuals, and individuals with end-stage renal disease. CMS provides direction and technical guidance for the administration of the Federal effort to plan, develop, manage, and evaluate health care financing programs and policies. OIG is committed to promoting positive change that helps CMS improve its programs and to ensuring the health and safety of the people served by them.

Relevant Top Management and Performance Challenges (TMCs):

- Ensuring the Financial Integrity of HHS Programs
- <u>Delivering Value, Quality, and</u>
 <u>Improved Outcomes in Medicare</u>
 <u>and Medicaid</u>
- Improving Collaboration to Better Serve Our Nation
- Protecting the Health and Safety of HHS Beneficiaries

Top Unimplemented Recommendations

To ensure that nursing homes are implementing actions to prevent the spread of COVID-19 and that they are protecting residents, CMS should assess the results of infection control surveys of nursing homes and revise the survey as appropriate, and clarify expectations for States to complete backlogs of standard surveys and high priority complaint surveys that were suspended in the early months of the pandemic.

Key OIG Findings

Nursing home residents are particularly vulnerable to infectious diseases because of age and underlying medical conditions. During the COVID-19 crisis, nursing homes have been extremely hard hit by infections and deaths. CMS and States share responsibility for oversight of the Nation's nearly 16,000 nursing homes, and one of the main tools used for the oversight of nursing homes are onsite surveys (inspections). From March 23 to May 30, 2020, States conducted onsite surveys at 31 percent of nursing homes. However, rates of surveys varied across the States. During the same time period in 2019—under normal operations—53 percent of nursing homes received an onsite survey. Surveys conducted during this timeframe in 2020 resulted in cited deficiencies for fewer nursing homes (only 3 percent of those surveyed), in part because of the limited scope and reduced time for onsite surveyors due to COVID-19. States reported that the pandemic exacerbated longstanding staffing shortages. States also raised concerns about survey backlogs they faced as a result of CMS's temporary suspension of standard surveys and high-priority complaint surveys.

Progress in Implementing the Recommendation

At the time the report was issued, CMS neither concurred nor nonconcurred with our recommendation. CMS described actions that it has taken to address the recommendation, such as continuing to assess and revise the infection control survey and issuing guidance regarding how States are to resume onsite surveys when they have the resources to do so. To ensure that nursing home surveys perform their critical function by protecting residents, further action by CMS to implement the recommendation should include continued assessment of and improvements to infection control surveys, as appropriate, and should address standard and complaint survey backlogs.

Relevant Report: OEI-01-20-00430 (December 2020)

CMS should take actions to ensure that incidents of potential abuse or neglect of Medicare and Medicaid beneficiaries are identified and reported.

Key OIG Findings

An estimated one in five high-risk hospital emergency room Medicare claims for treatment provided in 2016 resulted from potential abuse or neglect of beneficiaries residing in skilled nursing facilities (SNFs). SNFs failed to report many of these incidents to State Survey Agencies, and several agencies failed to report some findings of substantiated abuse to local law enforcement agencies. Additionally, CMS does not require all incidents of potential abuse or neglect and related referrals made to law enforcement and other agencies to be recorded and tracked. In another report, we identified 34,664 Medicare claims that contained diagnosis codes indicating the treatment of injuries potentially caused by abuse or neglect of beneficiaries from January 2015 through June 2017; an estimated 30,754 of these claims were supported by medical records that contained evidence of potential abuse or neglect. Additional OIG work identified cases of potential abuse of Medicare beneficiaries in hospice care and that hospices failed to act in some instances. These cases reveal vulnerabilities in beneficiary protections that CMS must address to better ensure that beneficiary harm is identified, reported, addressed, and ultimately prevented.

In Medicaid, we used claims data for emergency room services to identify incidents of potential child abuse or neglect. We estimated that of the 29,534 children in Medicaid with emergency room claims that included certain diagnosis codes indicative of potential abuse or neglect, the medical records for 29,260 of these children included evidence of incidents of potential child abuse or neglect. Furthermore, we estimated that 3,928 of the incidents associated with these children were not reported to child protective services. We also determined that most incidents of potential child abuse or neglect identified in our sample occurred in familiar settings involving perpetrators known to the victims. CMS did not identify similar incidents of potential child abuse or neglect during the same period or encourage the States to identify the incidents. Furthermore, we found in some of the cases of beneficiary harm we reviewed that beneficiaries have been seriously harmed when hospices provided poor care or failed to act in cases of abuse. These cases reveal vulnerabilities in beneficiary protections that CMS must address to better ensure that beneficiary harm is identified, reported, addressed, and ultimately prevented.

Progress in Implementing the Recommendation

With respect to using Medicare emergency room claims to identify potential abuse or neglect, CMS indicated it was in the process of revising its interpretive guidance that will clarify existing guidance on reporting violations. CMS stated it also is in the process of revising its instructions to Survey Agencies to assure that complaints of abuse and neglect are tracked and referred appropriately.

In the Medicare hospice setting, CMS is working to establish a hospice complaint hotline-related regulation and continues to strengthen guidance for surveyors to report crimes to local law enforcement agencies. CMS has not committed to revising the Condition of Participation regarding the reporting of abuse, neglect, and other harm but is planning to add new interpretive guidance for hospices to aid in the reporting of such harm.

Regarding potential child abuse and neglect of children in Medicaid, CMS stated that it will review existing Federal requirements to report suspected child abuse and neglect of Medicaid beneficiaries and assess their hospital Conditions of Participation and interpretive guidance for opportunities to strengthen the current language in order to address reporting of suspected abuse and neglect to appropriate authorities.

Relevant Reports: <u>A-01-16-00509</u> (June 2019); <u>A-01-17-00513</u> (June 2019); <u>OEI-02-17-00021</u> (July 2019); <u>A-01-19-00001</u> (July 2020)

CMS—Medicare Parts A and B

In 2019, approximately 38.6 million beneficiaries were enrolled in Medicare Parts A and B. Total expenditures for Medicare Parts A and B came to \$328.3 billion and \$365.7 billion, respectively, with Part A costs leading to a net loss of \$5.8 billion for the Hospital Insurance (HI) Trust Fund. The 2020 Annual Report by Medicare's Board of Trustees estimates that the Trust Fund for Medicare Part A (hospital insurance) will be depleted by 2026. It also projects that cost growth for Medicare Part B (medical insurance) will average 8.2 percent over the next 5 years, significantly outpacing U.S. economic growth. To ensure that Medicare effectively serves beneficiaries well into the future, HHS must foster sound financial stewardship, program integrity, and improved quality of care and health outcomes. This includes helping beneficiaries, clinicians, and providers; protecting Medicare dollars

Relevant TMCs:

- Ensuring the Financial Integrity of HHS Programs
- Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid
- Improving Collaboration to Better Serve Our Nation
- Protecting the Health and Safety of HHS Beneficiaries

from fraud, waste, and abuse; and implementing prudent payment policies. OIG's work promotes quality of care for Medicare beneficiaries in various settings. OIG also identifies and offers recommendations to reduce improper payments, prevent and deter fraud, and foster economical payment policies across Medicare Parts A and B benefits.

Top Unimplemented Recommendations

CMS should take steps to tie Medicare hospice payments to beneficiary care needs and quality of care to ensure that services rendered adequately serve beneficiaries' needs.

Key OIG Findings

Hospice payments are currently linked to length of stay and are independent of where the patient resides. Hospices receive the same payments for routine care for beneficiaries in nursing facilities as for beneficiaries at home, yet the nursing facilities already provide personal care services that are similar to hospice aide services included in Medicare hospice payments. Additionally, the hospice payment system does not take into account the quality of care provided by hospices, meaning there are no adjustments in overall payments, bonus payments, or other methods that tie payment to quality for hospices. OIG found that some hospices target certain beneficiaries who are likely to have long lengths of stay to maximize payments or target beneficiaries in settings where they can provide fewer services but receive the same payment rate. OIG also found that some hospices typically provide fewer than 5 hours of visits per week and seldom provide services on weekends—demonstrating that the payment system may not be aligned with beneficiaries' care needs and with providing appropriate and quality services.

Progress in Implementing the Recommendation

CMS indicated that it did not concur with this recommendation. CMS indicated that it is required by statute to pay hospice providers based on costs incurred when providing care.

Relevant Report: <u>OEI-02-16-00570</u> (July 2018)

4.

CMS should reevaluate the IRF payment system, which could include seeking legislative authority to make any changes necessary to more closely align IRF payment rates and costs.

Key OIG Findings

Medicare paid IRFs nationwide \$5.7 billion in 2013 for care to beneficiaries that was not reasonable and necessary. These errors occurred in part due to IRF payments that are not aligned with costs, which may have provided IRFs with a financial incentive to admit patients inappropriately.

Progress in Implementing the Recommendation

CMS indicated that it has taken several steps to ensure that IRF payments and costs align as closely as possible. In August 2020, CMS published a final rule that updated the IRF case-mix groups and the underlying data to better align IRF payments with patients' care needs. CMS indicated that it is continuing to monitor the changes to the IRF classification system, along with the effects of the COVID-19 pandemic, to determine what effects these have had on the relationship between IRF payments and costs. Furthermore, CMS stated that it is working on an IRF Review Choice Demonstration (RCD) to ensure that patients admitted to IRFs appropriately meet the Medicare criteria for IRF admission. In addition, CMS stated that it is collaborating with HHS/ASPE to develop a prototype and recommendations for a unified post-acute care payment system that will include IRFs, skilled nursing facilities, home health agencies, and long-term care hospitals. The goal of this project is to align Medicare post-acute care payments as closely as possible with the post-acute care needs of all Medicare beneficiaries, and break down the silos among post-acute care settings that currently incentivize post-acute care settings to seek out certain types of post-acute care patients over others. Finally, CMS is planning to issue the report to Congress containing the prototype and recommendations for the unified post-acute care payment system, as mandated by the IMPACT Act of 2014, in calendar year 2022.

Relevant Report: A-01-15-00500 (September 2018)

CMS should seek legislative authority to comprehensively reform the hospital wage index system.

Key OIG Findings

OIG identified significant vulnerabilities in the wage index system for Medicare payments. For instance, CMS lacks authority to penalize hospitals that submit inaccurate or incomplete wage data, and Medicare administrative contractor (MAC) limited reviews do not always identify inaccurate wage data. Additionally, wage indexes may not always accurately reflect local labor prices. Thus, Medicare payments to hospitals and other providers may not be appropriately adjusted to reflect local labor prices.

Progress in Implementing the Recommendation

In its final management decision regarding two, nonlegislative recommendations, CMS concurred with our recommendation that it work with MACs to develop a program of in-depth wage data audits at a limited number of hospitals each year, focusing on hospitals with wage data that highly influence wage indexes in their respective areas. CMS stated that it continuously evaluates the wage data audit process and is taking the recommendation into account when determining appropriate next steps. CMS nonconcurred with our recommendation that it rescind its own hold-harmless policy to use the wage data of a reclassified hospital to calculate the wage index of its original geographic area. CMS stated that it believes that using data from the most hospitals to calculate average wages for an area provides the most accurate and stable measure.

In CMS's final management decision regarding our legislative recommendations, CMS concurred and indicated that the President's Budget for Fiscal Year 2021 included a proposal for the creation of a statutory demonstration to test comprehensive wage index reform. The proposed demonstration is intended to redefine the labor market area to commuting data by ZIP Code, identify an alternative source for wage data, repeal the rural floor and other reclassifications and special payment adjustments, and provide civil monetary penalty authority to penalize hospitals that submit inaccurate or incomplete data.

Relevant Report: A-01-17-00500 (November 2018)

6.

CMS should recover overpayments of \$1 billion resulting from incorrectly assigning severe malnutrition diagnosis codes to inpatient hospital claims, ensure that hospitals bill appropriately moving forward, and conduct targeted reviews of claims at the highest severity level that are vulnerable to upcoding.

Key OIG Findings

Hospitals incorrectly billed Medicare for severe malnutrition diagnosis codes for 173 of the 200 claims that we reviewed. Hospitals used severe malnutrition diagnosis codes when they should have used codes for other forms of malnutrition or no malnutrition diagnosis code at all, resulting in net overpayments of \$914,128. On the basis of our sample results, we estimated that hospitals received overpayments of \$1 billion for FYs 2016 and 2017.

More generally, we found that hospitals are increasingly billing for inpatient stays at the highest severity level, which is the most expensive. The number of stays at the highest severity level increased almost 20 percent from FY 2014 through FY 2019, ultimately accounting for nearly half of all Medicare spending on inpatient hospital stays. The number of stays billed at each of the other severity levels decreased. At the same time, the average length of stay decreased for stays at the highest severity level, while the average length of all stays remained largely the same. Stays at the highest severity level are vulnerable to inappropriate billing practices such as upcoding—the practice of billing at a level that is higher than warranted. Specifically, nearly a third of these stays lasted a particularly short amount of time and more than half of the stays that were billed at the highest severity level had only one diagnosis qualifying them for payments at that level. Furthermore, hospitals varied significantly in billing these stays, with some billing much differently than most.

Progress in Implementing the Recommendation

With respect to the inappropriate diagnoses of severe malnutrition, CMS stated that it will instruct its contractors to recover the overpayments consistent with relevant law and CMS's policies and procedures, and will instruct its Medicare contractors to review a sample of inpatient claims in the sample frame that were not part of the sample but were within the reopening period to determine whether they were billed correctly. We continue to recommend that CMS review all claims in our sampling frame that were not part of our sample but were within the reopening period and work with the hospitals to ensure they correctly bill Medicare when using severe malnutrition diagnosis codes.

In response to our recommendation that CMS conduct targeted reviews of Medicare Severity Diagnosis Related Groups and stays that are vulnerable to upcoding, as well as the hospitals that frequently bill them, CMS did not concur but acknowledged that there is more work to be done to determine conclusively which changes in billing are attributable to upcoding. Further oversight, in addition to RAC reviews already being conducted, is essential to ensuring that Medicare dollars are spent appropriately.

Relevant Reports: A-03-17-00010 (July 2020); OEI-02-18-00380 (February 2021)

CMS should analyze the potential impacts of counting time spent as an outpatient toward the 3-night requirement for SNF services so that beneficiaries receiving similar hospital care have similar access to these services.

Key OIG Findings

Beneficiaries with similar post-hospital care needs have different access to and cost sharing for SNF services depending on whether they were hospital outpatients or inpatients. We found an increased number of beneficiaries in outpatient stays pay more and have more limited access to SNF services than they would as inpatients. We also found hospitals continue to vary in how they use inpatient and outpatient stays, even though the policy was intended to promote consistency among hospitals. In a separate report based on a sample of SNF claims, we found that many SNFs incorrectly used a combination of inpatient and non-inpatient hospital days to determine whether the 3-night requirement was met, leading CMS to improperly pay an estimated \$84.2 million between 2013 and 2015.

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Progress in Implementing the Recommendation

In 2019, CMS analyzed counting time spent as an outpatient toward the 3-day inpatient hospital stay requirement for SNF Medicare coverage; its analysis identified potential impacts of a 20-percent uptick in SNF admissions and an increase in Medicare SNF expenditures of \$65 billion from 2021 to 2030. To implement our recommendation, CMS still needs to conduct an updated analysis about whether, and to what extent, beneficiaries failed to qualify for Medicare coverage of their SNF services, because some or all of their time spent in the hospital was as an outpatient. CMS should also reanalyze the potential impacts of counting time spent as an outpatient toward the 3-night requirement for SNF Medicare coverage.

We note that in response to the President's March 2020 declaration of a national emergency concerning the COVID-19 outbreak, CMS temporarily waived the requirement for a 3-day prior hospitalization for coverage of a SNF stay. The waiver allows temporary emergency coverage of SNF services without a qualifying hospital stay for beneficiaries who experience dislocations or are otherwise affected by COVID-19.

Relevant Reports: A-05-16-00043 (February 2019); OEI-02-15-00020 (December 2016)

CMS should seek legislative authority to implement least costly alternative policies for Part B drugs under appropriate circumstances.

Key OIG Findings

If the least costly alternative policies, which base the payment amount for a group of clinically comparable products on that of the least costly one, had not been rescinded for Part B drugs, Medicare expenditures for certain prostate cancer drugs would have been reduced by \$33.3 million over 1 year (from \$264.6 million to \$231.3 million). After least costly alternative policies were removed, utilization patterns shifted dramatically in favor of certain costlier products.

Progress in Implementing the Recommendation

CMS did not concur with the recommendation and indicated in its annual update that it does not plan to take actions at this time.

Relevant Report: OEI-12-12-00210 (November 2012)

SIGNIFICANT PROGRESS: Top 25 Recommendation From 2020 Edition

CMS should provide consumers with additional information about hospices' performance via Hospice Compare. <u>OEI-02-17-00020</u> and <u>OEI-02-16-00570</u>

Update: On December 21, 2020, Congress passed the Consolidated Appropriations Act, 2021, granting CMS the authority to disclose survey and certification information from accrediting organizations on its public website. The information published must be "prominent, easily accessible, readily understandable, and searchable" to hospice consumers. The new Care Compare website will house this information for the use of beneficiaries and their families, allowing them to select suitable hospice care. OIG will consider this recommendation fully implemented when the survey information becomes available to consumers on Care Compare. The effective date of the hospice provision in the Consolidated Appropriations Act, 2021, for the public disclosure of the survey information provided by accrediting organizations is October 1, 2022.

9.

CMS—Medicare Parts C and D

Approximately 45.7 million beneficiaries received Medicare Part D benefits and 22.2 million beneficiaries were enrolled in Medicare Part C in 2019. Part D is a prescription drug benefit provided through private insurance companies known as Part D plan sponsors. Medicare Advantage (Part C) enrollees receive their coverage through private insurance companies that contract with CMS. OIG's body of work has identified challenges in ensuring program integrity in the Medicare Advantage and Part D programs. Among top priorities, OIG is specifically focused on curbing the opioid epidemic through enforcement mechanisms and identifying inappropriate prescribers and beneficiaries at risk of abuse or overdose in the Medicare Advantage and Medicare Part D programs.

Relevant TMCs:

- Ensuring the Financial Integrity of HHS Programs
- Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid
- Protecting the Health and Safety of HHS Beneficiaries
- Harnessing Data To Improve the Health and Well-Being of Individuals

Top Unimplemented Recommendations

CMS should pursue strategies to educate beneficiaries and providers about access to medication-assisted treatment drugs and naloxone (a drug that reverses opioid overdoses).

Key OIG Findings

An in-depth review of 71,260 Medicare Part D beneficiaries whom OIG identified as being at serious risk of opioid misuse or overdose in 2017 found that about half of these beneficiaries had been diagnosed with opioid use disorder or other conditions related to the misuse of opioids. However, only 7 percent of those who were diagnosed with opioid use disorder received medication-assisted treatment (MAT) drugs through Part D, possibly because of challenges that beneficiaries have in accessing prescribers. In addition, about one-quarter of these 71,260 beneficiaries received a prescription for naloxone through Part D, a drug that reverses opioid overdoses. Although opioids can be appropriate under certain circumstances, Part D plan sponsors and CMS should take steps to mitigate the risk of misuse and overdoses among Medicare beneficiaries, especially when beneficiaries receive high amounts of opioids for long periods of time.

Progress in Implementing the Recommendation

CMS concurred and stated that it partners with Part D plan sponsors to promote awareness of opioid treatment and coverage options and that it has also worked to increase awareness among both beneficiaries and prescribers about coverage of MAT drugs and naloxone by including information on its websites and in the Medicare & You handbook. Furthermore, CMS said that it will continue to work with its partners within HHS when developing strategies to educate beneficiaries and providers. In addition,

CMS also stated that it planned to include language about naloxone in the 2021 Medicare Dear Doctor Letter.

Relevant Reports: <u>OEI-02-19-00130</u> (May 2020)

10.

CMS should provide targeted oversight for Medicare Advantage organizations that received a disproportionate share of risk-adjusted payments for diagnoses identified through in-home HRAs with no other service records.

Key OIG Findings

The risk adjustment program is intended to level the playing field for Medicare Advantage Organizations (MAOs) that enroll beneficiaries who need a costlier level of care by paying MAOs higher payments for sicker beneficiaries, which helps to ensure these beneficiaries have continued access to MA plans. HRAs can be a tool for identifying beneficiary health risks to improve beneficiaries' care and health outcomes. However, some MAOs may be initiating and using HRAs to collect diagnoses and maximize risk-adjustment payments without improving beneficiary care. OIG found that diagnoses that MAOs reported only on HRAs and no other encounter records resulted in an estimated \$2.6 billion in risk-adjusted payments in 2017 with in-home HRAs generating 80 percent of these estimated payments. Additionally, 20 MAOs generated millions of dollars in payments from in-home HRAs for beneficiaries for whom there was not a single record of any other service being provided in 2016.

Progress in Implementing the Recommendation

CMS concurred with our recommendations to provide targeted oversight of the 10 MAO parent organizations that drove most of the risk-adjusted payments resulting from in-home HRAs, and to provide targeted oversight of the 20 MAOs that drove risk-adjusted payments resulting from in-home HRAs for beneficiaries with no other service records in the 2016 encounter data. In CMS's Final Management Decision, CMS stated that it is continuing to consider how to provide this targeted oversight.

Relevant Report: OEI-03-17-00471 (September 2020)

11.

CMS should require MAOs to submit the ordering provider NPI on encounter records for durable medical equipment, prosthetics, orthotics, and supplies, and for laboratory, imaging, and home health services.

Key OIG Findings

Ordering and referring provider identifiers are not required in, and were frequently absent from, Medicare Advantage encounter data for records of durable medical equipment (DME), prosthetics, orthotics, and supplies, clinical laboratory, imaging, and home health services. The lack of ordering and referring provider identifiers limits the use of these data for vital program oversight and enforcement activities. For example, these provider identifiers are critical for identifying questionable billing patterns

and pursuing fraud investigations for ordering and referring providers. National Provider Identifiers are an important tool for assessing whether ordering or referring providers have determined that services were appropriate for patients.

Progress in Implementing the Recommendation

In its Final Management Decision, CMS stated that the Medicare program will need to undertake rulemaking to implement this requirement and that CMS was unable to provide details or a timeline for taking rulemaking action at that time.

Relevant Reports: <u>OEI-03-15-00060</u> (January 2018); <u>OEI-03-19-00430</u> (August 2020)

CMS should develop and execute a strategy to ensure that Part D does not pay for drugs that should be covered by the Part A hospice benefit.

Key OIG Findings

12.

Medicare Part D paid for drugs during 2016 that should have been covered by the daily rates paid to hospices under the Part A hospice benefit. Hospices are required to provide the beneficiary's drugs that are used primarily for the relief of pain and symptom control related to the terminal illness. If Part D pays for them, Medicare is in effect paying twice. The estimated Part D total cost was \$160.8 million for the sample of drugs that hospice organizations should have covered in 2016. Hospices likely should have also covered many of the other drugs provided to beneficiaries in hospice care for which Part D paid an additional \$261.9 million that same year.

Progress in Implementing the Recommendation

Although CMS agreed with the importance of avoiding duplicate payments to Medicare Part D drug plan sponsors and hospices, CMS neither concurred nor nonconcurred with our recommendation. However, in its comments to the report, CMS stated that its then-current efforts would address this issue and ensure that no disruption occurs in beneficiary access. For instance, CMS stated that it would continue to engage in meaningful activities to reduce duplicate payment in this area by, for example, ensuring that hospice providers are proactively educating beneficiaries on covered services and items (including drugs) and that Part D drug plan sponsors are appropriately applying prior authorization criteria and coordinating with hospice providers on drug coverage issues. As of June 2021, we had not received a Final Management Decision for this recommendation. Furthermore, CMS does not have any planned actions to work directly with hospices to ensure that they are providing drugs covered under the hospice benefit.

Relevant Reports: A-06-17-08004 (August 2019); OEI-02-16-00570 (July 2018); OEI-02-10-00491 (March 2016)

CMS—Medicaid

Medicaid serves more enrollees than any other Federal health care program, and Medicaid spending represents one-sixth of the national health care economy. In 2019, Medicaid spending grew 2.9 percent to \$613.5 billion. As of November 2020, Medicaid served nearly 79 million individuals, including those in the Children's Health Insurance Program (CHIP). OIG's work has identified substantial improper payments to providers across a variety of Medicaid services and on behalf of ineligible individuals. OIG has also identified concerns with the completeness and reliability of national Medicaid data. Medicaid has experienced longstanding program integrity vulnerabilities and challenges in ensuring that beneficiaries have access to and receive high-quality care.

Relevant TMCs:

- Ensuring the Financial Integrity of HHS Programs
- Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid
- Harnessing Data To Improve the Health and Well-Being of Individuals

Top Unimplemented Recommendations

CMS should ensure that States' reporting of national Medicaid data is complete, accurate, and timely.

Key OIG Findings

Effective oversight of Medicaid requires a national system with complete and accurate data. However, national Medicaid data, known as the Transformed Medicaid Statistical Information System (T-MSIS), have deficiencies that hinder timely and accurate detection of potential fraud, waste, poor quality care, and/or insufficient access to care. OIG has repeatedly found that States did not always submit complete Medicaid data needed for oversight. In one review, OIG found States did not submit complete data on provider identifiers and diagnosis codes for opioid prescriptions, hindering the ability to monitor and address the opioid crisis in Medicaid. In another review, OIG found that most States did not provide complete or accurate payment data on managed care payments to providers.

Progress in Implementing the Recommendation

CMS has made improving data quality in T-MSIS a priority. It is currently focused on improving a number of data elements. CMS conducts periodic checks of T-MSIS data for quality issues, provides guidance on the submission of data in various documents, and works with the States one-on-one to address concerns related to priority areas, which include payment data. In addition, it provides certain T-MSIS data to the public for research purposes and plans to release more recent data as the data become more complete. Despite these actions, CMS needs to continue its efforts to improve the accuracy and completeness of Medicaid data in T-MSIS. Having complete and accurate Medicaid data is especially important given the COVID-19 pandemic. As Medicaid enrollment has increased and utilization has changed, it is critical that the Department is able to track Medicaid payments for services and monitor utilization to ensure that

enrollees are receiving necessary care. Also, these data can be used to detect potential fraud schemes and to inform public health efforts

Relevant Reports: <u>OEI-05-18-00480</u> (August 2019); <u>OEI-02-15-00260</u> (July 2018); <u>OEI-03-19-00070</u> (March 2020); <u>OEI-02-19-00180</u> (March 2021)

14.

CMS should develop policies and procedures to improve the timeliness of recovering Medicaid overpayments and recover uncollected amounts identified by OIG's audits.

Key OIG Findings

CMS had not recovered all overpayments identified in OIG audit reports in accordance with Federal requirements. As of May 2018, CMS had recovered about \$909.2 million of the \$2.7 billion in Medicaid overpayments identified in the current and prior periods. However, CMS did not collect the remaining \$1.8 billion for 84 OIG audit reports. Specifically, CMS had not collected about \$1.6 billion in overpayments identified in 77 current period audits and \$188.6 million in overpayments identified in 7 prior period audits.

Progress in Implementing the Recommendation

In October 2018, CMS indicated that it had issued or was in the process of issuing disallowance letters totaling \$383.5 million for 10 audits. CMS has been working to resolve complex policy questions related to 27 audits with \$948.6 million in OIG-identified overpayments and has issued demand letters for \$142.8 million related to these audits. CMS has issued or is in the process of issuing either audit compromise letters or disallowance letters totaling \$143.5 million for 14 audits. CMS is still reviewing 33 audits totaling \$357 million in OIG-identified overpayments. CMS is also exploring options for improving the timeliness of discussions with State officials, obtaining documentation from States, and issuing disallowance letters. As of June 2021, CMS had collected \$381.9 million from 19 of the 84 reports. However, CMS had still not collected about \$1.5 billion in overpayments identified in 73 of the 84 audit reports.

Additionally, CMS continues to explore options for improving the timeliness of recovering identified overpayments. For instance, it recently realigned the financial management staff in its Financial Management Group and updated standard operating procedures and technical guidelines that it believes will make its processes more efficient to allow for more timely resolutions of identified overpayments. Under this realignment, CMS created an Audit and Review Branch for audit resolutions, as well as a Development and Oversight Branch, to ensure that Medicaid and CHIP financial policy is applied consistently on a national basis. In addition, the Financial Management Group is currently developing a Medicaid and CHIP Financial System to oversee and manage Medicaid and CHIP financial reporting; this system will replace the Medicaid Budget and Expenditure System.

Relevant Report: A-05-17-00013 (December 2018)

16.

CMS should improve Medicaid managed care organizations' identifications and referrals of cases of suspected fraud or abuse.

Key OIG Findings

Managed care organizations (MCOs) have an important role in fighting fraud and abuse in Medicaid, yet weaknesses exist in their efforts to identify and address fraud and abuse. Although the number of cases varied widely, we found that some MCOs identified and referred few cases of suspected fraud or abuse to the State, and not all MCOs used proactive data analysis—a critical tool for fraud identification. In addition, MCOs took actions against providers suspected of fraud or abuse but did not typically inform the State, including when MCOs terminated provider contracts for reasons associated with fraud or abuse. Finally, MCOs did not always identify and recover overpayments, including those associated with fraud or abuse; overpayments are factored into future MCO payments from the State. These weaknesses may limit the States' abilities to effectively address fraud and abuse in their Medicaid programs.

Progress in Implementing the Recommendation

CMS concurred with the recommendation and indicated that it will work with States to provide technical assistance and education to identify fraud and abuse and share best practices to assist States in improving MCO identification and referral of cases of suspected fraud or abuse. CMS also indicated that Medicaid Managed Care subregulatory guidance on the program integrity provisions of the final rule will address weaknesses identified in the report.

Relevant Report: <u>OEI-02-15-00260</u> (July 2018)

CMS should identify States with limited availability of behavioral health services and develop strategies and share information to ensure that Medicaid managed care enrollees have timely access to these services.

Key OIG Findings

The State of New Mexico's Medicaid managed care program operates with limited availability of behavioral health services for its enrollees, including few behavioral health providers and difficulty arranging services. The challenges faced by New Mexico—including provider shortages and operating with limited availability of behavioral health services—are likely shared by other States and will require both State and national attention.

Progress in Implementing the Recommendation

CMS concurred with the recommendation and consulted with States and other stakeholders on the development of a template for States to attest to their plans' complying with managed care requirements. CMS intends that States' reporting requirements will be collected electronically through a web-based submission portal that will be available no later than June 2022. CMS indicated that its Annual Managed Care Program Report standardized template contains a category for availability, accessibility, and network adequacy standards as well as grievances related to access. After reviewing the information

submitted by States in these reports, CMS can assess whether additional standards are needed. Finally, CMS made available to States two toolkits. The first toolkit—the Behavioral Health Access Toolkit—highlights promising practices and strategies implemented by State Medicaid agencies and managed care plans. The second toolkit—the Quality Strategy Toolkit—describes regulatory requirements and provides consideration for State Medicaid agencies to improve their quality of managed care services, including reviewing existing network adequacy resources and detailing network adequacy standards.

Relevant Report: OEI-02-17-00490 (September 2019)

IMPLEMENTED: Top 25 Recommendation From 2020 Edition

CMS should collaborate with partners to develop strategies for improving rates of followup care for children treated for attention deficit hyperactivity disorder (ADHD). <u>OEI-07-17-00170</u>

Update: CMS collaborated with Federal partners and stakeholders to develop strategies for improving rates of followup care for children treated for ADHD. CMS worked with the Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration, Health Resources and Services Administration, and Administration for Children and Families to identify best practices that could be shared with States. CMS, along with Federal partners, also identified ways to work with States to improve rates of followup care for children treated for ADHD. CMS also met with the American Academy of Pediatricians (AAP) and invited the AAP to share its updated guidance regarding treatment of ADHD with States. AAP shared with the group information on its updated clinical guidelines and a companion article on the systemic barriers related to providing care to these children. Finally, CMS provided technical assistance to States through its Quality Technical Advisory Group. As a result of these actions, OIG has considered this recommendation as implemented.

17.

Administration for Children and Families (ACF)

ACF programs focus on promoting the economic and social well-being of families, children, individuals, and communities. OIG's work focuses on ensuring program integrity, quality of care, and safety in ACF's grants programs that provide critical health and human services to children, families, and communities. This includes ACF's Office of Refugee Resettlement (ORR) program, which is responsible for the care and well-being of unaccompanied migrant children who are in HHS custody prior to being released to sponsors in the United States.

Relevant TMCs:

- Protecting the Health and Safety of HHS Beneficiaries
- Improving Collaboration to Better Serve Our Nation

Top Unimplemented Recommendations

ACF and HHS should improve their operational, management, and communication systems to better address the safety, security, and mental health needs of unaccompanied children.

Key OIG Findings

OIG identified vulnerabilities in the mental health care provided to unaccompanied children (UC) as well as the safety incident reporting system and oversight of care provider facilities' physical security. In a September 2019 report, we found that ORR facilities faced challenges in addressing the mental health needs of children, especially those who had experienced significant trauma. In reports released in June 2020, OIG raised concerns about safety issues. We found that ORR's incident reporting system is not effective at capturing information about incidents that take place at provider facilities to assist ORR's efforts to ensure the safety of minors. Moreover, we found that ORR's reporting system lacks designated fields to capture information that ORR can use to oversee facilities and protect minors in their care. We also found that ORR relies primarily on facilities to self-identify and correct concerns with the physical security measures it requires. Furthermore, we found almost all facilities' inspection checklists did not include checks of whether all ORR-required physical security measures were present and working. In addition to these safety and welfare issues, we found that interagency communication failures and poor internal management decisions left HHS unprepared for the zero-tolerance policy. This lack of preparation impeded HHS's ability to identify, care for, and reunify separated children. Moreover, we found care provider facilities faced significant operational challenges at every stage of reunification, causing additional stress to children.

Progress in Implementing the Recommendation

ACF and HHS agreed with OIG's findings and have planned steps to implement the recommendations. Regarding the challenges in addressing the mental health needs of unaccompanied children, ACF indicated in its most recent update that it had taken steps to improve access to mental health treatment services for these children. ACF noted that it collaborated with the National Child Traumatic Stress Network to develop a four-part webinar series addressing trauma in unaccompanied children. ACF also

indicated that it requires that care provider staff have training in trauma-informed care to better understand and identify unaccompanied children with significant mental health needs. ORR is also taking action to hire and retain qualified mental health clinicians. There are still actions ACF must take to address the mental health needs of unaccompanied children, including demonstrating that ORR has developed a process for ensuring that the new training is required for all staff who have direct contact with children; fully implementing ORR's additional plans to hire and retain qualified mental health clinicians; evaluating maximum caseloads for individual mental health needs; and identifying strategies for connecting mental health specialists to care provider facilities, particularly those located in underserved areas.

Regarding ORR's incident reporting system, ACF indicated in a January 2021 update that it continues to incorporate new fields in its UC Path system. These new fields will allow ACF to ensure care providers have taken required steps in response to allegations of sexual misconduct and track the progress of third-party investigations. ACF indicated that the system was expected to be deployed in late 2021. Once the new system is deployed, ACF will need to document the relevant new fields, integrated definitions, and any updated or new guidance that helps care providers consistently identify and report significant incidents. ORR will also need to develop strategies to help care provider programs recruit and retain staff in order to ensure the reporting system is used correctly.

Regarding physical security measures, ACF indicated in a January 2021 update that it had updated its Site Visit Worksheet to confirm that facilities' inspection checklists include all ORR-required physical security measures. ACF still needs to document its updated Site Visit Worksheet and Walkthrough Checklist, as well as the final guidance that describes ORR's planned methods to ensure that facilities regularly report inspection checklist results to ORR. ORR also needs to complete its review to examine whether to enhance existing physical security requirements for facilities.

With respect to communication and management challenges, ACF indicated in a September 2020 update that it now routinely reports information about separated children to ACF and HHS leadership so that leadership is immediately aware of any new trends in separations. ACF also continues to coordinate with interagency partners to ensure the expeditious transfer of unaccompanied children. HHS still needs to take specific steps to address broader agency failures to prioritize children's interests, including directing ACF and ORR leadership to: 1) ensure that potential risks to children are explicitly assessed and considered in decisions about policies affecting unaccompanied children; 2) ensure that staff are not prevented from documenting concerns about children's well-being; and 3) clearly communicate to ACF and ORR leadership and staff that they are empowered and expected to elevate information, perspectives, and recommendations necessary to protect children's interests, with concerns about potential harm to children in HHS custody being taken seriously. ACF must also provide any new or revised interagency agreements designed to support UC Program operations. ORR still needs to ensure that any instructions facilities are expected to follow are in a searchable location with effective dates, as well as improve its UC Path system to include timely and accurate information on separation status.

Relevant Reports: <u>OEI-09-18-00431</u> (September 2019); <u>OEI-BL-18-00510</u> (March 2020); <u>OEI-09-18-00430</u> (June 2020); <u>OEI-05-19-00210</u> (June 2020); <u>A-12-20-20001</u> (December 2020)

ACF should develop a comprehensive strategy to improve States' compliance with requirements related to treatment planning and medication monitoring for children prescribed psychotropic medication.

Key OIG Findings

In the five States we reviewed, one in three children in foster care who were treated with psychotropic medications did not receive required treatment planning or medication monitoring. State requirements for psychotropic medication oversight in these States did not always incorporate suggested professional practice guidelines for treatment planning and medication monitoring.

Progress in Implementing the Recommendation

ACF plans to undertake several actions to improve States' compliance, including requesting that States report on successes and challenges in addressing psychotropic medication use requirements in their Child and Family Services Plans. ACF stated that it assessed the findings to the use of psychotropic medications in its State Child and Family Services Reviews and determined that it will continue to assess these concerns in future reviews. Furthermore, ACF plans to provide guidance for those States that must develop improvement plans in this area. Finally, ACF stated that the topic of oversight of psychotropic medications will be addressed with its constituency group of State foster care managers.

Relevant Report: OEI-07-15-00380 (September 2018)

Indian Health Service (IHS)

IHS, with an estimated annual budget of \$6.2 billion in FY 2021, is the largest HHS program serving the American Indian and Alaska Native (AI/AN) community, providing or funding health care services for approximately 2.6 million AI/ANs who belong to 574 federally recognized Tribes in 37 States. IHS services are administered through a system of 12 area offices and 170 IHS and tribally managed service

Relevant TMCs:

- Safeguarding Public Health
- <u>Protecting the Health and Safety</u>
 <u>of HHS Beneficiaries</u>

units. IHS faces longstanding challenges that have hindered its ability to provide quality care, ensure sound management of Federal funds, and comply with Medicare standards. OIG's body of IHS work continues to focus on improving the quality of care delivered by IHS, its management, and its infrastructure (including IT systems). OIG has also reviewed the use of funds across HHS programs that serve the AI/AN community.

Top Unimplemented Recommendation

As a management priority, IHS should develop and implement a staffing program for recruiting, retaining, and transitioning staff and leadership to remote hospitals.

Key OIG Findings

IHS closed the Rosebud Hospital emergency department in December 2015 due to Immediate Jeopardy deficiencies and staffing shortages. IHS reopened the hospital's emergency department in July 2016, but it was again cited with an Immediate Jeopardy deficiency in July 2018. Longstanding problems at Rosebud Hospital remain a concern, including difficulties with recruiting and retaining staff and frequent changes in leadership. Although IHS has made significant improvements since the closure, it continues to struggle with securing adequate onsite staffing and leadership, as indicated by recent deficiencies. In earlier OIG work that included all IHS-run hospitals, the inability to recruit and retain needed staff and the dependence on "acting" personnel and contracted providers emerged as key challenges for hospital administrators. In addition, remote hospitals often struggled to maintain their clinicians' skills necessary to treat complex inpatient cases.

Progress in Implementing the Recommendation

IHS stated that it will assemble a task force to create a workforce plan that was expected to be complete by May 2020. However, its initiation of the workforce plan was delayed by a number of factors, including its priority response to the COVID-19 public health emergency.

Prior to the COVID-19 public health emergency, IHS published in February 2019 a 5-year strategic plan for FYs 2019 through 2023. The strategic plan's objectives include a commitment to recruit and retain quality staff throughout IHS, including hospitals. As a part of the implementation plan for this objective, the IHS Deputy Director for Management Operations in July 2020 initiated the development of a multidisciplinary, senior-level working group to develop a comprehensive workforce plan to address recruitment, training, and placement of staff in hospital leadership positions, particularly in remote

locations. The target date for completion of the workgroup charge, with the final version of the comprehensive workforce plan and recommendations submitted to the IHS Director, was September 30, 2020.

Relevant Reports: OEI-06-17-00270 (July 2019); OEI-06-14-00011 (October 2016)

IMPLEMENTED: Top 25 Recommendation From 2020 Edition

IHS should increase oversight of information technology systems by IHS management. (A-18-17-11400)

Update: IHS has undertaken numerous activities to increase oversight through centralization of key IT systems, services, and cybersecurity functions that resulted in organizational changes that inherently increased oversight. IHS has a Health IT modernization project that includes a Roadmap and Strategic Options document issued by IHS in October 2019 that has been shared and is on the IHS Health Information Technology Modernization website. Other centralization efforts include the IHS implementation of centralized management of mobile devices across IHS, implementation of an enterprisewide, medical-provider credentialing system, implementation of a central enterprise architecture technical repository for enhanced technical tracking and control, and an enterprisewide IT service provider for all area offices. As a result of these actions, OIG has considered this recommendation as implemented.

National Institutes of Health (NIH)

NIH, the Nation's medical research agency, is the largest grant-making agency in HHS. It is made up of 27 Institutes and Centers, each with its own specific research agenda. It invests about \$41.7 billion annually in medical research, and more than 80 percent of its funding is awarded to extramural research projects. Recently, numerous congressional committees have expressed concerns about potential threats to the

Relevant TMC:

 Harnessing Data To Improve the Health and Well-Being of Individuals

integrity of taxpayer-funded research and intellectual property, including intellectual property theft and its diversion to foreign entities. OIG's work focuses on intellectual property and cybersecurity protections, compliance with Federal requirements and NIH grants and contract policies, and the integrity of grant application and selection processes.

Top Unimplemented Recommendation

NIH should continue to build on its efforts to identify and mitigate potential foreign threats to research integrity.

Key OIG Findings

NIH's Center for Scientific Review has strengths in its approach to vetting nominees' ability to be effective peer reviewers. However, its vetting gives little attention to foreign affiliation beyond requiring a justification for reviewers who are not based in North America. NIH enforces policies and procedures that protect confidential information in grant applications handled by peer reviewers, but it could do more to systemically and directly address concerns about foreign threats to the confidentiality of the peer review process. Additionally, although NIH has made progress in overseeing financial conflicts that extramural grantee institutions reported during the past decade, it could do more to ensure the adequacy and consistency of reviews. For instance, NIH cannot—and does not plan to—identify whether investigators' financial conflicts of interest (FCOIs) involve foreign interests. We also found that NIH has limited policies, procedures, and controls in place to ensure institutions report all sources of research support, financial interests, and affiliations.

Progress in Implementing the Recommendation

NIH concurred with the recommendation and is coordinating with Federal partners to update its peer-reviewer nominee guidance. For instance, it is working with the Office of National Security to develop a risk-based approach to identify peer reviewers who may pose a threat to integrity and working with other Federal agencies to develop a systematic, risk-based, data-driven approach to vetting nominees. NIH also is exploring ways to conduct targeted, risk-based oversight of peer reviewers using risk indicators identified from analysis of research integrity threats and peer review integrity violations. Additionally, NIH performs quarterly quality assurance reviews of pending Financial Conflict of Interest (FCOI) reports and the information exchange between NIH staff and grantee institutions. NIH is also developing procedures to document the FCOI quality assurance review process as well as whether FCOI processes

should be revised to address foreign influence concerns. Furthermore, NIH has completed its review of the 1,013 institutions that OIG identified as not having FCOI policies on their websites and plans to contact the institutions with active grant support to remind them of the requirement and request a link to a posted policy. It has also completed initial enhancements to its electronic research administration Commons Institutional Profile and FCOI Module that will require each institution to upload a FCOI policy prior to a grant award.

Relevant Reports: <u>OEI-01-19-00160</u> (September 2019); <u>OEI-03-19-00150</u> (September 2019); <u>A-03-19-03003</u> (September 2019); <u>OEI-05-19-00240</u> (March 2020)

Food and Drug Administration (FDA)

FDA is tasked with protecting public health by ensuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices. FDA is also responsible for regulating tobacco products and for the safety and

Relevant TMC:

Safeguarding Public Health

security of most of our Nation's food supply, cosmetics, dietary supplements, and products that give off radiation. FDA had an annual budget of approximately \$5.9 billion in FY 2020. It is responsible for the oversight of more than \$2.8 trillion in consumed food, medical products, and tobacco. FDA-regulated products account for approximately 20 percent of all U.S. consumer spending. FDA regulates about 78 percent of the U.S. food supply. OIG has a long history of FDA work focused on topics related to food safety, drug products, and medical devices. OIG's work on food safety has highlighted systemic and persistent public health and safety issues.

Top Unimplemented Recommendation

The FDA should improve its use of Risk Evaluation and Mitigation Strategies (REMS) by enhancing the assessment review process, ensuring that assessment reviews are timely, and strengthening REMS to better address the opioid crisis.

Key OIG Findings

While the opioid crisis continued with nearly 47,000 deaths in 2018, the FDA used REMS as tools to mitigate misuse and abuse of opioids. One REMS is a drug safety program that is intended to mitigate a specific serious risk associated with the use of a drug. The FDA specifies the requirements and approves the REMS. However, the drug manufacturer is responsible for developing and implementing the program. While REMS have the potential to help address the opioid crisis, OIG found that data quality issues made it challenging for the FDA to determine whether REMS for opioids have been effective. In addition to limitations in data from drug manufacturers, the FDA faced measurement challenges, such as a lack of baseline data, limited surveillance data, and an inability to distinguish the effects of REMS separate from other initiatives addressing opioid misuse and abuse. Furthermore, some opioid manufacturers engaged in deceptive marketing practices that undermined the REMS's educational messages regarding risk.

Progress in Implementing the Recommendation

The FDA indicated that it will update its policies, procedures, and guidance to ensure appropriate and timely reviews of the REMS assessments and clarify when other data might be useful to the FDA, including manufacturers' promotional materials submitted to the Office of Prescription Drug Promotion. However, staffing limitations make its timeline for completing these actions uncertain. Additionally, the FDA approved its modification of transmucosal immediate release fentanyl REMS (TIRF REMS), which includes a patient registry, on December 23, 2020. This registry will enable the FDA to better monitor usage in outpatients taking TIRF drugs with respect to opioid tolerance and

related serious adverse events including overdose and death. However, the FDA has not indicated it is monitoring the patient registry for known areas of risk, such as inappropriate conversions and off-label prescribing.

Relevant Reports: <u>OEI-04-11-00510</u> (February 2013); <u>OEI-01-17-00510</u> (September 2020)

SIGNIFICANT PROGRESS: Top 25 Recommendation From 2020 Edition

FDA should ensure an effective and timely process related to food facility inspections and food recalls. (A-01-16-01502) and (OEI-02-14-00420)

Update: The FDA took significant steps to address safety concerns in the food system. During the past two years, the FDA updated IT systems and created internal dashboards to better track and improve inspections of domestic food facilities and food recalls. The FDA conducted more timely followup inspections to ensure that significant violations are corrected and improved how it handles attempted inspections to ensure better use of resources. The FDA used tracking systems and updated audit plans to ensure that food recalls are conducted in a timely manner and procedures are followed throughout the process. In addition, the FDA launched its New Era of Smarter Food Safety initiative with goals such as enhanced traceability, improved predictive analytics, more rapid responses to outbreaks, reduced food contamination, and more.

OIG still has some unimplemented recommendations for the FDA related to food safety. We still recommend that the FDA consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements. We are also waiting for results from new FDA systems for tracking food recalls and FDA compliance actions to ensure that they are having their intended effects. However, while OIG will continue to track the FDA's progress in implementing its New Era of Food Safety and OIG's remaining food safety recommendations, we are no longer listing this issue as one of our Top 25 Unimplemented Recommendations given the significant progress made.

General Departmental

In FY 2020, HHS reported a total of approximately \$1.5 trillion in expenditures. HHS is the principal U.S. department for protecting the health of all Americans and providing essential human services. It also is responsible for coordinating and collaborating across its programs and with other Federal agencies, as well as outside the Federal Government with Tribal, State and local governments, international entities, industry, and other stakeholders. The COVID-19 pandemic underscores the critical importance of effective coordination in emergency preparedness and response. Moreover, all of HHS has to be vigilant in protecting programs and data from cyberattacks. OIG's work reveals the importance of effective and collaborative management within HHS and with HHS's partners, and areas for improvement.

Relevant TMCs:

- Safeguarding Public Health
- Harnessing Data To Improve the Health and Well-Being of Individuals
- Protecting the Health and Safety of HHS Beneficiaries
- Improving Collaboration To Better Serve Our Nation

Top Unimplemented Recommendations

HHS should ensure it has effective response plans and provides necessary guidance to effectively respond to domestic and international public health emergencies.

Key OIG Findings

In an August 2019 report, OIG found that HHS did not always efficiently plan and coordinate its international response efforts. Specifically, OIG found that HHS had no strategic framework in place to coordinate global health security at the international or departmental levels before the Ebola outbreak in 2014 and 2015. OIG also found that HHS was not prepared to deploy the resources needed for such a large-scale international response, and HHS did not have in place internal or external communication channels for responding to an international public health emergency. In an April 2020 report, OIG found that Health Care Coalitions (HCCs), which help prepare their community health care systems to respond to public health emergencies and other emergencies, such as natural disasters, faced developmental challenges following new ASPR and CMS requirements established in 2017. Specifically, OIG found that some hospital preparedness program (HPP) requirements and some ASPR guidance were not clear. Unclear requirements and guidance may limit HCCs' ability to prepare for a whole community response to public health emergencies.

Progress in Implementing the Recommendation

As of April 2020, HHS had concurred with our recommendation and CDC stated that HHS continues to coordinate international preparedness and response efforts. However, HHS has not provided OIG its final management decision on its international preparedness efforts.

Regarding the domestic emergency preparedness efforts, ASPR concurred with our recommendation and indicated that it may clarify future guidance and continue to build and leverage collaboration with CMS regarding emergency preparedness Conditions of Participation and making resources available to HCCs.

ASPR also stated that it will continue to work with partners, including national professional associations, to provide information on the CMS emergency preparedness CoPs, and program and policy updates. However, ASPR has not provided OIG its final management decision on its domestic emergency preparedness efforts.

Relevant Reports: A-04-16-03567 (August 2019); OEI-04-18-00080 (April 2020)

HHS should improve administration and management of contracts related to inherently governmental functions and personal services. HHS should also provide training to political appointees and senior leaders related to contract administration.

Key OIG Findings

23.

We determined HHS contracts for CMS's strategic communications services were not administered and managed in accordance with Federal requirements. Specifically, a subcontractor individual was allowed to perform inherently governmental functions, such as making managerial decisions and directing Federal employees. We also determined that these nonpersonal strategic communications services contracts were administered as personal services contracts. Improving administration and management of contracts by training political appointees and senior leaders is critical to ensuring the proper administration of future Government contracts.

Progress in Implementing the Recommendation

HHS recently began conducting a special review of service contracts awarded and administered by the Department's operating and staff divisions. HHS stated that the purpose of this review is to assess and identify the implications of contractors performing inherently governmental functions or closely related functions; to ensure that personal service contracts entered into are performed in accordance with applicable laws and regulations; and that safeguards are in place to ensure that nonpersonal service contracts are not administered as personal service contracts. Moreover, HHS stated that implementation of a permanent procurement management oversight review structure is being developed to provide further oversight of the HHS acquisition portfolio. It is anticipated that initial reviews will begin during the first quarter of FY 2022. HHS stated that it also intends to develop briefing materials emphasizing the appropriate use of service contracts and governing rules as part of HHS's overall ethics training for all political appointees and senior leaders.

Relevant Report: A-12-19-20003 (July 2020)

24.

HHS should ensure that all future web application developments incorporate security requirements from an industry-recognized web application security standard.

Key OIG Findings

Security controls across eight OpDivs needed improvements to more effectively detect and prevent certain types of cyberattacks. During testing, we identified vulnerabilities in configuration management, access control, data input controls, and software patching. We determined that the cybersecurity of publicly accessed websites could be improved through the utilization of secure coding standards. Cybersecurity enhancements after application deployment are less effective and more costly.

Progress in Implementing the Recommendation

The HHS Policy for Software Development Secure Coding Practices was completed and approved in August 2019. Additionally, the HHS Policy for Internet and Email Security was completed and approved in October 2019. These policies support the reinforcement of strong firewall protections. The HHS Policy for Internet and Email Security policy specifies the baseline requirements for OpDivs to implement in order to secure their IT infrastructures. OpDivs continue to follow and implement HHS policies. However, HHS will monitor progress among OpDivs once it deploys its integrated risk management tool across HHS. OIG is awaiting evidence from HHS to demonstrate that the recommendation was implemented at all OpDivs.

Relevant Report: A-18-18-08500 (March 2019)

25.

HHS should address gaps in incident response capabilities across the department.

Due to increased cyberactivity associated with the current public health emergency, we are including only the title of our audit in the list of the top 25 unimplemented recommendations and on our public website for OIG's cybersecurity audits issued during this time period.

Relevant Report: <u>A-18-17-04002</u> (May 2020)

Appendix A: Unimplemented Legislative Recommendations

This appendix identifies OIG unimplemented recommendations that require legislative change to implement or that might best be addressed by legislation. It includes several of OIG's top 25 unimplemented recommendations, as indicated below. The recommendations are grouped by OpDiv. Some recommendations also include estimated cost savings that we believe would be generated if the specific recommendation(s) were implemented.

Administration for Children and Families (ACF)

Recommendation	Relevant Report(s)
ACF should conduct oversight activities to identify States that may not appoint a Guardian Ad Litem to every child victim who undergoes a judicial proceeding, seeking statutory authority as necessary.	ACF Cannot Ensure That All Child Victims of Abuse and Neglect Have Court Representation, OEI-12-16-00120 (February 2021)

Centers for Medicare & Medicaid Services (CMS)

Recommendation	Relevant Report(s)
CMS should seek legislative authority to establish a mechanism to control costs for automated chemistry tests.	Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions, OEI-09-19-00100 (August 2020)
Top 25 Recommendation #13 CMS should implement a method to recover from States the Federal share of inappropriate managed care capitation payments associated with terminated providers.	States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries, OEI-03-19-00070 (March 2020)
CMS should take steps to disallow Federal reimbursements to States for expenditures associated with unenrolled managed care organization (MCO) network providers, including seeking necessary legislative authority.	Twenty-Three States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries, OEI-05-19-00060 (March 2020)
CMS should seek legislative authority to align Medicare allowable amounts for these items with payments made by select non-Medicare payers. Estimated Savings: \$337,547,542 for CYs 2012 through 2015	Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers, <u>A-05-17-00033</u> (October 2019)
Top 25 Recommendation #5	Significant Vulnerabilities Exist in the Hospital Wage Index System for Medicare Payments, <u>A-01-17-00500</u> (November 2018)

Recommendation	Relevant Report(s)
CMS should seek legislative authority to comprehensively reform the hospital wage index system.	
CMS should take all necessary actions, including seeking legislative authority, to require suppliers to refund to beneficiaries incorrectly collected Medicare Part B deductible and coinsurance amounts for items and services reimbursable under Medicare Part A.	Medicare Improperly Paid Suppliers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Provided to Beneficiaries During Inpatient Stays, A-09-17-03035 (November 2018)
CMS should ensure that the Medicare Drug Integrity Contractor (MEDIC) has the ability to require medical records from prescribers of Part D drugs not under contract with plan sponsors, obtaining legislative authority if necessary.	The MEDIC Produced Some Positive Results But More Could Be Done To Enhance Its Effectiveness, OEI-03-17-00310 (July 2018)
Top 25 Recommendations #3 and #12 CMS should modify the payments for hospice care in nursing facilities, obtaining legislative authority if necessary.	Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio, OEI-02-16-00570 (July 2018)
CMS should seek a legislative change that would provide the agency flexibility to determine when noncovered versions of a drug should be included in Part B payment amount calculations.	Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and Its Beneficiaries, OEI-12-17-00260 (November 2017)
CMS should set firm deadlines for marketplaces to fully develop system functionality for verifying applicants' eligibility and resolving inconsistencies, assess potential enforcement mechanisms to ensure that marketplaces meet those deadlines, and seek legislative authority to establish mechanisms that have been identified.	CMS Did Not Provide Effective Oversight To Ensure That State Marketplaces Always Properly Determined Individuals' Eligibility for Qualified Health Plans and Insurance Affordability Programs, A-09-16-01002 (September 2017)
CMS should seek legislation to eliminate the lump-sum payment option for all power mobility devices.	Medicare Could Save Millions by Eliminating the Lump-Sum Purchase Option for All Power Mobility Devices, <u>A-05-15-00020</u> (May 2017)
Top 25 Recommendation #7 CMS should explore ways to protect beneficiaries in outpatient stays from paying more than they would have paid as inpatients, including by legislative authority if necessary.	Vulnerabilities Remain Under Medicare's 2-Midnight Hospital Policy, OEI-02-15-00020 (December 2016)
CMS should require the use of claim-level methods to identify 340B claims, obtaining legislative authority if necessary.	State Efforts To Exclude 340B Drugs From Medicaid Managed Care Rebates, OEI-05-14-00430 (June 2016)

Recommendation	Relevant Report(s)
CMS should seek legislation to adjust critical-access hospital (CAH) swing-bed reimbursement rates to the lower SNF rates. Estimated Savings: \$4.1 billion over a 6-year period from CY 2005 to CY 2010	Medicare Could Have Saved Billions at Critical Access Hospitals if Swing-Bed Services Were Reimbursed Using the Skilled Nursing Facility Prospective Payment System Rates, A-05-12-00046 (March 2015)
CMS should seek legislative authority to modify how coinsurance is calculated for outpatient services received at CAHs.	Medicare Beneficiaries Paid Nearly Half of the Costs for Outpatient Services at Critical Access Hospitals, OEI-05-12-00085 (October 2014)
CMS should seek legislation that would exempt reduced expenditures resulting from lower outpatient prospective payment system (PPS) payment rates from budget neutrality adjustments for procedures approved by ambulatory surgical centers (ASCs). Estimated Savings: Up to \$15 billion over a 6-year period from CYs 2012 to 2017	Medicare and Beneficiaries Could Save Billions if CMS Reduces the Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates, A-05-12-00020 (April 2014)
CMS should seek legislative authority to expand the diagnosis- related group window to include: additional days prior to the inpatient admission; and other hospital ownership arrangements, such as affiliated hospital groups. Estimated Savings: \$318 million in 2011⁴	Medicare and Beneficiaries Could Realize Substantial Savings if the Diagnosis Related Group Window Were Expanded, OEI-05-12-00480 (February 2014)
CMS should seek legislative authority to: remove Necessary Provider CAHs' permanent exemption from the distance requirement, allowing CMS to reassess these CAHs; and revise the CAH Conditions of Participation to include alternative location-related requirements.	Most Critical Access Hospitals Would Not Meet the Location Requirements if Required To Re-Enroll in Medicare, OEI-05-12-00080 (August 2013)
Estimated Savings: \$449 million in 2011 ⁵	
CMS should examine the additional potential impacts of establishing a prescription drug rebate program under Medicare Part B and, if appropriate, seek legislative change.	Medicare Could Collect Billions if Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs, OEI-12-12-00260 (September 2013)

⁴ The estimated \$318 million in savings is based on OIG's analysis of claims for services provided just prior to the window or

provided at affiliated hospitals during the window in 2011.

⁵ Medicare and beneficiaries would have saved \$449 million if CMS had decertified CAHs that were 15 or fewer miles from the nearest hospitals in 2011.

Recommendation	Relevant Report(s)
CMS should seek legislative change to prevent States from using State Supplementary Payments to shift Medicare Part B premium costs for full-benefit dual eligibles to the Federal Government.	Iowa Has Shifted Medicare Cost-Sharing for Dual Eligibles to the Federal Government, OEI-07-13-00480 (April 2013)
CMS should consider seeking a legislative change to require manufacturers of Part B-covered drugs to submit both average sales prices and average manufacturer prices.	Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2011, OEI-03-12-00670 (January 2013)
Top 25 Recommendation #8 CMS should consider seeking legislative authority to implement least costly alternative policies for Part B drugs under appropriate circumstances.	Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B, OEI-12-12-00210 (November 2012)
CMS and the Office of Medicare Hearings and Appeals should improve the handling of appeals from appellants who are also under fraud investigation and seek statutory authority to postpone these appeals when necessary.	Improvements Are Needed at the Administrative Law Judge Level of Medicare Appeals, OEI-02-10-00340 (November 2012)
CMS should work with Congress to require that manufacturers of first generics submit monthly average sales price data during initial generic availability.	Medicare Payments for Newly Available Generic Drugs, OEI-03-09-00510 (January 2011)
CMS should seek legislative authority or administratively require rural health clinic applicants to document need and the impact on access to health care in rural underserved areas.	Status of the Rural Health Clinic Program, OEI-05-03-00170 (August 2005)

Food and Drug Administration (FDA)

Recommendation	Relevant Report(s)
FDA should seek legislative authority to include information about a drug product's complete physical path through the supply chain on drug product tracing information.	Ownership—But Not Physical Movement— of Selected Drugs Can Be Traced Through the Supply Chain, OEI-05-17-00460 (February 2020)
Top Recommendation #21 FDA should seek legislative authority to enforce FDA assessment plans.	FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety, OEI-04-11-00510 (February 2013)
FDA should seek statutory authority to impose civil monetary penalties on companies that do not comply with registration requirements.	Dietary Supplements: Companies May Be Difficult To Locate in an Emergency, OEI-01-11-00211 (October 2012)

Recommendation	Relevant Report(s)
FDA should seek explicit statutory authority to review substantiation for structure/function claims to determine whether claims are truthful and not misleading.	Dietary Supplements: Structure/Function Claims Fail To Meet Federal Requirements, OEI-01-11-00210 (October 2012)
FDA should consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements.	FDA Inspections of Domestic Food Facilities, OEI-02-08-00080 (April 2010)

Health Resources and Services Administration (HRSA)

Recommendation	Relevant Report(s)
HRSA should share 340B ceiling prices with States, obtaining legislative authority if necessary.	State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs, OEI-05-09-00321 (June 2011)

Appendix B: Significant Unimplemented Recommendations

This appendix includes a list of significant unimplemented recommendations compiled from OIG audit and evaluation reports. The recommendations represent opportunities to achieve expected impact through cost savings, improvements in program effectiveness and efficiency, and increased quality of care and safety among program beneficiaries.

This appendix includes significant recommendations from audits and evaluations issued through June 1, 2021. The recommendations describe problems, abuses, or deficiencies for which corrective action has not been completed. The recommendations are generally grouped by OpDiv. The appendix includes OIG's top 25 unimplemented recommendations, as indicated. Note that the recommendations in this appendix include the exact wording from the associated audits or evaluations, some of which has been paraphrased in the top 25 recommendations summaries. Some recommendations also include estimated cost savings that we believe would be generated if the specific recommendation(s) were implemented. The hyperlinks provide more information on the report(s) relevant to each recommendation.

Centers for Medicare & Medicaid Services (CMS)—Medicare Parts A and B

Recommendation	Relevant Report(s)
 CMS should: take additional steps to validate the information reported in MDS assessments and supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes. 	CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes, OEI-07-19-00490 (May 2021)
 CMS should: provide data to consumers on nurse staff turnover and tenure, as required by Federal law; consider residents' levels of need when identifying nursing homes for weekend inspections; ensure the accuracy of non-nurse staffing data used on Care Compare; and take additional steps to strengthen oversight of nursing home staffing. 	CMS Use of Data on Nursing Home Staffing: Progress and Opportunities To Do More, OEI-04-18-00451 (March 2021)
Top 25 Recommendation #6 With respect to Medicare inpatient hospital stays, CMS should conduct targeted reviews of MS-DRGs and stays that are vulnerable to upcoding, as well as hospitals that frequently bill for them.	Trend Toward More Expensive Inpatient Hospital Stays in Medicare Emerged Before COVID-19 and Warrants Further Scrutiny, OEI-02-18-00380 (February 2021)

Recommendation	Relevant Report(s)
 Top 25 Recommendation #1 With respect to nursing home surveys, CMS should: clarify expectations for States to complete backlogs of standard surveys and high-priority complaint surveys, work with States to help overcome challenges with PPE and staffing, and assess the results of infection control surveys and revise the surveys as appropriate. 	Onsite Surveys of Nursing Homes During the COVID-19 Pandemic: March 23-May 30, 2020, OEI-01-20-00430 (December 2020)
 ensure that all States receive training on CMS's updated triage guidance and identify new approaches to address those States that are consistently failing to meet the required timeframes for investigating the most serious nursing home complaints. 	States Continued To Fall Short in Meeting Required Timeframes for Investigating Nursing Home Complaints: 2016-2018, OEI-01-19-00421 (September 2020)
CMS should work with manufacturers associated with errors to correct and resubmit accurate product data.	Some Drug Manufacturers Reported Inaccurate Product Data to CMS, OEI-03-19-00200 (September 2020)
 enhance efforts to ensure nursing homes meet daily staffing requirements and explore ways to provide consumers with additional information on nursing homes' daily staffing levels and variability. 	Some Nursing Homes' Reported Staffing Levels in 2018 Raise Concerns; Consumer Transparency Could Be Increased, OEI-04-18-00450 (August 2020)
To attempt recovery of Medicare overpayments, which we estimate to be valued at \$1,024,623,449, CMS should: • review the 224,175 inpatient claims in our sampling frame that were not part of our sample but were within the reopening period to identify which were incorrectly billed and recover identified overpayments; and • review how hospitals are using diagnosis code E41 for nutritional marasmus and diagnosis code E43 for unspecified severe protein-calorie malnutrition, and work with hospitals to ensure that they correctly bill Medicare when using severe malnutrition diagnosis codes.	Hospitals Overbilled Medicare \$1 Billion by Incorrectly Assigning Severe Malnutrition Diagnosis Codes to Inpatient Hospital Claims, A-03-17-00010 (July 2020)
Top 25 Recommendation #2 With respect to identifying potential child abuse and neglect, CMS should issue guidance, such as an Informational Bulletin, to inform States that performing a data analysis to identify Medicaid claims containing one or more diagnosis codes indicating potential child abuse or neglect could help identify incidents of potential child abuse	Medicaid Data Can Be Used To Identify Instances of Potential Child Abuse or Neglect, <u>A-01-19-00001</u> (July 2020)

Recommendation	Relevant Report(s)
or neglect and help ensure compliance with the States' mandatory reporting laws.	
CMS should require reconciliation of all hospital cost reports with outlier payments during a cost-reporting period. Estimated Savings: \$125 million per year for FYs 2011 through 2014	Hospitals Received Millions in Excessive Outlier Payments Because CMS Limits the Reconciliation Process, A-05-16-00060 (November 2019)
CMS should identify any claims for transfers to post-acute care in which incorrect patient discharge status codes were used and direct the Medicare contractors to recover any overpayments after our audit period.	Medicare Improperly Paid Acute-Care Hospitals \$54.4 Million for Inpatient Claims Subject to the Post-Acute-Care Transfer Policy, A-09-19-03007 (November 2019)
CMS should review the 37,124 outpatient claims totaling \$1,162,562 in potential overpayments to determine whether the outpatient facilities met the requirement to bill for chronic care management services and recoup any overpayments from outpatient facilities and: • recoup any overpayments from outpatient facilities and • instruct the outpatient facilities to refund corresponding overcharges to beneficiaries.	Medicare Made Hundreds of Thousands of Dollars in Overpayments for Chronic Care Management Services, A-07-17-05101 (November 2019)
 CMS should review Medicare allowable amounts for 161 orthotic device HCPCS codes for which Medicare and beneficiaries paid an estimated \$337,547,542 more than select non-Medicare payers and: adjust the allowable amounts, as appropriate, using regulations promulgated under existing legislative authority; or if the allowable amounts cannot be adjusted using regulations promulgated under existing legislative authority, seek legislative authority to align Medicare allowable amounts for these items with payments made by select non-Medicare payers; and routinely review Medicare allowable amounts for new and preexisting orthotic devices to ensure that Medicare allowable amounts are in alignment with payments made by select non-Medicare payers or pricing trends. 	Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers, A-05-17-00033 (October 2019)
Estimated Savings: \$337,547,542 for CYs 2012 through 2015 CMS should instruct DME MACs to: • recover \$36,825 in overpayments for the 39 unallowable claim lines and • notify the 22 suppliers associated with the 39 claim lines with potential overpayments of \$36,825 so that those suppliers can exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation.	Medicare Improperly Paid Suppliers an Estimated \$92.5 Million for Inhalation Drugs, A-09-18-03018 (October 2019)

Recommendation	Relevant Report(s)
CMS should develop a fraud prevention model specific to emergency ambulance transports from hospitals to SNFs to help ensure that payments for these ambulance transports comply with Federal requirements. Estimated cost savings: \$849,170 during CYs 2015 through 2017 (audit period) and \$119,548 in CY 2018	Medicare Incorrectly Paid Providers for Emergency Ambulance Transports From Hospitals to Skilled Nursing Facilities, A-09-18-03030 (September 2019)
 review the impact of programmatic changes on the ability of Accountable Care Organizations (ACOs) to promote value-based care, adopt outcome-based measures and better align measures across programs, and identify and share information about strategies that encourage patients to share behavioral health data. 	ACOs' Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program, OEI-02-15-00451 (July 2019)
 expand the deficiency data that accrediting organizations report to CMS and use these data to strengthen its oversight of hospices; include on Hospice Compare the survey reports from State agencies; include on Hospice Compare the survey reports from accrediting organizations, once authority is obtained; educate hospices about common deficiencies and those that pose particular risks to beneficiaries; and increase oversight of hospices with a history of serious deficiencies. 	Hospice Deficiencies Pose Risks to Medicare Beneficiaries, OEI-02-17-00020 (July 2019)
Top 25 Recommendation #2 CMS should: • strengthen requirements for hospices to report abuse, neglect, and other harm; • strengthen guidance for surveyors to report crimes to local law enforcement; • monitor surveyors' use of the Immediate Jeopardy citation; and • improve and make user-friendly the process for beneficiaries and caregivers to make complaints.	Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm, <u>OEI-02-17-00021</u> (July 2019)
Top 25 Recommendation #2 With respect to identifying instances of potential abuse or neglect, CMS should: • work with Survey Agencies to improve training for the staff of SNFs on how to identify and report incidents of potential abuse or neglect among Medicare beneficiaries,	Incidents of Potential Abuse and Neglect at Skilled Nursing Facilities Were Not Always Reported and Investigated, <u>A-01-16-00509</u> (June 2019)

Recommendation	Relevant Report(s)
 require that Survey Agencies record and track all incidents of potential abuse or neglect in SNFs and referrals made to local law enforcement and other agencies, monitor Survey Agencies' reporting of findings of substantiated abuse to local law enforcement, and clarify guidance to clearly define and provide examples of incidents of potential abuse or neglect. 	
 With respect to identifying instances of potential abuse or neglect, CMS should: assess the sufficiency of existing Federal requirements, such as CoPs and section 1150B of the Act, to report suspected abuse and neglect of Medicare beneficiaries, regardless of where services are provided, and strengthen those requirements or seek additional authorities as appropriate; compile a complete list of diagnosis codes that indicate potential physical or sexual abuse and neglect; use the complete list of diagnosis codes to conduct periodic data extracts of all Medicare claims containing at least one of the codes indicating either potential abuse or neglect of adult and child Medicare beneficiaries; and inform States that the extracted Medicare claims data are available to help States ensure compliance with their mandatory reporting laws. 	CMS Could Use Medicare Data To Identify Instances of Potential Abuse or Neglect, A-01-17-00513 (June 2019)
 With respect to Medicare's 3-day inpatient hospital stay requirement, CMS should: require hospitals to provide a written notification to beneficiaries whose discharge plans include post-hospital SNF care, clearly stating how many inpatient days of care the hospital provided and whether the 3-day rule for Medicare coverage of SNF stays was met (and if necessary, CMS should seek statutory authority to do so); and require SNFs to obtain from the hospital or beneficiary, at the time of admission, a copy of the hospital's written notification to the beneficiary and retain it in the beneficiary's medical record (and if necessary, CMS should seek statutory authority to do so). Estimated Savings: \$84.2 million based on estimates from CY 2013 	CMS Improperly Paid Millions of Dollars for Skilled Nursing Facilities When the Medicare 3-Day Inpatient Hospital Stay Requirement Was Not Met, A-05-16-00043 (February 2019)

Recommendation	Relevant Report(s)
CMS should take all necessary actions, including seeking legislative authority, to require suppliers to refund to beneficiaries incorrectly collected Medicare Part B deductible and coinsurance amounts for items and services reimbursable under Medicare Part A.	Medicare Improperly Paid Suppliers for Durable Medical Equipment Prosthetics, Orthotics, and Supplies Provided to Beneficiaries During Inpatient Stays, A-09-17-03035 (November 2018)
 CMS and the Secretary of Health and Human Services should revisit the possibility of comprehensive reform of the hospital wage index system, including the option of a commuting-based wage index. If there will not be comprehensive reform, CMS should: seek legislative authority to penalize hospitals that submit inaccurate or incomplete wage data in the absence of misrepresentation or falsification; seek legislation to repeal the law creating the rural floor wage index; seek legislation to repeal the hold-harmless provisions in Federal law, allowing CMS to calculate each area wage index based on the wage data of hospitals that reclassify into the area and hospitals geographically located in the area provided that they do not reclassify out; rescind its hold-harmless policy relating to geographically reclassified hospitals' wage data; and work with MACs to develop a program of in-depth wage data audits at a limited number of hospitals each year, focusing on hospitals with wage data that highly influence wage indexes in their areas. 	Significant Vulnerabilities Exist in the Hospital Wage Index System for Medicare Payments, A-01-17-00500 (November 2018)
Top 25 Recommendation #4 With respect to Medicare inpatient rehabilitation facility stays, CMS should reevaluate the IRF payment system, which could include considering the high error rate found in this report and Comprehensive Error Rate Testing reviews in future acute inpatient rehabilitation service payment reform, which may be a component of a unified post-acute-care PPS system.	Many Inpatient Rehabilitation Facilities Stays Did Not Meet Medicare Requirements, <u>A-01-15-00500</u> (September 2018)
CMS should expand the price-substitution policy. Estimated Savings: \$2.7 million ⁶	Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2016 Average Sales Prices, OEI-03-18-00120 (August 2018)

⁶ If CMS had expanded its price-substitution criteria to include certain other Part B drugs in 2016, Medicare and its beneficiaries could have saved up to an additional \$2.7 million over 1 year.

Recommendation	Relevant Report(s)
Recommendation Top 25 Recommendations #3 and #12 With respect to the Medicare hospice program, CMS should: • analyze claims data to inform the survey process; • develop other claims-based information and include it on Hospice Compare; • include in Hospice Compare deficiency data from surveys, including information about complaints filed and resulting deficiencies; • work with its partners, such as hospitals and caregiver groups, to make available consumer-friendly information explaining hospice benefits to beneficiaries and their families and caregivers; • ensure that a physician is involved in decisions to start and continue general inpatient care; • analyze claims data to identify hospices that engage in practices or have characteristics that raise concerns; • take appropriate actions to follow up with hospices that engage in practices or have characteristics that raise concerns; • increase oversight of general inpatient care claims and focus particularly on general inpatient care provided in SNFs, given the higher rate at which these stays were inappropriate; • implement a comprehensive prepayment review strategy to address lengthy general inpatient care stays so that beneficiaries do not have to endure unnecessarily long time periods during which their pain and symptoms are not controlled;	Relevant Report(s) Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio, OEI-02-16-00570 (July 2018)
 develop and execute a strategy to work directly with hospices to ensure that they are providing drugs covered under the hospice benefit as necessary and that the costs of drugs covered under the benefit are not inappropriately shifted to Part D; 	
 assess the current payment system to determine what changes may be needed to tie payments to beneficiaries' care needs and quality of care to ensure that services rendered adequately serve beneficiaries' needs; 	
 adjust payments based on these analyses, if appropriate, to ensure that the payment system is aligned with beneficiary needs and quality of care; and modify payments for hospice care in nursing facilities. 	
CMS should:	CMS Paid Practitioners for Telehealth
 conduct periodic postpayment reviews for telehealth claim edits that cannot be implemented and implement all telehealth claim edits and 	Services That Did Not Meet Medicare Requirements, A-05-16-00058 (April 2018)

Recommendation	Relevant Report(s)
 work with Medicare contractors to implement all telehealth claims edits listed in the Manual. Estimated Savings: \$3.7 million during CYs 2014 and 2015 	
CMS should direct the Medicare contractors to recover the \$66,309,751 in identified improper payments. Estimated Savings: \$12.1 million over a 5-year period from January 2017 to December 2021.	Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination With Urine Drug Tests, A-09-16-02034 (February 2018)
CMS should seek a legislative change that would provide the agency flexibility to determine when noncovered versions of a drug should be included in Part B payment amount calculations.	Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and Its Beneficiaries, OEI-12-17-00260 (November 2017)
 identify strategies to increase MACs' collection of Zone Program Integrity Contractors and Unified Program Integrity Contractors referred overpayments and implement the surety bond requirement for home health providers and consider the feasibility of implementing surety bonds for other providers based on level of risk. 	Enhancements Needed in the Tracking and Collection of Medicare Overpayments Identified by Zone Program Integrity Contractors and Program Safeguard Contractors, OEI-03-13-00630 (September 2017)
CMS should continue to work with the Accredited Standards Committee to ensure that the device identifier is included on the next version of claim forms.	Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices, A-01-15-00504 (September 2017)
CMS should seek legislation to eliminate the lump-sum payment option for all power mobility devices. If such legislation had been in place during CY 2011 through CY 2014, Medicare could have saved at least an additional \$10,245,539.	Medicare Could Save Millions by Eliminating the Lump-Sum Purchase Option for All Power Mobility Devices, A-05-15-00020 (May 2017)
 Estimated Savings: \$10.2 million from CY 2011 through CY 2014 Top 25 Recommendation #7 With respect to Medicare's 2-midnight hospital policy, CMS should: conduct routine analysis of hospital billing and target for review the hospitals with high or increasing numbers of short inpatient stays that are potentially inappropriate under the 2-midnight policy, identify and target for review the short inpatient stays that are potentially inappropriate under the 2-midnight policy, 	Vulnerabilities Remain Under Medicare's 2-Midnight Hospital Policy, OEI-02-15-00020 (December 2016)

Recommendation	Relevant Report(s)
 analyze the potential impacts of counting time spent as an outpatient toward the 3-night requirement for SNF services so that beneficiaries receiving similar hospital care have similar access to these services, and explore ways of protecting beneficiaries in outpatient stays from paying more than they would have paid as inpatients. 	
CMS should provide guidance to hospices regarding the effects on beneficiaries when they revoke their election and when they are discharged from hospice care.	Hospices Should Improve Their Election Statements and Certifications of Terminal Illness, OEI-02-10-00492 (September 2016)
CMS should include information about potential events and patient harm in its quality guidance to rehabilitation hospitals.	Adverse Events in Inpatient Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries, OEI-06-14-00110 (July 2016)
 take appropriate action against hospitals and their off-campus provider-based facilities that we identified as not meeting requirements and require hospitals to submit attestations for all their provider-based facilities. 	CMS Is Taking Steps To Improve Oversight of Provider-Based Facilities, But Vulnerabilities Remain, OEI-04-12-00380 (June 2016)
CMS should revise and clarify site visit forms so that they can be more easily used by inspectors to determine whether a facility is operational.	Enhanced Enrollment Screening of Medicare Providers: Early Implementation Results, OEI-03-13-00050 (April 2016)
 CMS should: evaluate the extent to which Medicare payment rates for therapy should be reduced and adjust Medicare payments to eliminate any increases that are unrelated to beneficiary characteristics. 	The Medicare Payment System for Skilled Nursing Facilities Needs To Be Reevaluated, OEI-02-13-00610 (September 2015)
CMS should seek legislation to adjust CAH swing-bed reimbursement rates to the lower SNF PPS rates paid for similar services at alternative facilities. Estimated Savings: \$4.1 billion over a 6-year period from CY 2005 through CY 2010	Medicare Could Have Saved Billions at Critical Access Hospitals if Swing-Bed Services Were Reimbursed Using the Skilled Nursing Facility Prospective Payment System Rates, A-05-12-00046 (March 2015)
CMS should seek legislative authority to modify how coinsurance is calculated for outpatient services received at CAHs.	Medicare Beneficiaries Paid Nearly Half of the Costs for Outpatient Services at Critical Access Hospitals, OEI-05-12-00085 (October 2014)

Recommendation	Relevant Report(s)
CMS should amend current regulations to decrease the Part B payment rates for dispensing and supplying fees to rates similar to those of other payers, such as Part D and Medicaid. Estimated Savings: More than \$100 million in CY 2011 ⁷	Medicare Part B Prescription Drug Dispensing and Supplying Fee Payment Rates Are Considerably Higher Than the Rates Paid by Other Government Programs, A-06-12-00038 (September 2014)
CMS should conduct additional analysis to determine the extent to which financial incentives influence long-term care hospital readmission decisions.	Vulnerabilities in Medicare's Interrupted-Stay Policy for Long-Term- Care Hospitals, OEI-04-12-00490 (June 2014)
 explore the possibility of requiring providers to identify on the Part B claim the pharmacy that produced the compounded drug and explore the possibility of conducting descriptive analyses of Part B claims for compounded drugs. 	Compounded Drugs Under Medicare Part B: Payment and Oversight, OEI-03-13-00270 (April 2014)
CMS should seek legislative change to prevent States from using State Supplementary Payments to shift Medicare Part B premium costs for full-benefit dual eligibles to the Federal Government.	Iowa Has Shifted Medicare Cost- Sharing for Dual Eligibles to the Federal Government, <u>OEI-07-13-00480</u> (April 2014)
 Seek legislation that would exempt the reduced expenditures as a result of lower outpatient PPS payment rates from budget neutrality adjustments for ASC-approved procedures, reduce OPPS payment rates for ASC-approved procedures on beneficiaries with no-risk or low-risk clinical needs in outpatient departments, and then develop and implement a payment strategy in which outpatient departments would continue to receive the standard OPPS payment rate for ASC-approved procedures that must be provided in an outpatient department because of a beneficiary's individual clinical needs. Estimated Savings: Up to \$15 billion over a 6-year period from CY 2012 through CY 2017 	Medicare and Beneficiaries Could Save Billions if CMS Reduces the Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates, A-05-12-00020 (April 2014)
CMS should distinguish payments in the end-stage renal disease (ESRD) base rate between independent and hospital-based dialysis facilities.	Update: Medicare Payments for End Stage Renal Disease Drugs, OEI-03-12-00550 (March 2014)

⁷ Medicare Part B would have saved an estimated \$100 million if dispensing and supply fee payment rates were similar to Part D or Medicaid rates.

Recommendation	Relevant Report(s)
 CMS should seek legislative authority to expand the diagnosis-related group window to include: additional days prior to the inpatient admission and other hospital ownership arrangements, such as affiliated hospital groups; and other hospital ownership arrangements, such as affiliated hospital groups. 	Medicare and Beneficiaries Could Realize Substantial Savings if the Diagnosis Related Group Window Were Expanded, <u>OEI-05-12-00480</u> (February 2014)
Estimated Savings: \$318 million in 2011 ⁸	
CMS should work with AHRQ to add a question to the Consumer Assessment of Healthcare Providers and Systems to assess beneficiaries' fears of reprisal.	The ESRD Beneficiary Grievance Process, OEI-01-11-00550 (December 2013)
CMS should instruct Medicare contractors to increase monitoring of outlier payments.	Medicare Hospital Outlier Payments Warrant Increased Scrutiny, OEI-06-10-00520 (November 2013)
CMS should use the Medicare Appeals System to monitor Medicare contractor performance.	The First Level of the Medicare Appeals Process, 2008-2012: Volume, Outcomes, and Timeliness, OEI-01-12-00150 (October 2013)
CMS should examine the additional potential impacts of establishing a prescription drug rebate program under Medicare Part B and, if appropriate, seek legislative change.	Medicare Could Collect Billions if Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs, OEI-12-12-00260 (September 2013)
 CMS should seek legislative authority to: remove Necessary Provider CAHs' permanent exemptions from the distance requirement, allowing CMS to reassess these CAHs and revise the CAH Conditions of Participation to include alternative location-related requirements. 	Most Critical Access Hospitals Would Not Meet the Location Requirements if Required to Re-Enroll in Medicare, OEI-05-12-00080 (August 2013)
Estimated Savings: \$449 million in 2011 ⁹	
CMS should ensure that all claims with exception codes are processed consistently and pursuant to Federal requirements.	Medicare Improperly Paid Providers Millions of Dollars for Incarcerated Beneficiaries Who Received Services During 2009 Through 2011, A-07-12-01113 (January 2013)

⁸ The estimated \$318 million in savings is based on OIG's analysis of claims for services provided just prior to the window or

provided at affiliated hospitals during the window in 2011.

9 Medicare and beneficiaries would have saved \$449 million if CMS had decertified CAHs that were 15 or fewer miles from the nearest hospitals in 2011.

Recommendation	Relevant Report(s)
Top 25 Recommendation #8 CMS should consider seeking legislative authority to implement least costly alternative policies for Part B drugs under appropriate circumstances.	Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B, OEI-12-12-00210 (November 2012)
CMS should implement the home health agency surety bond requirement.	Surety Bonds Remain an Unused Tool To Protect Medicare From Home Health Overpayments, OEI-03-12-00070 (September 2012)
CMS should adjust the estimated number of evaluation and management (E&M) services within musculoskeletal global surgery fees to reflect the actual number of E&M services being provided to beneficiaries, which would have reduced payments in CY 2007 alone by an estimated \$49 million, or use the results of this audit during the annual update of the physician fee schedule. Estimated Savings: \$49 million ¹⁰	Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided, A-05-09-00053 (May 2012)
CMS should adjust the estimated number of E&M services within cardiovascular global surgery fees to reflect the actual number of E&M services being provided to beneficiaries, which would have reduced payments in CY 2007 alone by an estimated \$14.6 million, or use the results of this audit during the annual update of the physician fee schedule.	Cardiovascular Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided, A-05-09-00054 (May 2012)
Estimated Savings: \$14.6 million ¹¹ CMS should facilitate access to information necessary to ensure accurate coverage and reimbursement determination.	Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, OEI-07-08-00150 (May 2011)
CMS should work with Congress to require manufacturers of first generics to submit monthly average sales price data during initial generic availability.	Medicare Payments for Newly Available Generic Drugs, OEI-03-09-00510 (January 2011)
CMS should adjust the estimated number of E&M services within eye global surgery fees to reflect the number of E&M services actually being provided to beneficiaries, or use the financial results of the audit in conjunction with other information during the annual updates of the physician fee schedule.	Nationwide Review of E&M Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005, <u>A-05-07-00077</u> (April 2009)
Estimated Savings: \$97.6 million per year ¹²	

¹⁰ Estimate based on CY 2007 data.

 $^{^{\}rm 11}$ Estimate based on CY 2007 data.

¹² Estimate based on CY 2005 data.

Recommendation	Relevant Report(s)
CMS should seek legislative authority or administratively require rural	Status of the Rural Health Clinic
health clinic applicants to document need and impact on access to	<i>Program</i> , <u>OEI-05-03-00170</u> (August
health care in rural underserved areas.	2005)

CMS—Medicare Parts C and D

Recommendation	Relevant Report(s)
CMS should encourage MAOs to perform program integrity oversight using ordering NPIs.	Medicare Advantage Organizations Are Missing Opportunities To Use Ordering Provider Identifiers To Protect Program Integrity, OEI-03-19-00432 (April 2021)
 Top 25 Recommendation #10 With respect to Medicare Advantage payments, CMS should: require MAOs to flag any MAO-initiated HRAs in MA encounter data, provide targeted oversight of the 20 MAOs that drove riskadjusted payments resulting from in-home HRAs for beneficiaries who had no other service records in the 2016 encounter data, provide targeted oversight of the 10 parent organizations that drove most of the risk-adjusted payments resulting from in-home HRAs, require MAOs to implement best practices to ensure care coordination for HRAs, and reassess the risks and benefits of allowing in-home HRAs to be used as sources of diagnoses for risk adjustments and reconsider excluding such diagnoses from risk adjustments. 	Billions in Estimated Medicare Advantage Payments From Diagnoses Reported Only on Health Risk Assessments Raise Concerns, OEI-03-17-00471 (September 2020)
 Top 25 Recommendation #11 With respect to Medicare Advantage encounter data, CMS should: require MAOs to submit the ordering provider NPI on encounter records for DMEPOS and for laboratory, imaging, and home health services; and establish and implement "reject edits" that reject encounter records in which the ordering provider NPI is not present when required and reject encounter records that contain an ordering provider NPI that is not a valid and active NPI in the National Plan and Provider Enumeration System registry. 	CMS's Encounter Data Lack Essential Information That Medicare Advantage Organizations Have the Ability to Collect, OEI-03-19-00430 (August 2020)
Top 25 Recommendation #9 With respect to beneficiaries receiving treatment for opioid use disorder, CMS should educate Part D beneficiaries about access to medication-assisted drugs and naloxone.	Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look, OEI-02-19-00130 (May 2020)
 CMS should: allow revocation of Medicare enrollment for inappropriate billing of Part D, 	Issue Brief: Key Medicare Tools To Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D, OEI-02-15-00440 (March 2020)

Recommendation	Relevant Report(s)
 apply the Preclusion List payment prohibitions to pharmacies and other providers that dispense Part D drugs, and include on the Preclusion List pharmacies that inappropriately bill Part D. 	
 CMS should: provide targeted oversight of MAOs that had risk-adjusted payments resulting from unlinked chart reviews for beneficiaries who had no service records in the 2016 encounter data, conduct audits that validate diagnoses reported on chart reviews in the Medicare Advantage encounter data, and reassess the risks and benefits of allowing the use of chart reviews that are not linked to service records as sources of diagnoses for risk adjustment. 	Billions in Estimated Medicare Advantage Payments From Chart Reviews Raise Concerns, OEI-03-17-00470 (December 2019)
 take action to reduce inappropriate pharmacy rejections; take action to reduce inappropriate coverage denials; and provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials. 	Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs, OEI-09-16-00411 (September 2019)
 Top 25 Recommendation #12 With respect to Medicare Part D drugs, CMS should: work directly with hospices to ensure that they are providing drugs covered under the hospice benefit and develop and execute a strategy to ensure that Part D does not pay for drugs that should be covered by the Part A hospice benefit. Estimated Savings: \$160.8 million a year in Part D total costs 	Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit, A-06-17-08004 (August 2019)
 CMS should: enhance its oversight of MAO contracts, including those with extremely high overturn rates and/or low appeal rates, and take corrective action as appropriate and provide beneficiaries with clear, easily accessible information about serious violations by MAOs. 	Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials, OEI-09-16-00410 (September 2018)
 CMS should: require plan sponsors to report Part C and Part D fraud and abuse incidents and the corrective actions taken to address them to a centralized system; provide the MEDIC centralized access to all Part C encounter data; require that Part C and Part D providers and pharmacies enroll in Medicare; clarify the MEDIC's authority to require records from pharmacies, pharmacy benefit managers, and other entities under contract with Part C and Part D plan sponsors; 	The MEDIC Produced Some Positive Results But More Could Be Done To Enhance Its Effectiveness, OEI-03-17-00310 (July 2018)

Recommendation	Relevant Report(s)
 ensure that the MEDIC has the ability to require medical records from prescribers of Part D drugs not under contract with plan sponsors and if necessary obtain legislative authority; and establish measures to assess the MEDIC's effectiveness. 	
 Top 25 Recommendation #11 With respect to Medicare Advantage encounter data, CMS should: require MAOs to submit ordering and referring provider identifiers for applicable records; ensure that MAOs submit rendering provider identifiers for applicable records; provide targeted oversight of MAOs that submitted a higher percentage of encounter records with potential errors; track MAOs' responses to reject edits; and establish and monitor MA encounter data performance thresholds related to MAOs' submissions of records with complete and valid data. 	Medicare Advantage Encounter Data Show Promise for Program Oversight, But Improvements Are Needed, OEI-03-15-00060 (January 2018)
CMS should assign a single entity to assist MACs in making coverage determinations.	MACs Continue To Use Different Methods To Determine Drug Coverage, <u>OEI-03-13-00450</u> (August 2016)
 CMS should: determine whether outlier data values submitted by MAOs reflect inaccurate reporting or atypical performance and use appropriate Part C reporting requirements data as part of its reviews of MAOs' performance. 	CMS Regularly Reviews Part C Reporting Requirements Data, But Its Followup and Use of the Data Are Limited, OEI-03-11-00720 (March 2014)
 CMS should: review data from Part D plan sponsors to determine why certain sponsors reported especially high or low numbers of incidents of potential fraud and abuse, related inquiries, and corrective actions; and share Part D plan sponsors' data on potential fraud and abuse with all sponsors and law enforcement. 	Less Than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse, OEI-03-13-00030 (March 2014)
CMS should recoup \$26 million in improper payments in accordance with legal requirements.	Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2010 Through 2012, <u>A-07-13-01125</u> (April 2014)
 CMS should: define pharmacy benefit managers as entities that could benefit from formulary decisions; 	Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions, OEI-05-10-00450 (March 2013)

Recommendation	Relevant Report(s)
 establish minimum standards requiring sponsors to ensure that safeguards are established to prevent improprieties related to employment by the entity that maintains the Medicare Part D Pharmacy and Therapeutics committee; and oversee compliance with Federal Pharmacy and Therapeutics committee conflict-of-interest requirements and guidance. 	
CMS should explore methods to develop and implement a mechanism to recover payments from Part C and Part D plan sponsors when law enforcement agencies do not accept cases for further action involving inappropriate services.	Medicare Drug Integrity Contractor (MEDIC) Benefit Integrity Activities in Medicare Parts C and D, OEI-03-11-00310 (January 2013)
CMS should exclude Schedule II refills when calculating payments to sponsors.	Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, OEI-02-09-00605 (September 2012)
CMS should hold sponsors more accountable for inaccuracies in the bids.	Medicare Part D Reconciliation Payments for 2006 and 2007, OEI-02-08-00460 (September 2009)
 CMS should: determine whether the Part D sponsors that identified fraud and abuse initiated inquiries and corrective actions as required by CMS and made referrals for further investigation as recommended by CMS and use this required information to help determine the effectiveness of sponsors' fraud and abuse programs. 	Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse, OEI-03-07-00380 (October 2008)

CMS—Medicaid

Recommendation	Relevant Report(s)
 Top 25 Recommendation #13 With respect to data on Medicaid managed care payments, CMS should: review States' managed care payment data in T-MSIS and ensure that States have corrective action plans to improve data completeness and quality, as appropriate; make public its reviews of States' managed care payment data; and clarify and expand its initiative on payment data, and make public its reviews of States' managed care payment data. 	Data on Medicaid Managed Care Payments to Providers Are Incomplete and Inaccurate, OEI-02-19-00180 (March 2021)
 CMS should: collaborate with States to conduct greater oversight of Medicaid MCOs' management of specialty drugs, and this oversight could 	States Could Do More To Oversee Spending and Contain Medicaid Costs for Specialty

Recommendation	Relevant Report(s)
 include a review of contract language that allows States to obtain requested information on specialty drug categorizations, specialty drug reimbursement methodologies, and cost management strategies; provide States with acquisition cost data for a wider range of specialty drugs; and work with States to expand alternative reimbursement models to address rising costs for drugs often categorized as specialty drugs. 	Drugs, <u>OEI-03-17-00430</u> (December 2020)
 CMS should: assist participating States in addressing the challenge of coordination between State-level departments and require that participating States consistently submit data that allow for CMS and each State to calculate determinations of ineligibility. 	National Background Check Program for Long-Term-Care Providers: Assessment of State Programs Concluded in 2019, OEI-07-20-00180 (September 2020)
CMS should verify that all State plans comply with Federal requirements prohibiting payments for provider-preventable conditions and issue clarifying guidance to States in specific areas (e.g., to help ensure that States identify provider-preventable conditions on inpatient claims from all inpatient hospitals).	CMS Could Take Actions To Help States Comply With Federal Requirements Prohibiting Medicaid Payments for Inpatient Hospital Services Related to Provider-Preventable Conditions, A-09-18-02004 (March 2020)
 Top 25 Recommendation #13 With respect to preventing terminated providers from serving Medicaid beneficiaries, CMS should: recover from States the Federal share of inappropriate fee-forservice Medicaid payments associated with terminated providers, implement a method to recover from States the Federal share of inappropriate managed care capitation payments associated with terminated providers, follow up with States to remove terminated providers that OIG identified as inappropriately enrolled in Medicaid, confirm that States do not continue to have terminated providers enrolled in their Medicaid programs, safeguard Medicaid from inappropriate payments associated with terminated providers, and review States' contracts with MCOs to ensure that they specifically include the required provision that prohibits terminated providers from participating in Medicaid managed care networks. 	States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries, OEI-03-19-00070 (March 2020)
CMS should: • take steps to disallow Federal reimbursements to States for expenditures associated with unenrolled MCO network providers, including seeking necessary legislative authority;	Twenty-Three States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries, OEI-05-19-00060 (March 2020)

Recommendation	Relevant Report(s)
 work with States to ensure that unenrolled providers do not participate in Medicaid managed care and assist States in establishing ways to do so; work with States to ensure that they have the controls required to prevent unenrolled ordering, referring, or prescribing providers from participating in Medicaid fee-for-service; and work with States to ensure that they are complying with requirements to collect identifying information and ownership information on Medicaid provider enrollment forms. 	
Top 25 Recommendation #16 With respect to availability of Medicaid behavioral health services, CMS should identify States with limited availability of behavioral health services and develop strategies and share information to ensure that Medicaid managed care enrollees have timely access to these services.	Provider Shortages and Limited Availability of Behavioral Health Services in New Mexico's Medicaid Managed Care, OEI-02-17-00490 (September 2019)
 CMS should: assess the costs and benefits of implementing a targeted process to review certain assumptions; issue guidance related to the areas identified in the report, specifically value-based purchasing arrangements; and implement a system to share responses to manufacturer inquiries for technical assistance. 	Reasonable Assumptions in Manufacturer Reporting of Average Manufacturer Prices and Best Prices, OEI-12-17-00130 (September 2019)
 Top 25 Recommendation #13 With respect to opioid prescribing in Medicaid, CMS should: ensure the correct submission of prescriber National Provider Identifiers and work to ensure that individual beneficiaries can be uniquely identified at a national level using T-MSIS. 	National Review of Opioid Prescribing in Medicaid Is Not Yet Possible, OEI-05-18-00480 (August 2019)
CMS should analyze the effectiveness of strategies for improving rates of followup care for children treated for ADHD.	Many Medicaid-Enrolled Children Who Were Treated for Attention Deficit Hyperactivity Disorder Did Not Receive Recommended Followup Care, OEI-07-17-00170 (August 2019)
 CMS should: ensure that all States fully implement fingerprint-based criminal background checks for high-risk Medicaid providers, amend its guidance so that States cannot forego conducting criminal background checks on high-risk providers applying for Medicaid that have already enrolled in Medicare unless Medicare has conducted the checks, and 	Problems Remain for Ensuring All High Risk Medicaid Providers Undergo Criminal Background Checks, OEI-05-18-00070 (July 2019)

Recommendation	Relevant Report(s)
compare high-risk Medicaid providers' self-reported ownership information to Medicare's provider ownership information to help States identify discrepancies.	
CMS should work with States to recoup any potentially inappropriate Federal reimbursement for drugs that CMS determines were not FDA-approved and did not meet the criteria for an exception.	One Percent of Drugs With Medicaid Reimbursement Were Not FDA-Approved, OEI-03-17-00120 (May 2019)
 work with the States reviewed to ensure that the instances of noncompliance with health and safety and administrative requirements identified in this report are corrected; assist all States to ensure the health and safety of vulnerable adults by offering technical assistance to look at staffing models in centers, homes, and other home and community-based service settings; and assist all States to ensure the health and safety of vulnerable adults by offering technical assistance to look at possible templates for administrative records in centers, homes, and other home and community-based service settings. 	Four States Did Not Comply With Federal Waiver and State Requirements in Overseeing Adult Day Care Centers and Foster Care Homes, A-05-19-00005 (May 2019)
 reconsider its position on permitting State agencies to certify nursing homes' substantial compliance on the basis of correction plans without obtaining evidence of correction for less serious deficiencies (deficiencies with ratings of D, E, and F without substandard quality of care); revise guidance to State agencies to provide specific information on how State agencies should verify and document their verifications of nursing homes' corrections of less serious deficiencies before certifying nursing homes' substantial compliance with Federal participation requirements; revise guidance to State agencies to clarify the type of supporting evidence of correction that should be provided by nursing homes with or in addition to correction plans; strengthen guidance to State agencies to clarify who must attest that a correction plan will be implemented by a nursing home; consider improving its forms related to the survey and certification process, such as the Forms CMS-2567, CMS-2567B, and CMS-1539, so that surveyors can explicitly indicate how a State agency verified correction of deficiencies and what evidence was reviewed; and work with State agencies to address technical issues with the automated survey processing environment system for maintaining 	CMS Guidance to State Survey Agencies on Verifying Correction of Deficiencies Needs To Be Improved To Help Ensure the Health and Safety of Nursing Home Residents, A-09-18-02000 (February 2019)

Recommendation	Relevant Report(s)
 CMS should: continue to follow its policies and procedures related to the audit resolution process and enhance them where possible to ensure that all management decisions are issued within the required 6-month resolution period; and promptly resolve the 140 outstanding audit recommendations that were past due as of September 30, 2016. 	Although CMS Has Made Progress, It Did Not Always Resolve Audit Recommendations in Accordance With Federal Requirements, A-07-18-03228 (January 2019)
CMS should instruct all State agencies to review, revise, develop, and implement policies and procedures to monitor school district administrative claiming and school-based health services programs in their States.	Vulnerabilities Exist in State Agencies' Use of Random Moment Sampling To Allocate Costs for Medicaid School-Based Administrative and Health Services Expenditures, A-07-18-04107 (December 2018)
Top 25 Recommendation #14 With respect to identified Medicaid overpayments, CMS should: • recover the remaining \$1,644,235,438 due the Federal Government from the current period; • recover the remaining \$188,593,212 due the Federal Government from the prior period; • develop policies and procedures to improve the timeliness of recovering overpayments when States disagree with recommendations by setting guidelines for the amount of time CMS has to: • discuss with State officials regarding the audit findings, • obtain documentation to substantiate the State's position, and • issue the disallowance letter to the State; • verify that future overpayment recoveries are reported correctly on line 10 of the CMS-64; • require States to submit corrected CMS-64s to identify recovered overpayments on line 10 when done incorrectly; and • continue to educate States about their responsibility to report overpayments on the correct line of the CMS-64 to improve oversight of the reporting process.	CMS Had Not Recovered More Than a Billion Dollars in Medicaid Overpayments Identified by OIG Audits, A-05-17-00013 (December 2018)
CMS should re-evaluate the effects of the health care-related tax safe-harbor threshold and the associated 75/75 requirement to determine whether modifications are needed.	Although Hospital Tax Programs in Seven States Complied With Hold-Harmless Requirements, the Tax Burden on Hospitals Was Significantly Mitigated, A-03-16-00202 (November 2018)

Recommendation	Relevant Report(s)
Top 25 Recommendations #13 and #15 With respect to Medicaid MCOs' efforts to identify and address fraud and abuse, CMS should: • improve the MCO identification and referral of cases of suspected fraud or abuse; • increase the MCO reporting of corrective actions taken against providers suspected of fraud or abuse to the State; • clarify the information MCOs are required to report regarding providers that are terminated or otherwise leave the MCO network; • identify and share best practices about payment retention policies and incentives to increase recoveries; • improve coordination between MCOs and other State program integrity entities; • standardize reporting of referrals across all MCOs in a State; • ensure that MCOs provide complete, accurate, and timely encounter data; and • monitor encounter data and impose penalties on States for submitting inaccurate or incomplete encounter data.	Weaknesses Exist in Medicaid Managed Care Organizations' Efforts To Identify and Address Fraud and Abuse, OEI-02-15-00260 (July 2018)
CMS should require the use of claim-level methods to identify 340B claims.	State Efforts To Exclude 340B Drugs From Medicaid Managed Care Rebates, OEI-05-14-00430 (June 2016)
CMS should require State Medicaid programs to verify the completeness and accuracy of provider ownership information.	Medicaid: Vulnerabilities Related to Provider Enrollment and Ownership Disclosure, OEI-04-11-00590 (May 2016)
 CMS should: help States implement fingerprint-based criminal background checks for all high-risk providers, develop a central system by which States can submit and access screening results from other States, strengthen minimum standards for fingerprint-based criminal background checks and site visits, and work with States to develop a plan to complete their revalidation screening in a timely way. 	Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented, OEI-05-13-00520 (May 2016)
 CMS should: issue guidance that clarifies requirements and provides further interpretation of the "as needed" language in 42 CFR § 430.30(d)(3) as it relates to the withdrawal of Medicaid funds; 	Opportunities for Program Improvements Related to States' Withdrawals of Federal Medicaid Funds, A-06-14-00068 (March 2016)

Recommendation	Relevant Report(s)
 publish regulations that are consistent with Department of the Treasury provisions in 31 CFR part 205 and educate States; publish and enforce formal guidance based on CMS's instructional email from November 8, 2011, so that States are aware of the appropriate Payment Management System account from which to withdraw or return funds; and require States to reconcile total Federal Medicaid funds withdrawn with the Federal share of net expenditures and issue appropriate reconciliation guidelines. 	
 CMS should: develop benchmarks for dental services and require States to create mandatory action plans to meet them, work with States to analyze the effects of Medicaid payments on access to dental providers, and work with States to track children's utilization of required dental services. 	Most Children With Medicaid in Four States Are Not Receiving Required Dental Services, OEI-02-14-00490 (January 2016)
CMS should issue Medicaid regulations to clarify the requirements of the Affordable Care Act that parallel its proposed Medicare rules and require that States ensure that providers exercise reasonable diligence to identify, report, and return overpayments.	Providers Did Not Always Reconcile Patient Records With Credit Balances and Report and Return the Associated Medicaid Overpayments to State Agencies, A-04-14-04029 (August 2015)
 CMS should work with States to: ensure that plans are complying with State standards and assess whether additional standards are needed, ensure that plans' networks are adequate and meet the needs of their Medicaid managed care enrollees, and assess the number of providers offering appointments and improve the accuracy of plan information. 	Access to Care: Provide Availability in Medicaid Managed Care, OEI-02-13-00670 (December 2014)
 CMS should: strengthen its oversight of State standards and ensure that States develop standards for key providers, strengthen its oversight of States' methods to assess plan compliance and ensure that States conduct direct tests of access standards, and improve States' efforts to identify and address violations of access standards. 	State Standards for Access to Care in Medicaid Managed Care, OEI-02-11-00320 (September 2014)
CMS should require at least one onsite visit before a waiver program is renewed and develop detailed protocols for such visits.	Oversight of Quality of Care in Medicaid Home and Community- Based Services Waiver Programs, OEI-02-08-00170 (June 2012)

Recommendation	Relevant Report(s)
 CMS should: take action against States that do not meet the Deficit Reduction Act of 2005 requirement to collect rebates on physician-administered drugs and ensure that all State agencies are accurately identifying and collecting physician-administered drug rebates owed by manufacturers. 	States' Collection of Medicaid Rebates for Physician- Administered Drugs, OEI-03-09-00410 (June 2011)
CMS should provide States with definitive guidance for calculating the Medicaid upper payment limit, which should include using facility-specific upper payment limits that are based on actual cost report data. Estimated Savings: \$3.87 billion over 5 years	Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers, A-03-00-00216 (September 2001)

CMS—General

Recommendation	Relevant Report(s)
 work with the Treasury and Qualified Health Plan (QHP) issuers to recover the \$43,455 in improper advanced premium tax credits (APTCs) identified in our sample, or take other remedial action; work with the Treasury and QHP issuers to recover the remaining improper APTCs, which we estimate to be \$950 million, or take other remedial action for policies for which the payments were not allowable; and develop a process to collect from QHP issuers: information related to individuals' premium payments paid during the benefit year and enrollees' policy termination information so that CMS can provide accurate enrollment data to the IRS. 	CMS Authorized Hundreds of Millions of Dollars in Advanced Premium Tax Credits on Behalf of Enrollees Who Did Not Make Their Required Premium Payments, A-02-19-02005 (March 2021)
 CMS should: continue to enhance the data analysis of Medicaid claims-level data to develop robust analytical procedures and measures against benchmarks in order to monitor and identify risks associated with the Medicaid program; establish a process to perform a claims-level detailed look-back analysis on the Medicaid Entitlement Benefits Due and Payable to 	Summary of recommendations from CMS Financial Report Fiscal Year 2020, Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2020, A-17-20-53000 (November 2020)
determine the reasonableness of the methodology utilized for recording the approximately \$45.9 billion accrual;	

Recommendation	Relevant Report(s)
 continue to adhere to established policies and procedures to ensure that the Statement of Social Insurance model methodology and related calculation and estimate are reviewed at a level of sufficient precision; consider additional opportunities to further reduce improper payments that are consistent with the organization's objective of improving payment accuracy levels; continue to improve the operating effectiveness of information security controls including access; and continually assess the governance and oversight across its organizational units charged with responsibility for configuration management and information security of its IT systems and data, at both headquarters and among CMS Medicare fee-for-service contractors. 	
CMS should pursue strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone through Medicaid.	CMS Should Pursue Strategies To Increase the Number of At-Risk Beneficiaries Acquiring Naloxone Through Medicaid, OEI-BL-18-00360 (September 2020)
 • work with Treasury and Qualified Health Plan issuers to collect improper financial assistance payments, which we estimate to be \$434,398,168, for policies for which the payments were not authorized in accordance with Federal requirements and clarify guidance with QHP issuers on Federal requirements for terminating an enrollee's coverage when the enrollee fails to pay his or her monthly premium; and • work with Treasury and Qualified Health Plan issuers to resolve potentially improper financial assistance payments, which we estimate to be \$504,889,518, for policies for which there was no documentation provided to verify that enrollees had paid their premiums. 	CMS Did Not Always Accurately Authorize Financial Assistance Payments to Qualified Health Plan Issuers in Accordance With Federal Requirements During the 2014 Benefit Year, A-02-15-02013 (August 2018)
 e set firm deadlines for marketplaces to fully develop system functionality for verifying applicants' eligibility and resolving inconsistencies, assess potential enforcement mechanisms that would ensure that marketplaces meet those deadlines, and seek legislative authority to establish mechanisms that are identified; e continue to work with marketplaces to develop the reporting capability to ensure that all required data elements in the Quarterly Metrics Reports are submitted; and 	CMS Did Not Provide Effective Oversight To Ensure That State Marketplaces Always Properly Determined Individuals' Eligibility for Qualified Health Plans and Insurance Affordability Programs, A-09-16-01002 (September 2017)

Recommendation	Relevant Report(s)
 require marketplaces to submit additional data elements related to: (1) average length of time to resolve inconsistencies, (2) number of unresolved inconsistencies, and (3) number of applicants for whom the marketplace received an FTR response code from the IRS and who were determined eligible for insurance affordability programs. 	
CMS should assist IHS in its oversight efforts by conducting more frequent surveys of hospitals, informing IHS leadership of deficiency citations, and continuing to provide technical assistance and training.	IHS Hospitals: More Monitoring Needed To Ensure Quality Care, OEI-06-14-00010 (October 2016)

Administration for Children and Families (ACF)

Recommendation	Relevant Report(s)
 ACF should: proactively provide technical assistance to States that face challenges in appointing a Guardian Ad Litem for every child victim and proactively identify and address obstacles that States face in reporting complete and accurate Guardian Ad Litem data. 	ACF Cannot Ensure That All Child Victims of Abuse and Neglect Have Court Representation, OEl-12-16-00120 (February 2021)
 Top 25 Recommendation #17 With respect to contracts, ORR should: develop plans for upcoming service needs by using all available data and indicators to ensure adherence to the Federal Acquisition Regulation (FAR) competition requirements; establish a policy and procedure for protecting public funds when an influx care facility is not fully staffed due to a reduced number of children at the facility; establish a policy and procedure for designating employees to serve as Contracting Officer Representatives (CORs); work with PSC to document roles and responsibilities for designating a COR and defining contracts in accordance with FAR; establish written policies and procedures for reviewing invoices; and 	The Office of Refugee Resettlement Did Not Award and Manage the Homestead Influx Care Facility Contracts in Accordance With Federal Requirements, A-12-20-20001 (December 2020)

Recommendation	Relevant Report(s)
work with PSC to recoup the \$2,581,157 overpayment of fixed fees from Comprehensive Health Service, LLC.	
 Top 25 Recommendation #17 With respect to its incident reporting systems, ORR should: track and trend incident report information to better safeguard minors in ORR care; improve ORR's guidance to facilities to help them consistently identify and report significant incidents; systematically collect key information about incidents that allows for efficient and effective oversight to ensure that facilities are taking appropriate actions to protect minors; and work with care provider facilities to address staffing shortages of youth care workers that impact the ability to prevent, detect, and report incidents. 	The Office of Refugee Resettlement's Incident Reporting System Is Not Effectively Capturing Data To Assist Its Efforts To Ensure the Safety of Minors in HHS Custody, OEI-09-18-00430 (June 2020)
 Top 25 Recommendation #17 With respect to security, ORR should: develop and implement methods to ensure that care provider facilities regularly report inspection checklist results to ORR, conduct a review to determine whether to enhance required physical security measures, and develop and implement methods to ensure that care provider facilities' inspection checklists include all required physical security measures. 	Unaccompanied Alien Children Program Care Provider Facilities Do Not Include All Required Security Measures in Their Checklists, OEI-05-19-00210 (June 2020)

Recommendation	Relevant Report(s)
Top 25 Recommendation #17	Communication and Management Challenges Impeded HHS's
 With respect to the Unaccompanied Children Program, HHS should: take steps to ensure that children's interests are prioritized and represented in decisions affecting the Unaccompanied Children Program, both internally and when engaging with interagency partners; modify or pursue formal agreements with the Department of Homeland Security and Department of Justice to ensure that HHS is receiving information that supports its operating of and ability to provide care for children in the Unaccompanied Children Program; improve communication to care provider facilities regarding interim guidance, operational directives, and other instructions that are not immediately available in published policy documents; and further improve its ability to identify and track separated children by reducing reliance on manual processes. 	Response to the Zero-Tolerance Policy, OEI-BL-18-00510 (March 2020)
Top 25 Recommendation #17	Care Provider Facilities Described Challenges Addressing Mental
 With respect to the mental health needs of children in HHS custody, ACF's ORR should: identify and disseminate evidence-based approaches to addressing trauma in short-term therapy, develop and implement strategies to assist care provider facilities in overcoming obstacles to hiring and retaining qualified mental health clinicians, assess whether to establish maximum caseloads for individual mental health clinicians, help care provider facilities improve their access to mental health specialists, increase therapeutic placement options for children who require more intensive mental health treatment, and take all reasonable steps to minimize the time that children remain in ORR custody. 	Health Needs of Children in HHS Custody, OEI-09-18-00431 (September 2019)

Recommendation	Relevant Report(s)
 reiterate to facilities that ORR requires all background checks be completed prior to an employee's start date and having access to children; require facilities to ensure that Child Protective Services (CPS) checks are completed for all employees who lived outside of the current State of residence during the previous 5 years, and where necessary ORR should work with facilities to ensure that CPS checks are completed; provide additional guidance to facilities so they can better ensure that case managers and mental health clinicians meet ORR's minimum required education qualifications; reiterate to all facilities the ORR policy requiring that facilities obtain ORR written approval prior to hiring a case manager or mental health clinician who does not meet minimum requirements and require a supervision plan or additional training for the potential employee as needed; and work with facilities to develop a process for facilities to report when case manager or mental health clinician staffing ratios are not met so that ORR can use this information when making placement decisions and ensuring that children's needs are met. 	Unaccompanied Alien Children Care Provider Facilities Generally Conducted Required Background Checks But Faced Challenges in Hiring, Screening, and Retaining Employees, A-12-19-20001 (September 2019)
ACF should establish a forum for States to share strategies regarding how they set payment rates to ensure equal access for eligible families while balancing competing program priorities.	States' Payment Rates Under the Child Care and Development Fund Program Could Limit Access to Child Care Providers, OEI-03-15-00170 (August 2019)
 Top 25 Recommendation #18 With respect to children in foster care, ACF should: develop a comprehensive strategy to improve States' compliance with requirements related to treatment planning and medication monitoring for psychotropic medication, and help States strengthen their requirements for oversight of psychotropic medication by incorporating professional practice guidelines for monitoring children at the individual level. 	Treatment Planning and Medication Monitoring Were Lacking for Children in Foster Care Receiving Psychotropic Medication, OEI-07-15-00380 (September 2018)
ACF should expand the scope of Child and Family Services Reviews to determine whether children in foster care receive required health screenings according to the timeframes specified in States' plans.	Not All Children in Foster Care Who Were Enrolled in Medicaid Received Required Health Screenings, <u>OEI-07-13-00460</u> (March 2015)

Agency for Healthcare Research and Quality (AHRQ)

Recommendation	Relevant Report(s)
 AHRQ should: take steps to encourage participation by patient safety organizations in the Network of Patient Safety Databases, including accepting data into the Network of Patient Safety Databases in other formats in addition to the Common Formats and update guidance for patient safety organizations on the initial and continued listing processes. 	Patient Safety Organizations: Hospital Participation, Value, and Challenges, OEI-01-17-00420 (September 2019)

Food and Drug Administration (FDA)

Recommendation	Relevant Report(s)
Top 25 Recommendation #21 With respect to REMS, FDA should: • seek additional authority to ensure that manufacturers are held accountable when appropriate; • enhance its REMS assessment review process; • strengthen REMS for opioid analgesics (the successor to ER/LA opioids) by requiring prescriber training; and • use the new TIRF REMS patient registry to monitor for known areas of risk, such as inappropriate conversions and off-label prescribing.	FDA's Risk Evaluation and Mitigation Strategies: Uncertain Effectiveness in Addressing the Opioid Crisis, OEI-01-17-00510 (September 2020)
 FDA should: provide educational outreach to trading partners about required drug product tracing information and data standardization guidelines and seek legislative authority to include information about a drug product's complete physical path through the supply chain in drug product tracing information. 	Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain, OEI-05-17-00460 (February 2020)
 DA should: develop a policy for defining and a procedure for identifying retrospectively the date that FDA learns of a potentially hazardous product and consider adding a field for the date to the Recall Enterprise System or another FDA system so that FDA staff involved in managing a recall have access to this information and establish performance measures for the amount of time between the date FDA learns of a potentially hazardous product and the date a firm initiates a voluntary recall, monitor performance, and refine operating procedures, as needed. 	FDA's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply, A-01-16-01502 (December 2017)

Recommendation	Relevant Report(s)
FDA should provide technical assistance regarding exempt products.	Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information, OEI-05-14-00640 (September 2017)
 DA should: build capacity in the Document Archiving, Reporting, and Regulatory Tracking System to support postmarketing requirements oversight and provide a standardized form for annual status reports, ensure that they are complete, and require sponsors to submit them electronically. 	FDA Is Issuing More Postmarketing Requirements, But Challenges With Oversight Persist, OEI-01-14-00390 (July 2016)
Top 25 Recommendation #21 With respect to REMS, FDA should ensure that assessment reviews are conducted in a timely manner.	FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety, OEI-04-11-00510 (February 2013)
FDA should seek statutory authority to review substantiation for structure/function claims to determine whether claims are truthful and not misleading.	Dietary Supplements: Structure/Function Claims Fail To Meet Federal Requirements, OEI-01-11-00210 (October 2012)
FDA should seek statutory authority to impose civil monetary penalties on companies that do not comply with registration requirements.	Dietary Supplements: Companies May Be Difficult To Locate in an Emergency, OEI-01-11-00211 (October 2012)
FDA should consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements.	FDA Inspections of Domestic Food Facilities, <u>OEI-02-08-00080</u> (April 2010)

Health Resources and Services Administration (HRSA)

Recommendation	Relevant Report(s)
HRSA should share 340B ceiling prices with States.	State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs, OEI-05-09-00321 (June 2011)

Indian Health Service (IHS)

Recommendation	Relevant Report(s)
 assess the costs and benefits of updating its EHR system with tools to support more automated monitoring and request support from States and from Federal partners to address challenges with State-run prescription drug monitoring programs. 	Few Patients Received High Amounts of Opioids from IHS-Run Pharmacies, OEI-05-18-00470 (December 2020)
 extend policies to address more types of perpetrators, victims, and abuse; ensure that the new incident reporting system is effective and addresses the risks identified in the current system; designate a central owner at IHS headquarters to ensure clear roles and responsibilities for shared ownership in implementing patient protection policies, and managing and responding to abuse reports; continue to actively promote an organizational culture of transparency and work to resolve barriers to staff reporting of abuse; and conduct additional outreach to Tribal communities to inform them of patient rights, solicit community concerns, and address barriers to reporting of patient abuse. 	Indian Health Service Has Strengthened Patient Protection Policies But Must Fully Integrate Them Into Practice and Organizational Culture, OEI-06-19-00330 (December 2019)
 establish patient harm monitoring and reduction as a key priority of the Office of Quality; implement quality improvement plans to improve patient safety across IHS, including plans that focus specifically on smaller hospitals and patient groups at higher risk of harm; and effectively track and monitor patient harm events using an improved incident reporting system. 	Incidence of Adverse Events in Indian Health Service Hospitals, OEI-06-17-00530 (December 2020)
 examine and revise, as needed, the reporting structure in the policies and the incident reporting system to ensure that staff and patients can report abuse anonymously; improve the process for and timeliness of conducting staff background investigations, and notifying facilities when staff are approved; provide additional guidance and training to facilities on patient protection policies, including the role of law enforcement and the reporting process related to patient abuse; and establish and enforce a deadline by which all facilities must fully incorporate the new requirements into their policies and procedures, and actively monitor facility adherence. 	Indian Health Service Facilities Made Progress Incorporating Patient Protection Policies, But Challenges Remain, OEI-06-19-00331 (December 2020)

Recommendation	Relevant Report(s)
 encourage and support greater adoption of the Alliance for Innovation on Maternal Health's bundles of maternal-safety best practices; take steps to ensure that IHS providers employ best practices in diagnosing and treating postpartum hemorrhage; and assess its labor and delivery practices and consider practice improvements based on the findings of this assessment. 	Instances of IHS Labor and Delivery Care Not Following National Clinical Guidelines or Best Practices, OEI-06-19-00190 (December 2020)
 With respect to IHS operated hospitals, IHS should: as a management priority, develop and implement a staffing program for recruiting, retaining, and transitioning staff and leadership to remote hospitals; enhance training and orientation for new hospital leaders to ensure that they follow IHS directives and continue improvement efforts; continue to take steps to ensure early and effective intervention when IHS identifies problems at hospitals; and develop procedures for temporary emergency department closures and communicate those procedures with receiving hospitals and emergency medical services to ensure that they are adequately prepared to receive diverted patients during such events. 	Case Study: IHS Management of Rosebud Hospital Emergency Department Closure and Reopening, OEI-06-17-00270 (July 2019)
 IHS should work with hospitals to: develop policies and procedures to review the electronic health records (EHRs) of patients with opioid prescriptions from non-IHS providers and document the results of the review in the EHR, particularly for those patients who had previously violated their chronic opioid therapy agreements; and track all opioids prescribed at the hospital in the patient EHRs, including those being filled at an outside pharmacy. 	IHS Needs To Improve Oversight of Its Hospitals' Opioid Prescribing and Dispensing Practices and Consider Centralizing Its Information Technology Functions, A-18-17-11400 (July 2019)
 implement a quality-focused compliance program to support Federal requirements for health care programs; continue to invest in training for hospital administration and staff, and assess the value and effectiveness of training efforts; establish standards and expectations for how Area Offices and Governing Boards oversee and monitor hospitals and monitor adherence to those standards; and continue to seek new, meaningful ways to monitor hospital quality through the use of outcomes and/or process measures. 	IHS Hospitals: More Monitoring Needed To Ensure Quality Care, OEI-06-14-00010 (October 2016)

Recommendation	Relevant Report(s)
IHS should identify all hospitals with unsupported networking equipment and implement a system development life cycle plan to ensure hardware and software replacement before end-of-life.	Two IHS Hospitals Had System Security and Physical Controls for Prescription Drug and Opioid Dispensing But Could Still Improve Controls, A-18-16-30540 (November 2017)
Top 25 Recommendation #19 With respect to the quality of care delivered in IHS hospitals, IHS should conduct a needs assessment culminating in an agencywide strategic plan with actionable initiatives and target dates.	IHS Hospitals: Longstanding Challenges Warrant Focused Attention To Support Quality Care, OEI-06-14-00011 (October 2016)

National Institutes of Health (NIH)

Recommendation	Relevant Report(s)
 Top 25 Recommendation #20 With respect to peer reviewers, NIH should: conduct targeted, risk-based oversight of peer reviewers using analysis of information about threats to research integrity; update its training materials routinely to include information about breaches of peer reviewer confidentiality and possible undue foreign influence; and require all peer reviewers to attend periodic training about peer review integrity. 	NIH Has Acted To Protect Confidential Information Handled by Peer Reviewers, But It Could Do More, OEI-05-19-00240 (March 2020)
Top 25 Recommendation #20 With respect to vetting peer reviewers, NIH should: • update its guidance on vetting peer reviewer nominees to identify potential foreign threats to research integrity, in consultation with national security experts, as needed; and • work with the HHS Office of National Security to develop a risk-based approach for identifying those peer reviewer nominees who warrant extra scrutiny.	Vetting Peer Reviewers at NIH's Center for Scientific Review: Strengths and Limitations, OEI-01-19-00160 (September 2019)
Top 25 Recommendation #20 With respect to overseeing FCOIs for extramural research, NIH should use information regarding foreign affiliations and support that it collects during the pre-award process to decide whether to revise its FCOI review process to address concerns regarding foreign influence.	NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More, OEI-03-19-00150 (September 2019)

Recommendation	Relevant Report(s)
Top 25 Recommendation #20 With respect to FCOI compliance, NIH should ensure that the 1,013 institutions identified by this review as not having FCOI policies on their websites post these policies as required.	NIH Has Limited Policies, Procedures, and Controls in Place for Helping To Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations, A-03-19-03003 (September 2019)
NIH should promulgate regulations that address institutional FCOIs.	Institutional Conflicts of Interest at NIH Grantees, OEI-03-09-00480 (January 2011)
NIH should develop and disseminate guidance on methods to verify researchers' financial interests.	How Grantees Manage Financial Conflicts of Interest in Research Funded by the NIH, OEI-03-07-00700 (November 2009)

General Departmental

Recommendation Relevant Report(s) HHS should: U.S. Department of Health and **Human Services Met Many** continue to work with the Office of Management and Budget and Requirements, but It Did Not Fully other stakeholders to develop and implement an approach to Comply With the Payment reporting on Temporary Assistance for Needy Families (TANF) improper payments in FY 2021, which will aid in identifying root Integrity Information Act of 2019 and Applicable Improper Payment causes of TANF improper payments and allow HHS to develop and Guidance for Fiscal Year 2020, report corrective action plans; A-17-21-52000 (May 2021) focus on the root causes of the improper payment percentage and evaluate critical and feasible action steps to assist States with their compliance efforts for new requirements of the Medicaid and CHIP programs; continue to follow up with States during the interim period to verify that corrective actions identified after the improper payment error rate measurement review for the Medicaid and CHIP programs are being implemented;¹³ continue to explore a vehicle to conduct recovery audits that will fit into the larger Medicare Part C program in FY 2021; continue to work with OMB and other stakeholders, including considering recommendations from recent OIG audits, to develop and implement an approach to reporting on APTC improper payments in FY 2021; and continue to work with OMB and other stakeholders to develop and implement an approach to reporting on CDC and OHS Disaster Relief improper payments in FY 2021. HHS should: Summary of recommendations • continue to develop and refine its financial management systems from OIG Report on the Financial Statement Audit of HHS for Fiscal and processes to improve accounting, analysis, and oversight of *Year 2020,* **A-17-20-00001** financial management activity; and • continue to strengthen oversight of remediation activities to limit (November 2020) new deficiencies and improve internal control over financial information systems.

¹³ Note: The current COVID-19 public health emergency may impact the ability of States to analyze and follow up on corrective action plans. Consequently, this will impact the information reported to CMS.

Recommendation	Relevant Report(s)
Top 25 Recommendation #23 With respect to contract administration and management, HHS should: • determine whether any HHS contractors or subcontractors are performing inherently governmental functions and whether any active CMS service contracts or task orders are being administered as personal services contracts, and take action to correct their administration; and • provide training to political appointees and senior leaders related to proper contract administration.	CMS Did Not Administer and Manage Strategic Communications Services Contracts in Accordance With Federal Requirements, A-12-19-20003 (July 2020)
 Provide training to program staff and contracting personnel, such as contracting officers and CORs, on FAR requirements specifying that contracts must not be used for the performance of inherently governmental functions and related to written consent for the use of subcontractors; ensure that contracting personnel, such as a contracting officer, review contracts before being awarded to determine whether language is included that could lead to those contracts being administered as personal services contracts; ensure that for all future contracts CMS receives and accepts deliverables in accordance with the Statement of Work (SOW), CORs maintain working contract files, and CORs document all changes made to the SOW; and expand the "COR Invoice Approval Operating Guidance" to include a description of acceptable documentation to support contractor payments. 	
Top 25 Recommendation #25 Due to the current public health emergency and increased cyberactivity, we are only including the title of our cybersecurity audits in the list of the Top 25 unimplemented recommendations.	HHS Should Address Gaps in Incident Response Capabilities Across the Department, A-18-17-04002 (May 2020)

Recommendation	Relevant Report(s)
 Top 25 Recommendation #22 With respect to HCCs, ASPR should: clarify Hospital Preparedness Program guidance that HCC membership should ensure strategic, comprehensive coverage of community gaps in preparedness and response; continue to work with CMS to help health care entities comply with the CMS emergency preparedness CoPs; identify ways to incentivize core member participation in HCCs; and clarify to HPP awardees the flexibility available in meeting cooperative agreement requirements. 	Selected Health Care Coalitions Increased Involvement in Whole Community Preparedness But Face Developmental Challenges Following New Requirements in 2017, OEI-04-18-00080 (April 2020)
 Top 25 Recommendation #22 With respect to emergency response, HHS should: develop departmentwide objectives and a strategic framework for responding to international public health emergencies; develop policies and procedures that clearly define HHS components' roles and responsibilities for responding to international public health emergencies; develop large-scale international response plans; develop various means of obtaining and using quality data for decision-making; and work with other Federal Government agencies to develop a flexible, multiagency international response framework. 	HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts, A-04-16-03567 (August 2019)
Top 25 Recommendation #24 With respect to security, HHS should ensure that: • all future web application developments incorporate security requirements from an industry-recognized web application security standard, and • OpDivs implement properly configured web application firewalls in accordance with an agreed-upon baseline standard established by HHS. HHS should address factors that may limit the Office for Human Research	Summary Report for OIG Penetration Testing of Eight HHS Operating Division Networks, A-18-18-08500 (March 2019) OHRP Generally Conducted Its
Protection's (OHRP's) ability to operate independently. HHS should revise its guidance to include specific standards for conducting past performance reviews of companies under consideration during contract procurement.	Compliance Activities Independently, But Changes Would Strengthen Its Independence, OEI-01-15-00350 (July 2017) Federal Marketplace: Inadequacies in Contract Planning and Procurement,

Recommendation	Relevant Report(s)
	OEI-03-14-00230 (January 2015)
ASFR should: • ensure compliance with Small Business Innovation Research Program eligibility requirements and • improve procedures to check for duplicative awards.	Vulnerabilities in the HHS Small Business Innovation Research Program, OEI-04-11-00530 (April 2014)
The Office of the National Coordinator for Health Information Technology and CMS should strengthen collaborative efforts to develop a comprehensive plan to address fraud vulnerabilities in EHRs.	Not All Recommended Fraud Safeguards Have Been Implemented in Hospital Electronic Health Record Technology, OEI-01-11-00570 (December 2013)

Appendix C: Implemented and Closed Recommendations Reported in 2020 Edition

This appendix identifies 95 significant recommendations described in the 2020 edition of this publication that were implemented or closed since the publication was issued. OIG may close recommendations that were not implemented for a range of reasons; for example, the underlying problem may have been solved in a different way, a program change may make a recommendation no longer relevant, or OIG may conduct new work on the same issue and make a new, superseding recommendation to address the problem. The recommendations listed below are generally grouped by OpDiv. We have indicated which recommendations below were on the 2020 Top 25 list and legislative recommendations. The status of each recommendation is also included. The hyperlinks below provide more information on the report relevant to each recommendation.

CMS—Medicare Parts A and B

Recommendation	Relevant Report(s)	Status
CMS should consider reducing the need for clinical judgment when processing claims under the post-acute-care transfer policy by taking necessary actions, including seeking legislative authority if necessary, to deem any home health service within 3 days of discharge to be "related" (which would have saved an estimated \$46.6 million during our 2-year audit period).	Inadequate Edits and Oversight Caused Medicare To Overpay More Than \$267 Million for Hospital Inpatient Claims With Post-Acute-Care Transfers to Home Health Services, A-04-18-04067 (August 2020)	Closed
 attempt recovery of the \$93,591,531 in estimated incorrect net incentive payments made during our audit period and ensure that all final and nonfinal payments made after our audit period are correct, and address the 50 incorrect net incentive payments in our sample, recover from acute-care hospitals in accordance with CMS policies the portion of the \$1,266,111 in incorrect net incentive payments that are within the reopening period. 	CMS Made an Estimated \$93.6 Million in Incorrect Medicare Electronic Health Record Incentive Payments to Acute-Care Hospitals, or Less Than 1 Percent of \$10.8 Billion in Total Incentive Payments, A-09-18-03020 (December 2019)	Closed

¹⁴ OIG, OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs, August 2020. Available at https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2020.pdf.

Recommendation	Relevant Report(s)	Status
 direct Medicare contractors to recover the \$54,372,337 in identified overpayments in accordance with CMS's policies and procedures; and ensure that Medicare contractors are receiving postpayment edit automatic notifications of improperly billed claims and are taking action by adjusting original inpatient claims to initiate recoveries of overpayments. 	Medicare Improperly Paid Acute- Care Hospitals \$54.4 Million for Inpatient Claims Subject to the Post-Acute-Care Transfer Policy, A-09-19-03007 (November 2019)	Implemented
CMS should recoup \$640,452 from providers and instruct providers to refund overcharges totaling up to \$173,495 to beneficiaries, consisting of: • \$436,877 in overpayments to providers that billed for the same chronic care management services for the same beneficiaries and up to \$121,573 in overcharges to these beneficiaries; and • \$203,575 in overpayments to providers that billed for both CCM services and overlapping care management services for the same beneficiaries and up to \$51,922 in overcharges to these beneficiaries.	Medicare Made Hundreds of Thousands of Dollars in Overpayments for Chronic Care Management Services, A-07-17-05101 (November 2019)	Implemented
 continue to work with contractors and MACs to develop strategies that improve timely coordination to give MACs a better opportunity to recover overpayments, establish a uniform methodology for contractors to use when reporting estimates for the value of law enforcement referrals, and update the Fraud Prevention System's law enforcement referral adjustment factor. 	CMS Could Improve Its Processes for Evaluating and Reporting Payment Recovery Savings Associated With the Fraud Prevention System, A-01-15-00510 (October 2019)	Implemented

Recommendation	Relevant Report(s)	Status
 CMS should also work with DME MACs to: expand reviews of suppliers' claims to include additional inhalation drugs (e.g., those with the highest reimbursement rates); provide additional training to suppliers on Medicare documentation requirements for inhalation drugs; and identify suppliers that consistently bill for inhalation drugs that do not comply with Medicare documentation requirements, perform reviews of those suppliers, collect the amount overpaid for unallowable claims, and educate them on Medicare requirements for inhalation drugs. 	Medicare Improperly Paid Suppliers an Estimated \$92.5 Million for Inhalation Drugs, A-09-18-03018 (October 2019)	Implemented
 Prioritize ACO referrals of potential fraud, waste, and abuse; identify and share information about strategies that integrate physical and behavioral health services and address social determinants of health; and assess and share information about ACOs' use of the 3-day waiver and apply these results when making changes to the Shared Savings Program or other programs. 	ACOs' Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program, OEI-02-15-00451 (July 2019)	Implemented
2020 Top 25 Recommendation #5 CMS should take the steps necessary to seek statutory authority to include information from accrediting organizations on Hospice Compare.	Hospice Deficiencies Pose Risks to Medicare Beneficiaries, OEI-02-17-00020 (July 2019)	Implemented
 CMS should instruct the MACs to: recover the portion of the \$56,668 in identified net overpayments that are within the 4-year reopening period; 	Medicare Payments to Providers for Polysomnography Services Did Not Always Meet Medicare Billing Requirements, A-04-17-07069 (July 2019)	Implemented

Recommendation	Relevant Report(s)	Status
 notify the 117 providers associated with 147 claims (83 beneficiaries with 150 corresponding lines of service) with potential overpayments of \$56,668 so that those providers can exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation; and work with MACs to conduct data analysis allowing for targeted reviews of claims for polysomnography services and educate providers on properly billing for polysomnography services. 		
 ensure that when SNF claims are being processed for payment, the Common Working File qualifying inpatient hospital stay edit for SNF claims is enabled and operating properly to identify SNF claims ineligible for Medicare reimbursement; require SNFs to provide written notice to beneficiaries if Medicare is expected to deny payment for the SNF stay when the 3-day rule is not met (and if necessary, CMS should seek statutory authority to do so); 	CMS Improperly Paid Millions of Dollars for Skilled Nursing Facilities When the Medicare 3-Day Inpatient Hospital Stay Requirement Was Not Met, A-05-16-00043 (February 2019)	Implemented

Recommendation	Relevant Report(s)	Status
 educate hospitals about the importance of explicitly communicating the correct number of inpatient days to beneficiaries and whether the inpatient days qualify subsequent SNF care for Medicare reimbursement so that beneficiaries understand their potential financial liability related to SNF care; and educate SNFs about their responsibility to submit accurate and valid claims for payment supported with documentation that clearly show that the SNF services qualify for reimbursement. 		
 CMS should: include information about potential events and patient harm in its quality outreach to Long-Term Care Hospitals (LTCHs) and collaborate with AHRQ to create and disseminate a list of potential adverse events at LTCHs. 	Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries, OEI-06-14-00530 (November 2018)	Implemented
CMS should take steps to ensure that no resident is counted as more than one full-time employee. This could include implementing policies and procedures to analyze Intern and Resident Information System data or requiring MACs to determine whether residents claimed by hospitals in their jurisdiction were claimed as more than one full-time employee.	CMS Did Not Always Ensure Hospitals Complied With Medicare Reimbursement Requirements for Graduate Medical Education, A-02-17-01017 (November 2018)	Closed
CMS should ensure that valid national drug codes are reported for drugs.	Open Payments Data: Review of Accuracy, Precision, and Consistency in Reporting, OEI-03-15-00220 (August 2018)	Implemented
2020 Top 25 Recommendations #5 and #10 CMS should seek statutory authority to establish additional, intermediate remedies for poor hospice performance.	Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio, OEI-02-16-00570 (July 2018)	Implemented

Recommendation	Relevant Report(s)	Status
CMS should work with Medicare contractors to establish periodic reviews of claims for replacement positive airway pressure device supplies and take remedial action for suppliers that the contractors find consistently bill claims that do not meet Medicare requirements. Estimated Savings: \$631.2 million during CYs 2014 and 2015	Most Medicare Claims for Replacement Positive Airway Pressure Device Supplies Did Not Comply With Medicare Requirements, A-04-17-04056 (June 2018)	Implemented
2020 Top 25 Recommendation #6 CMS should: • instruct its Medicare contractors (assuming the OIG recommendation requiring use of condition codes 49 and 50 is implemented) to implement a postpayment process to follow up with any hospital that submits a claim for certain cardiac device replacement procedures with condition code 49 or 50 but no value code FD (a credit of 50 percent or greater received from a manufacturer for a replaced medical device) to determine whether an adjustment claim should be submitted; and • consider studying alternatives to implementing edits to eliminate the current Medicare requirements for reporting device credits by, for instance, reducing inpatient PPS and outpatient PPS payments for device-intensive procedures.	Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits, A-05-16-00059 (March 2018)	Closed
CMS should strengthen its system edits to prevent improper payments for specimen validity tests and instruct Medicare contractors to educate providers on properly billing for specimen validity and urine drug tests, which could result in savings of an estimated \$12,146,760 over a 5-year period.	Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination With Urine Drug Tests, A-09-16-02034 (February 2018)	Implemented

Recommendation	Relevant Report(s)	Status
CMS should require hospitals to use condition codes 49 or 50 on claims for reporting a device replacement procedure if the procedure resulted from a recall or premature failure independent of whether there was a device provided at no cost or with a credit.	Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices, A-01-15-00504 (September 2017)	Closed
CMS should evaluate the cost-effectiveness of edits and medical reviews that are designed to ensure appropriate payments for covered uses on Part B drug claims.	MACs Continue To Use Different Methods To Determine Drug Coverage, OEI-03-13-00450 (September 2016)	Implemented
 CMS should: raise awareness of adverse events in rehabilitation hospitals and work to reduce harm to patients; collaborate with the Agency for Healthcare Research and Quality (AHRQ) to create and promote a list of potential rehab hospital events. 	Adverse Events in Inpatient Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries, OEI-06-14-00110 (July 2016)	Implemented
CMS should ensure that Provider Enrollment, Chain, and Ownership System contains the complete and accurate data needed to execute and evaluate CMS's enrollment-screening enhancements.	Enhanced Enrollment Screening of Medicare Providers: Early Implementation Results, OEI-03-13-00050 (April 2016)	Implemented
CMS should finalize the implementation of automated average sales price-related procedures by using average manufacturer price-related processes as a model and subsequently require all manufacturers to submit average sales prices through the automated system.	Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs, OEI-12-13-00040 (July 2014)	Implemented
CMS should implement policies and procedures to detect and recoup improper payments when entitlement termination information is received on previously paid Medicare claims, and identify improper payments after our audit period but before implementation of policies and procedures, and ensure that Medicare contractors recoup the improper payments.	Medicare Improperly Paid Providers Millions of Dollars for Entitlement-Terminated Beneficiaries Who Received Services During 2010 Through 2012, A-07-13-01127 (April 2014)	Implemented
CMS should implement requirements for face-to-face encounters with a referring physician.	Questionable Billing by Suppliers of Lower Limb Prostheses, OEI-02-10-00170 (April 2011)	Implemented

CMS—Medicare Parts C and D

Recommendation	Relevant Report(s)	Status
 CMS should: continue to monitor providers submitting a high number of E1 transactions relative to prescriptions processed, issue guidance that clearly states that E1 transactions should not be used for marketing purposes, ensure that only pharmacies and other authorized entities submit E1 transactions, and take appropriate enforcement action when abuse is identified. 	The Majority of Providers Reviewed Used Medicare Part D Eligibility Verification Transactions for Potentially Inappropriate Purposes, A-05-17-00020 (February 2020)	Closed
CMS should research remaining records for which we estimated missed Coverage Gap discounts totaling \$406,755 and instruct Part D sponsors to validate and adjust PDE records accordingly and remit applicable amounts to beneficiaries.	CMS's Implementation of a 2014 Policy Change Resulted in Improvements in the Reporting of Coverage Gap Discounts Under Medicare Part D, A-07-16-06067 (January 2020)	Implemented
CMS should take additional steps to improve electronic communication between Part D sponsors and prescribers to reduce avoidable pharmacy rejections and coverage denials.	Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs, OEI-09-16-00411 (September 2019)	Implemented
 CMS should: conduct additional analysis on compounded topical drugs, conduct training for Part D sponsors on fraud schemes and safety concerns related to compounded topical drugs, and follow up on pharmacies with questionable Part D billing and the prescribers associated with these pharmacies. 	Questionable Billing for Compounded Topical Drugs in Medicare Part D, OEI-02-16-00440 (July 2018)	Implemented

Recommendation	Relevant Report(s)	Status
 resolve improper Part D payments made for prescription drugs provided to unlawfully present beneficiaries by reopening and revising CY 2009 through CY 2011 final payment determinations to remove prescription drug costs for unlawfully present beneficiaries; develop and implement controls to ensure that Medicare does not pay for prescription drugs for unlawfully present beneficiaries by preventing enrollment of unlawful beneficiaries, disenrolling any currently enrolled unlawful beneficiaries, and automatically rejecting PDE records submitted by sponsors for prescription drugs provided to this population; and identify and resolve improper payments made for prescription drugs provided to unlawfully present beneficiaries by reopening and revising final payment determinations for periods after the period of this review but before implementation of policies and procedures. 	Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2009 Through 2011, A-07-12-06038 (October 2013)	Implemented
CMS should change the method for paying for therapy.	The Medicare Payment System for Skilled Nursing Facilities Needs To Be Reevaluated, OEI-02-13-00610 (September 2015)	Implemented
CMS should follow up on sponsors and pharmacies with high numbers of refills.	Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, OEI-02-09-00605 (September 2012)	Implemented
CMS should provide Part D plan sponsors with specific guidelines on how to define and count incidents of potential fraud and abuse, related inquiries, and corrective actions.	Less Than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse, OEI-03-13-00030 (March 2014)	Closed

Recommendation	Relevant Report(s)	Status
 implement policies and procedures to notify MAOs of unlawful-presence information and thereby prevent their enrollment in MAOs, prevent enrollment of unlawfully present beneficiaries in Part D, disenroll such beneficiaries already enrolled, automatically reject such prescription drug event records, and recoup any improper payments; and identify and recoup improper payments made to MAOs for unlawfully present beneficiaries after our audit period and until policies and procedures have been implemented. 	Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2010 Through 2012, A-07-13-01125 (April 2014)	Implemented

CMS—Medicaid

Recommendation	Relevant Report(s)	Status
2020 Top 25 Recommendation #12 CMS should • collaborate with partners to develop strategies for improving rates of followup care for children treated for ADHD and • provide technical assistance to States to implement strategies for improving rates of followup care for children treated for ADHD.	Many Medicaid-Enrolled Children Who Were Treated for ADHD Did Not Receive Recommended Followup Care, OEI-07-17-00170 (August 2019)	Implemented
CMS should clarify requirements for diagnosis codes.	National Review of Opioid Prescribing in Medicaid Is Not Yet Possible, OEI-05-18-00480 (August 2019)	Implemented
CMS should work with all States to review current training that States provide to centers and homes.	Four States Did Not Comply With Federal Waiver and State Requirements in Overseeing Adult Day Care Centers and Foster Care Homes, <u>A-05-19-00005</u> (May 2019)	Implemented

Recommendation	Relevant Report(s)	Status
CMS should work with States to ensure that they prevent inappropriate reimbursements for drugs that are not FDA-approved and do not meet the criteria for an exception.	One Percent of Drugs With Medicaid Reimbursement Were Not FDA-Approved, OEI-03-17-00120 (May 2019)	Implemented
CMS should provide additional technical assistance to help Medicaid agencies fully utilize Medicaid payment suspensions as a program integrity tool.	Challenges Appear To Limit States' Use of Medicaid Payment Suspensions, OEI-09-14-00020 (September 2017)	Implemented
 enable States to substitute Medicare screening data by ensuring the accessibility and quality of Medicare data and help States overcome challenges in conducting site visits. 	Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented, OEI-05-13-00520 (June 2016)	Implemented
CMS should take appropriate action to ensure that States fully implement National Correct Coding Initiative edits.	Inconsistencies in State Implementation of Correct Coding Edits May Allow Improper Medicaid Payments, OEI-09-14-00440 (April 2016)	Implemented
CMS should ensure that States pay for services in accordance with their periodicity schedules.	Most Children With Medicaid in Four States Are Not Receiving Required Dental Services, OEI-02-14-00490 (February 2016)	Implemented
CMS should establish a deadline for when national T-MSIS data will be available.	Early Outcomes Show Limited Progress for the Transformed Medicaid Statistical Information System, OEI-05-12-00610 (August 2013)	Implemented
CMS should improve the quality of data that Review MICs can access for conducting data analysis.	Early Assessment of Review Medicaid Integrity Contractors, OEI-05-10-00200 (October 2011)	Implemented

CMS—General

Recommendation	Relevant Report(s)	Status
CMS should ensure that critical security updates are applied to internet-facing systems regularly and follow vendor-provided security recommendations for configuring software.	OIG Penetration Test of CMS's Network, <u>A-18-17-08200</u> (April 2018)	Implemented

Recommendation	Relevant Report(s)	Status
CMS should standardize case files and make them electronic.	Improvements Are Needed at the Administrative Law Judge Level of Medicare Appeals, OEI-02-10-00340 (August 2012)	Implemented

Administration for Children and Families (ACF)

Recommendation	Relevant Report(s)	Status
ACF should proactively monitor Head Start grantee performance results to verify that those grantees designated for automatic, noncompetitive renewal perform better than their peers.	Head Start Grant Recompetition: Early Implementation Results Suggest Opportunities for Improvement, OEI-12-14-00650 (August 2016)	Implemented

Administration for Community Living (ACL)

Recommendation	Relevant Report(s)	Status
2020 Top 25 Recommendation #17 ACL should: • determine whether it can allocate its funds differently to enable onsite compliance reviews, • seek additional department funding or resources to conduct onsite compliance reviews, and • perform required onsite compliance reviews of independent living programs.	ACL Failed To Conduct Any of the Required Onsite Compliance Reviews of Independent Living Programs, A-05-18-00034 (August 2019)	Closed

Agency for Healthcare Research and Quality (AHRQ)

Recommendation	Relevant Report(s)	Status
AHRQ should develop and execute a communications strategy to increase awareness of the program among hospitals and its value to participants.	Patient Safety Organizations: Hospital Participation, Value, and Challenges, OEI-01-17-00420 (September 2019)	Implemented

Food and Drug Administration (FDA)

Recommendation	Relevant Report(s)	Status
FDA should follow up with the wholesale distributor that did not provide tracing information to OIG.	Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain, OEI-05-17-00460 (February 2020)	Implemented
FDA should implement more effective tools and methods, such as application whitelisting, to detect and prevent execution of unauthorized commands or programs on FDA systems.	FDA Continues To Mature Its Preventative and Detective Controls To More Effectively Mitigate the Risk of Compromise, A-18-18-08300 ¹⁵ (October 2019)	Implemented
 further communicate to hospitals the importance of obtaining nonpatient-specific compounded drugs from outsourcing facilities, and take appropriate followup action with unregistered compounding facilities on the list we provided. 	Most Hospitals Obtain Compounded Drugs From Outsourcing Facilities, Which Must Meet FDA Quality Standards, OEI-01-17-00090 (June 2019)	Implemented
2020 Top Recommendation #18 FDA should conduct timely followup inspections to ensure that significant inspection violations are corrected.	Challenges Remain in FDA's Inspections of Domestic Food Facilities, OEI-02-14-00420 (September 2017)	Implemented
FDA should identify REMS that are not meeting their goals and take appropriate actions to protect public health.	FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety, OEI-04-11-00510 (December 2012)	Implemented

Health Resources and Services Administration (HRSA)

Recommendation	Relevant Report(s)	Status
 HRSA should: improve its procedures for monitoring how health centers meet targets for future HRSA grant funding opportunities; 	In Selected States, 67 of 100 Health Centers Did Not Use Their HRSA Access Increases in Mental Health and Substance Abuse Services Grant Funding in Accordance With Federal Requirements,	Implemented

¹⁵ This report is not publicly available.

Recommendation	Relevant Report(s)	Status
 require the 34 health centers in our sample identified as having claimed unallowable AIMS grant costs to refund \$773,114 to the Federal Government and work with the other health centers in our sampling frame to identify additional unallowable costs, which we estimate to be \$5,217,709; require the 34 health centers in our sample identified as having improperly allocated AIMS grant costs to refund \$1,722,271 to the Federal Government or work with the health centers to determine what portion of these costs is allocable to their AIMS grants, and work with other health centers in our sampling frame to determine what portion of an estimated \$9,207,958 in improperly allocated grant costs is allocable; and improve its monitoring of grant expenditures, including requiring health centers to develop and maintain financial management systems that ensure only allowable, allocable, and documented costs are charged to their HRSA grants. 	A-02-19-02001 (November 2020)	
HRSA should clarify its guidance on preventing duplicate discounts for MCO drugs.	State Efforts To Exclude 340B Drugs From Medicaid Managed Care Rebates, OEI-05-14-00430 (May 2016)	Implemented

Indian Health Service (IHS)

Recommendation	Relevant Report(s)	Status
 2020 Top 25 Recommendation #21 IHS should: increase oversight of IT systems by IHS management; present findings and cost savings analysis to Tribal leadership and the IHS user community to get buy-in for any significant IT enterprise changes; implement a strategic and phased approach to centralization of IT systems, services, and cybersecurity functions; and work with hospitals to ensure that opioid dispensing data are complete, accurate, and submitted in a timely manner to the State Prescription Drug Monitoring Program for use by providers and pharmacists. 	IHS Needs To Improve Oversight of Its Hospitals' Opioid Prescribing and Dispensing Practices and Consider Centralizing Its Information Technology Functions, A-18-17-11400 (July 2019)	Implemented

National Institutes of Health (NIH)

Recommendation	Relevant Report(s)	Status
NIH should implement procedures to ensure that all institutions that are required to have FCOI policies have FCOI policies.	The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place for Helping To Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations, A-03-19-03003 (September 2019)	Implemented
NIH should perform periodic quality assurance reviews of information in the FCOI module to ensure adequacy of oversight regarding FCOIs.	NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, But Could Do More, OEI-03-19-00150 (September 2019)	Implemented

Recommendation	Relevant Report(s)	Status
NIH should maintain official files in accordance with HHS policy.	NIH Administration of the Clinical and Translational Science Awards Program, OEI-07-09-00300 (February 2011)	Implemented

Substance Abuse and Mental Health Services Administration (SAMHSA)

Recommendation	Relevant Report(s)	Status
SAMHSA should geographically target its efforts to increase the participation of waivered providers in high-need counties.	Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder, OEI-12-17-00240 (January 2020)	Implemented

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