# 2022

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 2022 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 or the Department), Office of Inspector General (OIG). In this edition, we focus on the top 25 unimplemented recommendations that, in OIG'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 OIG 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.<sup>1</sup>

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. Please note that the list of top 25 recommendations is not limited to 25 distinct recommendations but may comprise a set of priority recommendations representing the most significant opportunities to positively impact the Department's programs. 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 July 1, 2022.

Additionally, in Appendix C we include a list of 72 significant recommendations reported in the 2021 edition of this publication that have since been implemented or closed.<sup>2</sup> This list includes several top 25 recommendations from the 2021 edition that were implemented by OpDivs in critical areas, such as ensuring that beneficiaries are educated about access to medication assisted drugs and naloxone to treat opioid use disorder and a recommendation on improving cybersecurity requirements for HHS web applications.

In addition to this publication, OIG reports annually on the top management and performance challenges facing HHS.<sup>3</sup> 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.

The top 25 unimplemented recommendations in this edition derive from audits and evaluations issued through December 31, 2021. As such, many of these recommendations predate the COVID-19 public health emergency. As of November 2022, OIG had 49 audits and evaluations underway related to COVID-19 response and recovery, which may result in recommendations that appear in future editions. OIG continues to advance the four goals with respect to HHS's COVID-19 response and recovery. These goals are to: (1) protect people, (2) protect funds, (3) protect infrastructure, and (4) promote effectiveness of HHS programs, now and into the future. OIG's completed and ongoing work related to COVID-19 is available via the COVID-19 Portal on our website.

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> OIG, 2021 OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs, Oct. 2021. Available at <a href="https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2021.pdf">https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2021.pdf</a>.

<sup>&</sup>lt;sup>3</sup> OIG, 2022 Top Management and Performance Challenges Facing HHS, Nov. 2022. Available at <a href="https://oig.hhs.gov/reports-and-publications/top-challenges/2022/2022-tmc.pdf">https://oig.hhs.gov/reports-and-publications/top-challenges/2022/2022-tmc.pdf</a>.

#### For more information

More information on OIG's work, including the reports mentioned in this publication, appears on our website at <a href="https://oig.hhs.gov/">https://oig.hhs.gov/</a>. For questions about OIG's Top Unimplemented Recommendations and the lists of legislative and significant unimplemented recommendations, please contact Public Affairs at <a href="mailto:Public.Affairs@oig.hhs.gov">Public.Affairs@oig.hhs.gov</a>.

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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. CMS should take actions to ensure that incidents of potential abuse or neglect of Medicare and Medicaid beneficiaries, including those in nursing homes and hospice care as well as children enrolled in Medicaid, are identified and reported.
- 2. CMS should address inappropriate nursing home discharges through training, by implementing deferred initiatives, and by assessing the effectiveness of its enforcement against inappropriate facility-initiated discharges.\*
- 3. CMS should take steps to reduce the costs for Medicare and its beneficiaries by promoting the use of less costly, clinically appropriate drugs.
- 4. CMS should improve and implement system edit processes for its durable medical equipment (DME) Medicare contractors to prevent improper payments for services provided to hospice beneficiaries.\*

#### CMS—Medicare Parts A and B

- 5. CMS should take the necessary steps to establish an inpatient rehabilitation facility (IRF) transfer payment policy for early discharges to home health care and 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.
- 6. CMS should seek legislative authority to comprehensively reform the hospital wage index system.
- 7. 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.

#### CMS—Medicare Parts C and D

- 8. CMS should take steps to increase access to treatments for opioid use disorder.
- 9. CMS should monitor and provide targeted oversight for Medicare Advantage Organizations (MAOs) that had a disproportionate share of risk-adjusted payments from chart reviews and health reimbursement arrangements (HRAs).
- 10. CMS should require MAOs to submit and encourage MAOs to provide program oversight based on an ordering provider's national provider identifier (NPI) on encounter records for DME, prosthetics, orthotics, and supplies, as well as for laboratory, imaging, and home health services.
- 11. 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

- 12. CMS should ensure that States' reporting of national Medicaid data is complete, accurate, and timely.
- 13. CMS should monitor national performance data for blood lead screening tests for children and target efforts toward low-performing States to develop action plans for increasing the provision of blood lead screening tests.\*
- 14. CMS should develop policies and procedures to improve the timeliness of recovering Medicaid overpayments and recover uncollected amounts identified by OIG's audits.
- 15. CMS should improve Medicaid managed care organizations' (MCOs') 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 should improve access to appropriate mental health treatment services for unaccompanied children and take all reasonable steps to minimize the amount of time that they remain in ORR's custody.
- 18. ACF and HHS should improve their operational, management, and communication systems to better address the safety and security needs of unaccompanied children.
- 19. ACF should develop a comprehensive strategy to improve States' compliance with requirements related to treatment planning and medication monitoring for children in foster care who are prescribed psychotropic medication.

## Indian Health Service (IHS)

20. 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)

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

## Food and Drug Administration (FDA)

22. 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

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

- 24. 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.
- 25. HHS should ensure that cybersecurity incident response capabilities are fully implemented across the Department.

<sup>\*</sup> These recommendations appear on OIG's Top 25 list for the first time in this edition.

## 1.

# 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 (CHIP) 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,

# Relevant Top Management and Performance Challenges (TMCs):

- Safeguarding Public Health
- Safeguarding the Well-Being of HHS Beneficiaries
- Ensuring the Financial Integrity of HHS Programs

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.

# Top Unimplemented Recommendations

CMS should take actions to ensure that incidents of potential abuse or neglect of Medicare and Medicaid beneficiaries, including those in nursing homes and hospice care as well as children enrolled in Medicaid, 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 State Survey Agencies to record and track all incidents of potential abuse or neglect and related referrals made to law enforcement and other agencies. 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.

We used Medicaid 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 had 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 and that the revisions will clarify existing guidance on reporting violations. CMS stated it is also in the process of revising its instructions to survey agencies to ensure that complaints of abuse and neglect are tracked and referred appropriately.

In the Medicare hospice setting, CMS indicated that State Survey Agencies must have a complaint hotline that includes collecting and maintaining hospice complaints based on the Consolidated Appropriations Act of 2021. CMS developed and published a video to educate the public on how to file complaints about health care treatment issues including poor quality of care, patient rights, and abuse. Additionally, CMS indicated that it continues to strengthen guidance for surveyors to report crimes to local law enforcement agencies. CMS has not committed to revising the Condition of Participations regarding the reporting of abuse, neglect, and other harm, but is planning to add new interpretive guidance for hospices regarding reporting.

Regarding potential child abuse and neglect of children in Medicaid, CMS stated that it reviewed existing Federal requirements to report suspected child abuse and neglect of Medicaid beneficiaries and assessed 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. However, CMS determined that the current Federal requirements are sufficient and that no further action is required from CMS.

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); <u>A-04-17-04063</u> (July 2020); <u>A-02-18-01006</u> (August 2020); <u>A-09-19-02005</u> (June 2021); <u>A-04-17-03084</u> (April 2021); <u>A-04-17-08058</u> (March 2021)

CMS should address inappropriate nursing home discharges through training, by implementing deferred initiatives, and by assessing the effectiveness of its enforcement against inappropriate facility-initiated discharges.

#### Key OIG Findings

OIG identified multiple challenges that exist in identifying and addressing inappropriate facility-initiated discharges by nursing homes and assessing their frequency. CMS does not collect data on the number of facility-initiated discharges from nursing homes and many State ombudsmen do not count or track the notices they receive. In addition, ombudsmen, CMS, and State agencies may differ in their perspectives

on regulations and enforcement of facility-initiated discharges. Following CMS's initiative to review and take appropriate enforcement action in cases of noncompliance with facility-initiated discharge requirements, State agencies cited many more nursing homes for not complying with notice requirements for discharges in 2018. However, CMS has not yet determined the trends and outcomes of its initiative.

#### Progress in Implementing the Recommendation

In its April 2022 final management decision, CMS stated that it plans to provide training, including clarification of guidance around facility-initiated discharges and/or transfers. CMS will also incorporate an assessment of the effectiveness of enforcement actions in response to inappropriate facility-initiated discharges. Lastly, CMS indicated that it is working to implement as soon as possible a variety of initiatives that it had previously deferred.

Relevant Report: OEI-01-18-00250 (November 2021)

CMS should take steps to reduce the costs for Medicare and its beneficiaries by promoting the use of less costly, clinically appropriate drugs.

#### **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 from the third quarter 2010 and the second quarter 2011, 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.

Biosimilars also have the potential to significantly reduce costs for Part D and beneficiaries if their use becomes more widespread. We estimated that annual Part D spending on biologics with available biosimilars could have decreased by \$84 million, or 18 percent, in 2019 if all biosimilars had been used as frequently as the most used biosimilars. Additionally, beneficiaries' out-of-pocket costs for these drugs could have decreased by \$1.8 million, or 12 percent. Far greater spending reductions will be possible as additional biosimilars become available, particularly with the expected launches of biosimilars for the blockbuster drug Humira in 2023.

## Progress in Implementing the Recommendation

CMS did not concur with the recommendation in our 2012 report to seek authority to implement least costly alternative policies in appropriate circumstances in Part B, and has since indicated that it does not plan to take action at this time.

CMS concurred with OIG's recommendation to encourage Part D plans to increase access to and use of biosimilars, such as through a demonstration project or the Star Ratings system. CMS neither concurred nor nonconcurred with our recommendation to monitor Part D plans' submitted formularies to determine whether they discourage beneficiaries from using biosimilars. In its final management decision, CMS stated it will examine how demonstration projects could be used to test methods to lower

beneficiary and program spending on drugs and incentivize the use of biosimilars. Additionally, although it did not concur with the second recommendation, CMS reported that as part of its annual review of formularies it would monitor submitted formularies to determine whether they discourage biosimilar use.

Relevant Report: OEI-12-12-00210 (November 2012); OEI-05-20-00480 (March 2022)

4.

CMS should improve and implement system edit processes for its DME Medicare contractors to prevent improper payments for services provided to hospice beneficiaries.

#### **Key OIG Findings**

For 121 of 200 sampled durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items, Medicare improperly paid suppliers for DMEPOS items they provided to hospice beneficiaries. These items were provided to palliate or manage the beneficiaries' terminal illnesses and related conditions and, as such, are considered included in the per diem payments that Medicare pays to hospices. These items should have been provided directly by the hospices or under arrangements between the hospices and the suppliers and not separately paid by Medicare.

Medicare improperly paid the suppliers because the system edit processes that should have prevented the improper payments were not effective or did not exist. In some of these cases (67), the suppliers inappropriately used a modifier (GW) to indicate that the items were not related to the beneficiaries' terminal illness or conditions, but our audit found that these items were related. On the basis of our sample results, we estimated that Medicare could have saved \$116.9 million in payments during our audit period from January 1, 2015, through April 30, 2019, and beneficiaries could have saved \$29.8 million in deductibles and coinsurance that may have been incorrectly collected from them or from someone on their behalf.

## Progress in Implementing the Recommendation

CMS instructed the DME Medicare contractors to deny DMEPOS claims submitted by suppliers without the GW modifier for DMEPOS items provided to hospice beneficiaries and direct the DME and hospice Medicare contractors, or other contractors as appropriate, to conduct prepayment or postpayment reviews of supplier claims billed with the GW modifier. However, CMS does not concur with the recommendation to implement a postpayment edit process. CMS stated that the Recovery Audit Contractors were approved to begin reviewing DMEPOS claims billed after the admission date and before the discharge date of a hospice election beginning in October 2018. We believe given the volume of claims that would need to be reviewed by the Recovery Audit Contractors, implementing an automatic postpayment edit process would lead to timely review of claims and recovery of improper payments. We also continue to recommend that CMS study the feasibility of including palliative items and services not related to a beneficiary's terminal illness and related conditions within the hospice per diem, a recommendation with which CMS disagreed. The report findings and prior OIG work indicates that there is potential inappropriate unbundling of items and services from the hospice benefit. A requirement to include palliative items and services not related to the beneficiary's terminal illness and related conditions

within the hospice per diem may promote better coordination of care by making the hospice responsible for the provision and coordination of these items and services.

Relevant Report: A-09-20-03026 (November 2021)

## SIGNIFICANT PROGRESS: Top 25 Recommendations From 2021 Edition

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. CMS should 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. Moreover, CMS should take steps to better ensure that nursing homes are adequately staffed. OEI-01-20-00430, OEI-04-18-00450, and OEI-04-18-00451.

UPDATE: CMS has taken important steps to implement OIG recommendations related to improving infection control surveys and leveraging nursing home staffing data to better target oversight and increase transparency for consumers. With respect to focused infection control surveys (FICSs), CMS has assessed and documented their adequacy by monitoring results of these surveys monthly. CMS concluded, based on this monitoring, that FICSs continue to help surveyors identify noncompliance with CMS's prevention and control standards, and CMS has incorporated elements from the surveys into the standard survey process used to certify facility compliance. Regarding nursing home staffing data, in January 2022 CMS began posting weekend staffing and staff turnover measures on the Care Compare website. CMS also shares Payroll Based Journal staffing data, including lists of facilities that potentially have insufficient weekend staffing, with state survey agencies. Lastly, CMS is in the process of generating reports and updating survey documents, including the Critical Elements Pathways, which are used for investigating areas of concern. This progress is part of larger nursing home reforms that the administration and CMS are pursuing. OIG continues to invest substantially in oversight of nursing home quality and safety and will continue to monitor CMS's progress on related reforms.

# CMS—Medicare Parts A and B

In 2021, approximately 36 million beneficiaries were enrolled in Medicare Part A and/or Part B. Total expenditures for Medicare Parts A and B came to \$328.9 billion and \$405.5, respectively, with Part A costs leading to a net loss of \$60.4 billion for the Hospital Insurance Trust Fund. The 2022 Annual Report by Medicare's Board of Trustees estimates that the Trust Fund for Medicare Part A (hospital insurance) will be depleted by 2028. It also projects that cost growth for Medicare Part B (medical insurance) will average 10.5 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 from fraud, waste, and abuse; and implementing prudent

#### **Relevant TMCs:**

- Ensuring the Financial Integrity of HHS Programs
- Delivering Value, Quality, and Improved Outcomes in CMS Programs
- <u>Strengthening</u>
   <u>Coordination for Better</u>
   <u>Programs and Services</u>
- Safeguarding the Well-Being of HHS Beneficiaries

payment policies. OIG's work promotes quality of care for Medicare beneficiaries in various settings. As a top priority, OIG is specifically focusing on improving nursing homes.

# Top Unimplemented Recommendations

CMS should take the necessary steps to establish an IRF transfer payment policy for early discharges to home health care and 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.

Medicare could have also saved approximately \$993 million in 2017 and 2018 if CMS had expanded its IRF transfer payment policy to apply to early discharges to home health care. This payment policy would be consistent with the transfer payment policies currently in effect for early discharges from one IRF to another IRF, a long-term care hospital, an inpatient hospital, or a nursing home. Moreover, it would generally provide IRFs with payments that are greater than their costs to provide care. However, CMS did not explain why it has not expanded the IRF transfer payment policy to cover discharges to home health care.

## 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 impact these have had on the relationship between IRF payments and costs. Furthermore, CMS stated that it is working on an IRF Review Choice Demonstration to ensure that patients admitted to IRFs appropriately meet the Medicare criteria for IRF admission. In addition, CMS collaborated with the HHS Assistant Secretary for Planning and Evaluation to develop a prototype and recommendations for a unified post-acute care payment system that includes IRFs, skilled nursing facilities, home health agencies, and long-term care hospitals. CMS indicated that the prototype aligns Medicare post-acute care payments as closely as possible with the post-acute care needs of all Medicare beneficiaries and breaks 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. The report containing the prototype was delivered to Congress on July 1, 2022, as per the requirements of the IMPACT Act of 2014.

CMS included a request for information from the public in the FY 2023 IRF PPS proposed rule about the recommendation to establish an IRF transfer payment policy for early discharges to home health care. We are reviewing the information we received during the comment period for the rule and will use this information, as well as other data analysis, to inform future policy in this area.

Relevant Reports: A-01-15-00500 (September 2018); A-01-20-00501 (December 2021)

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 related 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. However, Congress has not passed legislation authorizing the demonstration request. The proposed demonstration was 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. However, this proposal was not included in the FY 2023 President's Budget.

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

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 for the claims in our sample. On the basis of our sample results, we estimated that hospitals received overpayments of \$1 billion for incorrect severe malnutrition diagnosis codes for FYs 2016 and 2017.

More generally, we also 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. 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. Many of these stays at the highest severity level had other patterns that raise questions, such as particularly short durations and having only one diagnosis that elevated the stay to that highest severity level. Furthermore, hospitals varied significantly in billing these stays, with some billing much differently than most.

## Progress in Implementing the Recommendation

CMS has taken initial steps toward implementing the recommendations related to severe malnutrition diagnosis codes. Specifically, CMS tasked its Supplemental Medical Review Contractor (SMRC) with research and analysis to develop a medical review strategy for malnutrition claims. The SMRC determined providers' use of the severe malnutrition diagnosis codes (E41 and E43) continued to trend

upward and made several recommendations to CMS, including development and creation of policy regarding malnutrition diagnostic criteria in the form of local coverage determinations to provide consistent guidance from the MACs. With respect to the net overpayment amount identified for the claims in our sample, CMS has so far recovered \$400,208 of the \$505,400 that was within the 4-year reopening period. CMS also tasked the SMRC with postpayment review of claims with E41 and E43 from calendar year (CY) 2019; this project is in progress. The SMRC is currently conducting discussions, education, and re-reviews. During this process, providers can submit missing and/or additional documentation, have their claims re-reviewed, and receive education.

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 and recovery audit contractor reviews, which are already being conducted, are essential to ensuring that Medicare dollars are spent appropriately.

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

## 8.

# CMS—Medicare Parts C and D

Approximately 52.9 million beneficiaries received Medicare Part D benefits and 28.9 million beneficiaries were enrolled in Medicare Part C in 2022. Part D is a prescription drug benefit provided through private insurance companies known as Part D plan sponsors. Part C (Medicare Advantage) 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. As a top priority, OIG is specifically focusing 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 Part D programs.

#### **Relevant TMCs:**

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

# Top Unimplemented Recommendations

CMS should take steps to increase access to treatments for opioid use disorder.

## **Key OIG Findings**

Based on Medicare Parts B, C, and D claims, just over 1 million Medicare beneficiaries had a diagnosis of opioid use disorder in 2020. Although this chronic disease can be treated with medication, less than 16 percent of these beneficiaries received medication to treat their opioid use disorder in 2020.

Even fewer beneficiaries received both medication and behavioral therapy for treatment. Less than half of the beneficiaries who received medication to treat their opioid use disorder also received behavioral therapy. Most beneficiaries received medication in an office-based setting, as opposed to an opioid treatment program, and of those beneficiaries less than one-third of the beneficiaries received behavioral therapy.

Furthermore, Asian/Pacific Islander, Hispanic, and Black beneficiaries were less likely to receive medication to treat their opioid use disorder than White beneficiaries, raising health equity concerns. Older beneficiaries and those not receiving Part D low-income subsidies were also less likely to receive medication to treat their opioid use disorder.

## Progress in Implementing the Recommendation

CMS has taken several steps to educate beneficiaries about access to medications for the treatment of opioid use disorder and naloxone. In June 2021, CMS released the <u>CMS Action Plan to Enhance</u>

Prevention and Treatment of Opioid Use Disorder, which outlines plans to address many of OIG's findings.

CMS confirmed that it is working on conducting additional outreach to beneficiaries to increase awareness about coverage for the treatment of opioid use disorder; taking steps to increase the number

9.

of provider and opioid treatment programs for Medicare beneficiaries with opioid use disorder; taking steps to address disparities in the treatment of opioid use disorder; collecting data on the use of telehealth in opioid treatment programs; increasing the utilization among beneficiaries receiving medication to treat opioid use disorder; and continuing to update its existing Medicare print and web content.

CMS has not yet explicitly indicated whether it will assist the Substance Abuse and Mental Health Services Administration (SAMHSA) by providing data about the number of Medicare beneficiaries receiving buprenorphine in office-based settings or the geographic areas where Medicare beneficiaries remain underserved.

Relevant Report: OEI-02-20-00390 (December 2021)

CMS should monitor and provide targeted oversight for MAOs that had a disproportionate share of risk-adjusted payments from chart reviews and HRAs.

#### **Key OIG Findings**

The MA program makes risk-adjusted payments to MAOs to account for health status differences among enrolled beneficiaries in order to determine a monthly payment. MAOs are paid higher payments for beneficiaries who need a costlier level of care (based on diagnoses submitted by MAOs), which helps to ensure these beneficiaries have continued access to MA plans. Chart reviews are retrospective reviews of beneficiary medical records to identify and add diagnoses that providers did not originally submit to MAOs and delete any invalid diagnoses. Chart reviews are intended to ensure accurate risk-adjustment payments. HRAs collect information on health status, health risks, and daily activities from beneficiaries. When used properly, HRAs can improve beneficiaries' care coordination and health outcomes. However, OIG has identified concerning patterns in diagnoses arising from chart reviews and HRAs. Specifically, OIG found that \$2.7 billion in risk-adjusted payments resulted from chart review diagnoses that MAOs did not link to specific services provided to the beneficiaries. OIG also found 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. These findings raise concern that these diagnoses only on chart reviews or HRAs may not be accurate and that, if these diagnoses are accurate, beneficiaries may not be receiving all needed care for often-serious conditions. Twenty of the 162 MAOs drove a disproportionate share of the payments from diagnoses that were reported only on chart reviews and HRAs—and no other service records—with one company driving almost 40 percent of these payments yet having enrolled only 22 percent of MA beneficiaries.

## Progress in Implementing the Recommendation

CMS implemented our recommendation to provide targeted oversight of MAOs that had risk-adjusted payments from unlinked chart reviews for beneficiaries by providing data exchange reports directly to MAOs with unlinked chart reviews. 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

Relevant Reports: <u>OEI-03-17-00470</u> (December 2019); <u>OEI-03-17-00471</u> (September 2020); <u>OEI-03-17-00474</u> (September 2021)

resulting from in-home HRAs for beneficiaries with no other service records in the 2016 encounter data.

CMS intends to provide documentation of their increased oversight efforts pertaining to HRAs in November 2022. CMS nonconcurred with our recommendations to provide oversight of the 20 MAO companies that had a disproportionate share of the risk-adjusted payments from chart reviews and HRAs, stating that HRAs and chart reviews are allowable sources of diagnoses for risk-adjusted payments in the

CMS should require MAOs to submit and encourage MAOs to provide program oversight based on an ordering provider's NPI on encounter records for DME, prosthetics, orthotics, and supplies, as well as for laboratory, imaging, and home health services.

#### **Key OIG Findings**

MAO program.

Ordering and referring provider identifiers are not required in, and were frequently absent from, Medicare Advantage encounter data for records of 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. In an OIG survey conducted in 2020, almost half of the MAOs that lacked ordering NPIs on at least some MA encounter records raised concerns that this hindered their data analysis for program integrity. An NPI is 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 January 2022 update, 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); <u>OEI-03-19-00432</u> (April 2021)

11.

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**

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 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. In a final management decision received in October 2021, CMS did not indicate that it had any planned actions to work directly with hospices to ensure that they are providing drugs covered under the hospice benefit, as we have recommended.

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

## IMPLEMENTED: Top 25 Recommendation From 2021 Edition

With respect to beneficiaries receiving treatment for opioid use disorder, CMS should educate Part D beneficiaries about access to medication assisted drugs and naloxone. <u>OEI-02-19-00130</u>

Update: In a 2020 Call Letter, CMS published information about the coverage of both MAT drugs and naloxone as well as the co-prescribing of naloxone. In the 2021 Dear Doctor Letter, CMS included language about co-prescribing naloxone, the coverage of naloxone and MAT available under Medicare, and information about Medicare Part D opioid policies. CMS also has language in its 2022 Medicare & You handbook about Medicare coverage of treatment for opioid use disorder and naloxone. In addition, under 42 C.F.R. § 423.128(b)(11) all Part D sponsors are required to educate their enrollees about opioid risks and alternatives as of January 1, 2022. Finally, CMS also provided OIG with a copy of CMS Publication 12033, Safer Use of Opioid Pain Medication, to demonstrate its efforts to educate beneficiaries about access to naloxone and MAT drugs. This publication includes information about naloxone and encourages beneficiaries to talk to their doctors about opioid alternatives.

## 12.

## 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 2020, Medicaid spending grew 9.2 percent to \$671.2 billion. As of March 2022, Medicaid served nearly 88 million individuals, including those in 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 CMS Programs
- Safeguarding the Well-Being of HHS Beneficiaries
- Harnessing and Protecting Data and Technology 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. For example, 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. CMS indicated that it reviews T-MSIS data submissions as part of the T-MSIS State compliance process, and that CMS also sent all State Medicaid directors a compliance letter indicating enhanced systems funding is at risk for each State that does not address its respective, remaining priority data quality issues. CMS developed new data elements that can be used to uniquely report multiple identifiers associated with a single beneficiary. Finally, CMS indicated that it will work with a State to rectify incomplete, inaccurate, or untimely encounter data submissions when deficiencies are found in T-MSIS data submissions. These actions have led to some important improvements, but more needs to be done as T-MSIS data deficiencies persist. For example, CMS can strengthen its efforts to improve the accuracy and completeness of managed care payment data in

T-MSIS. 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 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)

CMS should monitor national performance data for blood lead screening tests for children and target efforts toward low-performing States to develop action plans for increasing the provision of blood lead screening tests.

#### **Key OIG Findings**

There is no safe level of lead exposure; even low-level blood lead concentrations during childhood have been associated with behavioral and physical impairments. Children exposed to lead may suffer stunted cognitive development and delayed reproductive development. Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit covers preventive medical services—including blood lead screening tests—for enrolled children. In the 5 States we reviewed, 38 percent of 1 million Medicaid-enrolled children did not receive a blood lead screening test at 12 months or 24 months of age, as required by Medicaid's schedule during FYs 2015—18.

#### Progress in Implementing the Recommendation

CMS concurred with the recommendation and stated that it would monitor national EPSDT performance data for blood lead screening tests for children in order to identify States performing in the lowest quartile. CMS will request that States performing in the lowest quartile develop an action plan, and CMS will provide technical assistance, as necessary.

Relevant Report: <u>OEI-07-18-00371</u> (October 2021)

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 (FYs 2010–15) and prior (FYs 2004–09) 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.

14.

#### Progress in Implementing the Recommendation

As of April 2022, 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. Specific details of CMS's progress toward these collections, as reported by CMS, are as follows. 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.

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)

CMS should improve Medicaid MCOs' identifications and referrals of cases of suspected fraud or abuse.

#### **Key OIG Findings**

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 a State, and not all MCOs used proactive data analysis—a critical tool for fraud identification, based on analysis of data collected in 2015. In addition, MCOs took actions against providers suspected of fraud or abuse but did not typically inform a State. For example, MCOs that terminated provider contracts for reasons associated with fraud or abuse did not typically inform a State. Finally, MCOs did not always identify and recover overpayments, including those associated with fraud or abuse. Instead, overpayments were 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 continues to 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 referring cases of suspected fraud or abuse. CMS also indicated it has plans to offer a Medicaid Managed Care course at the Medicaid Integrity Institute for State Medicaid staff.

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**

16.

OIG found that the State of New Mexico's Medicaid managed care program operated with a limited availability of behavioral health services for its enrollees, including few behavioral health providers and difficulty arranging services. In a 2019 report, New Mexico's Behavioral Health Organizations reported challenges with finding and retaining staff, based on an analysis of 2017 managed care data. They also reported challenges with continuity of care for enrollees, citing limited care coordination, provider shortages, and barriers to sharing health information. The challenges faced by New Mexico are likely shared by other States and will require both State and national attention. Telehealth is a key tool that New Mexico and many other States use to try to ensure that Medicaid managed care enrollees have sufficient access to behavioral health services. In a 2021 report, OIG found that most States reported multiple challenges with using telehealth to provide these services, including a lack of training for providers and enrollees, limited internet connectivity for providers and enrollees, difficulties with providers' protecting the privacy and security of enrollees' personal information, and the cost of telehealth infrastructure and interoperability issues for providers. These findings were based a survey of State Medicaid Directors in 2020. CMS plays an important role in facilitating the exchange of information about approaches to addressing States' efforts to ensure access to behavioral health services. Sharing this information among States will help States address concerns about shortages of behavioral health providers and realize the potential benefits of telehealth.

## Progress in Implementing the Recommendation

CMS concurred with our recommendation to identify States that have 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. CMS consulted with States and other stakeholders on the development of a template for States to attest to their plans' compliance with managed care requirements. CMS intended that States' reporting requirements would be collected electronically through a web-based submission portal. Moreover, 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.

CMS also concurred with the recommendation to share information to help States address challenges with using telehealth to provide behavioral health services to Medicaid enrollees. CMS noted that it will

take into account the broader concerns OIG identified with using telehealth in determining how it can further support States with using telehealth to ensure the provision of high-quality behavioral health services to Medicaid enrollees. The Bipartisan Safer Communities Act, passed in June 2022, also directs the Secretary to provide technical assistance and issue guidance to States on improving access to telehealth services covered under Medicaid and CHIP.

Relevant Reports: <u>OEI-02-17-00490</u> (September 2019); <u>OEI-02-19-00400</u> (September 2021); <u>OEI-02-19-00401</u> (September 2021)

# 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 in HHS custody prior to being released to sponsors in the United States.

#### Relevant TMCs:

- Safeguarding the Well-Being of HHS Beneficiaries
- Strengthening Coordination for Better Programs and Services

# Top Unimplemented Recommendations

ACF should improve access to appropriate mental health treatment services for unaccompanied children and take all reasonable steps to minimize the amount of time that they remain in ORR's custody.

#### **Key OIG Findings**

In a September 2019 report, OIG found that ORR facilities faced challenges in addressing the mental health needs of unaccompanied children (UC), especially those who had experienced significant trauma, given the uncertainty of how long a child would remain in ORR care. Facilities reported challenges in areas that included employing mental health clinicians, a shortage of which resulted in high caseloads and limited their effectiveness in addressing children's needs; accessing external mental health care providers; and transferring children to facilities within ORR's network that provide specialized treatment.

## Progress in Implementing the Recommendation

ORR has taken steps to improve access to mental health treatment services for UC. ACF indicated that it established the ORR Trauma Training Initiative in September 2021 to build partnerships and assist ORR programs, including ORR programs' staff and grantees, in improving trauma-informed knowledge and competencies. In addition, ACF developed a workgroup to discuss strategies for enhancing the recruitment of clinicians. ORR also made progress in increasing therapeutic placement options for children who require more intensive mental health treatment. As of January 2021, ACF has funded 11 therapeutic programs. There are still actions ACF can take to address the mental health needs of UC, including 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.

Relevant Report: OEI-09-18-00431 (September 2019)

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

#### **Key OIG Findings**

OIG identified vulnerabilities in the safety incident reporting system and oversight of care provider facilities' physical security. In reports released in June 2020, we found that ORR's incident reporting system is ineffective at capturing information about incidents occurring at provider facilities that assists 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, aside from ORR's monitoring tools used to review physical security measures and variations in State and local licensing requirements, 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, under which immigration officials separated children from their parents or legal guardians and referred them to ORR. While HHS was not responsible for separating families, this lack of interagency preparation and coordination impeded HHS's ability to identify, care for, and reunify children with their parents or guardians. We also found care provider facilities faced significant operational challenges at every stage of reunification, causing children to experience additional stress.

## Progress in Implementing the Recommendation

ACF and HHS agreed with OIG's findings and have planned steps to implement the recommendations. Regarding ORR's incident reporting system, ACF continues to stabilize and gradually improve the current UC Portal platform. ORR's UC Portal team has made improvements to the portal over the past year and releases biweekly updates, ranging from case management user experience improvements to adding features and functions required by ORR policy. Timely updates to the UC Portal platform are important for oversight of ORR's program and for protecting children in ORR's care.

Regarding physical security measures, ACF updated its Site Visit Worksheet and Walkthrough Checklist to confirm that facilities' inspection checklists include all ORR-required physical security measures. ACF also finalized guidance that describes ORR's planned methods to ensure that facilities regularly report inspection checklist results to ORR. ORR examined whether to enhance existing physical security requirements for facilities, and such efforts are currently underway.

With respect to communication and management challenges, ACF reported in a December 2021 update that it had established an online directory of field guidance issued to care provider facilities and engaged in various efforts to improve coordination with interagency partners. In addition, ACF recently indicated that ORR has developed an emergency policy development protocol that provides input from staff with expertise in child welfare whenever ORR develops and reevaluates existing policies and field guidance.

HHS still needs to take specific steps to ensure that children's interests are prioritized and represented in decisions affecting the UC program, including directing ACF and ORR leadership to: (1) ensure that potential risks to children are explicitly assessed and considered in decisions about policies affecting UC; (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 expected to elevate information and recommendations necessary to protect children's interests. Finally, ACF noted that it is taking a stepwise approach to upgrading the UC Portal in coordination with DHS by reducing manual processes used to identify and track separated children.

Relevant Reports: <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>OEI-07-21-00251</u> (September 2022)

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

#### **Key OIG Findings**

In the five States we reviewed between October 1, 2014, and March 31, 2015, one in three children in foster care 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

In its final management decision, ACF indicated that the topic of oversight of psychotropic medications would be addressed with its constituency group of State foster care managers. In its latest update in September 2021, ACF stated that it assessed the findings from the third round of its State Child and Family Services Reviews related to the use of psychotropic medications and determined that it will continue to evaluate these concerns in future reviews. Furthermore, ACF plans to provide guidance for States that must develop improvement plans in this area. Finally, ACF restated 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)

# 20.

# Indian Health Service (IHS)

IHS, with an estimated annual budget of \$9.1 billion in FY 2022, 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:**

- Strengthening Coordination for Better Programs and Services
- Safeguarding the Well-Being of HHS Beneficiaries

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 has had chronic issues with recruiting and retaining an adequate workforce in its hospitals. These issues have affected the stability of IHS hospital services and continuity of care, prompted facilities to update policies related to patient protections, and limited the clinical support and guidance that IHS Area Offices are able to provide. Notably, 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. IHS also reported to OIG that it was concerned that the COVID-19 pandemic could exacerbate staffing challenges.

## Progress in Implementing the Recommendation

IHS stated that it would assemble a task force to create a workforce plan that was expected to be completed 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,

IHS 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 workgroup completed the comprehensive workforce plan and made recommendations to ensure current and future succession planning for IHS hospital leadership in September 2020. IHS stated that shifts in priorities in response to the COVID-19 pandemic delayed progress on implementing the workgroup recommendations, but it plans to reevaluate the recommendations in FY 2023.

Relevant Reports: <u>OEI-06-20-00700</u> (September 2021); <u>OEI-06-19-00330</u> (July 2019); <u>OEI-06-17-00270</u> (July 2019); <u>OEI-06-14-00011</u> (October 2016); <u>OEI-06-16-00390</u> (August 2019)

With an annual budget of approximately \$45 billion in FY 2022, NIH is the Nation's medical research agency and the largest grant-making agency in HHS. It is made up of 27 Institutes and Centers (ICs), each with its own specific research agenda. More than 84 percent of NIH's funding is awarded for extramural research, largely through competitive grants. Numerous congressional committees have

#### **Relevant TMC:**

 Ensuring the Financial Integrity of HHS Programs

expressed concerns about potential threats to the 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, a 2019 report found that NIH could not—and did 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 OIG's recommendation to update its guidance on vetting peer review nominees. To this end, NIH has centralized the vetting of peer reviewer nominees in its Office of Extramural Research, which is now responsible for peer review nominee vetting across the agency. NIH also concurred with OIG's recommendation to develop a risk-based approach to identify peer reviewers who may pose a threat to integrity. NIH also is exploring ways to conduct targeted, risk-based oversight of peer reviewers using risk indicators identified through analyses of research integrity threats and peer review integrity violations. NIH concurred with OIG's recommendation from a June 2022 report to require grantees to report whether investigators' significant financial interests and other support involve foreign entities. NIH

has taken steps to address our recommendations. NIH needs to provide documentation of updates to its policies and training materials to address concerns related to undue foreign influence.

Relevant Reports:  $\underline{OEI-01-19-00160}$  (September 2019);  $\underline{OEI-05-19-00240}$  (March 2020);  $\underline{OEI-03-20-00210}$  (June 2022)

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 security of most of our Nation's food supply, cosmetics, dietary

#### **Relevant TMC:**

Safeguarding Public Health

supplements, and products that give off radiation. FDA had an annual budget of approximately \$6.1 billion in FY 2021. It is responsible for the oversight of more than \$2.7 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, among other issues.

# Top Unimplemented Recommendation

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**

REMS is a drug safety program that is intended to mitigate a specific serious risk associated with the use of a drug, and FDA has used REMS as tool to mitigate misuse of opioids. FDA specifies the requirements and approves REMS. However, the drug manufacturer is responsible for developing and implementing the program. Although REMS has the potential to help address the opioid crisis, OIG found that data quality issues made it challenging for FDA to determine whether REMS for opioids has been effective. In addition to limitations in data from drug manufacturers, 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. Furthermore, some opioid manufacturers have engaged in deceptive marketing practices that undermined REMS's educational messages regarding risk.

## Progress in Implementing the Recommendation

FDA is in the process of updating two relevant REMS Manuals of Policies and Procedures and Guidance. FDA has also undertaken a number of activities and is planning additional activities related to opioid prescriber education. However, OIG still encourages FDA, in re-examining the feasibility of mandatory training, to revisit requiring manufacturers to conduct more aggressive outreach or partnering with State medical license boards. FDA has also reported that its new patient registry appears to be operational and functioning as intended. All patients who received at least one

prescription for a transmucosal immediate-release fentanyl (TIRF) REMS appear to have been enrolled in the registry. FDA is currently reviewing the first assessment report that contains registry data and analysis. OIG will then review the assessment, including documentation of the extent to which FDA identified 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)

## General Departmental

In FY 2021, 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
- Safeguarding the Well-Being of HHS Beneficiaries
- Strengthening
   Coordination for Better
   Programs and Services
- <u>Ensuring the Financial</u> Integrity of HHS Programs

## 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 during the Ebola health crisis. 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 community health care systems to respond to public health emergencies and other emergencies, such as natural disasters, faced developmental challenges following new Administration for Strategic Preparedness and Response (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 the ability of HCCs to prepare for a whole community response to public health emergencies.

## Progress in Implementing the Recommendation

HHS has not provided OIG with its final management decision on its international preparedness efforts, and the recommendations associated with this review remain unimplemented. As a result of these unimplemented recommendations, along with GAO's recent elevation of HHS's leadership and

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coordination of public health emergencies to its High Risk List (January 2022), OIG has initiated a new review of HHS's emergency response capabilities.

Regarding 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 (CoPs) and continue 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 with 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**

We determined HHS contracts for CMS's strategic communications services during our audit period June 1, 2017, through April 30, 2019, 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 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. 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)

## HHS should ensure that cybersecurity incident response capabilities are fully implemented across the Department.

### **Key OIG Findings**

HHS did not sufficiently implement cybersecurity incident response capabilities across all OpDivs and did not sufficiently assess or obtain assurance of compliance by the OpDivs with the HHS cybersecurity incident response policy. Furthermore, HHS did not effectively define cybersecurity incident response roles or responsibilities, ensure that cloud and service contractors met cybersecurity incident response reporting as required by their contracts, or establish adequate oversight, guidance, and coordination over its cybersecurity incident response process to ensure OpDivs implemented adequate response capabilities. Finally, HHS did not create a policy to manage waivers for systems that did not meet HHS's security requirements.

#### Progress in Implementing the Recommendation

HHS provided evidence that it had taken several steps to implement and address cybersecurity incident response capabilities across all OpDivs and Components by defining response roles and responsibilities. However, HHS should ensure that all OpDivs comply with HHS's cybersecurity incident response policy that cloud and service contractors meet cybersecurity incident response reporting as required by their contracts. To address the response capabilities across the Department, HHS provided evidence of the effort taken by two OpDivs but, due to budget and contracting issues, one of the OpDivs was not able to complete its implementation.

Relevant Report: A-18-17-04002 (May 2020)

## IMPLEMENTED: Top 25 Recommendation From 2021 Edition

HHS should ensure that all future web application developments incorporate security requirements from an industry-recognized web application security standard. A-18-18-08500

UPDATE: HHS provided OIG with the HHS Policy for Software Development Secure Coding Practices, which includes generally acceptable secure coding practices in 12 areas (e.g., user authentication, password complexity, and access control) from the Open Web Application Security Project. It is stated in the policy that the OpDivs must update each area with secure coding recommendations specific to each OpDiv's policies and risk tolerance.

# 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 (March 2021)

## Centers for Medicare & Medicaid Services (CMS)

Recommendation	Relevant Report(s)
CMS should evaluate the potential impacts of updating the DRG window policy to include affiliated hospitals, and seek the necessary legislative authority to update the policy as appropriate.	Medicare and Beneficiaries Pay More for Preadmission Services at Affiliated Hospitals Than at Wholly Owned Settings, OEI-05-19-00380 (December 2021)
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)
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 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, A-05-17-00033 (October 2019)

Recommendation	Relevant Report(s)
CMS should seek legislative change to exclude authorized generic drug transactions to secondary manufacturers from the AMP calculation of the brand name drug. This change may increase manufacturer Medicaid rebate obligations by hundreds of millions of dollars each year.	Medicaid Could Save Hundreds of Millions by Excluding Authorized Generic Drug Transactions to Secondary Manufacturers from Brand Name Drugs' Average Manufacturer Price Calculations, A-06-18-04002 (April 2019)
Estimated Savings: \$595 million in CY 2015	
Top 25 Recommendation #6  CMS should seek legislative authority to comprehensively reform the hospital wage index system.	Significant Vulnerabilities Exist in the Hospital Wage Index System for Medicare Payments, A-01-17-00500 (November 2018)
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 Recommendation #11  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, <u>OEI-02-16-00570</u> (July 2018)
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)
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)

Recommendation	Relevant Report(s)
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)
CMS should evaluate the extent to which Medicare payment rates for therapy should be reduced.	The Medicare Payment System for Skilled Nursing Facilities Needs To Be Reevaluated, OEI-02-13-00610 (September 2015)
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 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)
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 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 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.  Estimated Savings: \$318 million in 2011 <sup>4</sup>	Medicare and Beneficiaries Could Realize Substantial Savings If the DRG Window Were Expanded, <u>OEI-05-12-00480</u> (February 2014)

<sup>&</sup>lt;sup>4</sup> 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.

Recommendation	Relevant Report(s)
<ul> <li>CMS should seek legislative authority to:         <ul> <li>remove Necessary Provider CAHs' permanent exemption from the distance requirement, allowing CMS to reassess these CAHs; and</li> <li>revise the CAH Conditions of Participation to include alternative location-related requirements.</li> </ul> </li> <li>Estimated Savings: \$449 million in 2011<sup>5</sup></li> </ul>	Most Critical Access Hospitals Would Not Meet the Location Requirements If Required To Re-Enroll in Medicare, OEI-05-12-00080 (August 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 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 #3  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 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 #22	FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and
FDA should seek legislative authority to enforce FDA assessment plans.	Mitigation Strategies Improve Drug Safety, OEI-04-11-00510 (February 2013)

<sup>&</sup>lt;sup>5</sup> 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)
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 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)

## National Institutes of Health (NIH)

Recommendation	Relevant Report(s)
NIH should promulgate regulations that address institutional FCOIs.	Institutional Conflicts of Interest at NIH Grantees, OEI-03-09-00480 (January 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 July 1, 2022. 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 summaries of the top 25 unimplemented recommendations. 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)
<ul> <li>CMS should:         <ul> <li>take additional steps to validate the information reported in Minimum Data Set assessments and</li> <li>supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes.</li> </ul> </li> </ul>	CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes, <u>OEI-07-19-00490</u> (May 2021)
<ul> <li>CMS should:         <ul> <li>provide data to consumers on nurse staff turnover and tenure, as required by Federal law;</li> <li>consider residents' levels of need when identifying nursing homes for weekend inspections;</li> <li>ensure the accuracy of non-nurse staffing data used on Care Compare; and</li> <li>take additional steps to strengthen oversight of nursing home staffing.</li> </ul> </li> </ul>	CMS Use of Data on Nursing Home Staffing: Progress and Opportunities To Do More, OEI-04-18-00451 (March 2021)
Top 25 Recommendation #7  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)
With respect to nursing home surveys, CMS should:  • clarify expectations for States to complete backlogs of standard surveys and high-priority complaint surveys,	Onsite Surveys of Nursing Homes During the COVID-19 Pandemic:

Recommendation	Relevant Report(s)
<ul> <li>work with States to help overcome challenges with PPE and staffing, and</li> <li>assess the results of infection control surveys and revise the surveys as appropriate.</li> </ul>	March 23-May 30, 2020, <u>OEI-01-20-00430</u> (December 2020)
<ul> <li>CMS should:         <ul> <li>ensure that all States receive training on CMS's updated triage guidance and</li> <li>identify new approaches to address those States that are consistently failing to meet the required timeframes for investigating the most serious nursing home complaints.</li> </ul> </li> </ul>	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 Manufacturers Reported Inaccurate Drug Product Data to CMS, OEI-03-19-00200 (September 2020)
<ul> <li>enhance efforts to ensure nursing homes meet daily staffing requirements and</li> <li>explore ways to provide consumers with additional information on nursing homes' daily staffing levels and variability.</li> </ul>	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)
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 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 • instruct the outpatient facilities to refund corresponding overcharges to beneficiaries.	Medicare Made Hundreds of Thousands of Dollars in Overpayments for Chronic Care Management Services, <u>A-07-17-05101</u> (November 2019)

Recommendation	Relevant Report(s)
CMS should review Medicare allowable amounts for 161 orthotic device Healthcare Procedure Common Coding System 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 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)
<ul> <li>CMS should: <ul> <li>expand the deficiency data that accrediting organizations report to CMS and use these data to strengthen its oversight of hospices;</li> <li>include on Hospice Compare the survey reports from State agencies;</li> <li>include on Hospice Compare the survey reports from accrediting organizations, once authority is obtained; and</li> <li>increase oversight of hospices with a history of serious deficiencies.</li> </ul> </li> </ul>	Hospice Deficiencies Pose Risks to Medicare Beneficiaries, OEI-02-17-00020 (July 2019)
Top 25 Recommendation #1  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	Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm, <u>OEI-02-17-00021</u> (July 2019)

Recommendation	Relevant Report(s)
improve and make user-friendly the process for beneficiaries and caregivers to make complaints.	
<ul> <li>Top 25 Recommendation #1</li> <li>With respect to identifying instances of potential abuse or neglect, CMS should:         <ul> <li>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,</li> <li>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,</li> <li>monitor Survey Agencies' reporting of findings of substantiated abuse to local law enforcement, and</li> <li>clarify guidance to clearly define and provide examples of incidents of potential abuse or neglect.</li> </ul> </li> </ul>	Incidents of Potential Abuse and Neglect at Skilled Nursing Facilities Were Not Always Reported and Investigated, A-01-16-00509 (June 2019)
Top 25 Recommendation #1  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	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)
<ul> <li>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).</li> <li>Estimated Savings: \$84.2 million based on estimates from CY 2013 through CY 2015</li> </ul>	
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)
<ul> <li>Top 25 Recommendation #6</li> <li>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: <ul> <li>seek legislative authority to penalize hospitals that submit inaccurate or incomplete wage data in the absence of misrepresentation or falsification;</li> <li>seek legislation to repeal the law creating the rural floor wage index;</li> <li>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;</li> <li>rescind its hold-harmless policy relating to geographically reclassified hospitals' wage data; and</li> <li>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.</li> </ul> </li> </ul>	Significant Vulnerabilities Exist in the Hospital Wage Index System for Medicare Payments, A-01-17-00500 (November 2018)
Top 25 Recommendation #5  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 Facility Stays Did Not Meet Medicare Coverage and Documentation Requirements, A-01-15-00500 (September 2018)

Recommendation	Relevant Report(s)
Top 25 Recommendation #5  CMS should expand the IRF transfer payment policy to apply to early discharges to home health care. If this expanded policy had been in place, Medicare could have saved \$993,134,059 in CYs 2017 and 2018.	Medicare Could Have Saved Approximately \$993 Million in 2017 and 2018 if It Had Implemented an Inpatient Rehabilitation Facility Transfer Payment Policy for Early Discharges to Home Health Agencies, A-01-20-00501 (December 2021)
Estimated Savings: \$993 million in CY 2017 and 2018	
CMS should expand the price-substitution policy.  Estimated Savings: \$2.7 million <sup>6</sup>	Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2016 Average Sales Prices, OEI-03-18-00120 (August 2018)
<ul> <li>With respect to the Medicare hospice program, CMS should: <ul> <li>analyze claims data to inform the survey process;</li> <li>develop other claims-based information and include it on Hospice Compare;</li> <li>include in Hospice Compare deficiency data from surveys, including information about complaints filed and resulting deficiencies;</li> <li>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;</li> <li>ensure that a physician is involved in decisions to start and continue general inpatient care;</li> <li>analyze claims data to identify hospices that engage in practices or have characteristics that raise concerns;</li> <li>take appropriate actions to follow up with hospices that engage in practices or have characteristics that raise concerns;</li> <li>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;</li> <li>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;</li> </ul> </li> </ul>	Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio, OEI-02-16-00570 (July 2018)

<sup>&</sup>lt;sup>6</sup> 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)
<ul> <li>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;</li> <li>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;</li> <li>adjust payments based on these analyses, if appropriate, to ensure that the payment system is aligned with beneficiary needs and quality of care; and</li> <li>modify payments for hospice care in nursing facilities.</li> </ul>	
<ul> <li>CMS should:         <ul> <li>conduct periodic postpayment reviews for telehealth claim edits that cannot be implemented and implement all telehealth claim edits and</li> <li>work with Medicare contractors to implement all telehealth claims edits listed in the Manual.</li> </ul> </li> <li>Estimated Savings: \$3.7 million during CYs 2014 and 2015</li> </ul>	CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements, A-05-16-00058 (April 2018)
CMS should direct 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 through December 2021.	Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination With Urine Drug Tests, A-09-16-02034 (February 2018)
<ul> <li>identify strategies to increase MACs' collection of Zone         Program Integrity Contractors and Unified Program Integrity         Contractors referred overpayments and</li> <li>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.</li> </ul>	Enhancements Needed in the Tracking and Collection of Medicare Overpayments Identified by ZPICs and PSCs, OEI-03-13-00630 (September 2017)
CMS should continue to work with the Accredited 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	

Recommendation	Relevant Report(s)
<ul> <li>With respect to Medicare's 2-midnight hospital policy, CMS should:</li> <li>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,</li> <li>identify and target for review the short inpatient stays that are potentially inappropriate under the 2-midnight policy,</li> <li>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</li> <li>explore ways of protecting beneficiaries in outpatient stays from paying more than they would have paid as inpatients.</li> </ul>	Vulnerabilities Remain Under Medicare's 2-Midnight Hospital Policy, OEI-02-15-00020 (December 2016)
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, <u>OEI-02-10-00492</u> (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)
<ul> <li>take appropriate action against hospitals and their off-campus, provider-based facilities that we identified as not meeting requirements; and</li> <li>require hospitals to submit attestations for all of their provider-based facilities.</li> </ul>	CMS Is Taking Steps To Improve Oversight of Provider-Based Facilities, But Vulnerabilities Remain, OEI-04-12-00380 (June 2016)
<ul> <li>evaluate the extent to which Medicare payment rates for therapy should be reduced and</li> <li>adjust Medicare payments to eliminate any increases that are unrelated to beneficiary characteristics.</li> </ul>	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 <sup>7</sup>	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)
<ul> <li>explore the possibility of requiring providers to identify on the Part B claim the pharmacy that produced the compounded drug and</li> <li>explore the possibility of conducting descriptive analyses of Part B claims for compounded drugs.</li> </ul>	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)
<ul> <li>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,</li> <li>reduce PPS payment rates for ASC-approved procedures on beneficiaries with no-risk or low-risk clinical needs in outpatient departments, and then</li> <li>develop and implement a payment strategy in which outpatient departments would continue to receive the standard PPS payment rate for ASC-approved procedures that must be provided in an outpatient department because of a beneficiary's individual clinical needs.</li> </ul>	Medicare and Beneficiaries Could Save Billions If CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates, A-05-12-00020 (April 2014)
Estimated Savings: Up to \$15 billion over a 6-year period from CY 2012 through CY 2017	
CMS should distinguish payments in the end-stage renal disease base rate between independent and hospital-based dialysis facilities.	Update: Medicare Payments for End Stage Renal Disease Drugs, OEI-03-12-00550 (March 2014)

<sup>&</sup>lt;sup>7</sup> 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.  Estimated Savings: \$318 million in 20118	Medicare and Beneficiaries Could Realize Substantial Savings If the DRG Window Were Expanded, OEI-05-12-00480 (February 2014)
CMS should work with the Agency for Healthcare Research and Quality 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)
<ul> <li>CMS should seek legislative authority to:         <ul> <li>remove Necessary Provider CAHs' permanent exemptions from the distance requirement, allowing CMS to reassess these CAHs and</li> <li>revise the CAH Conditions of Participation to include alternative location-related requirements.</li> </ul> </li> <li>Estimated Savings: \$449 million in 2011<sup>9</sup></li> </ul>	Most Critical Access Hospitals Would Not Meet the Location Requirements If Required to Re-enroll in Medicare, OEI-05-12-00080 (August 2013)
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)
Top 25 Recommendation #3  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)

<sup>&</sup>lt;sup>8</sup> 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)
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.	Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided, <u>A-05-09-00053</u> (May 2012)
Estimated Savings: \$49 million <sup>10</sup>	
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, <u>A-05-09-00054</u> (May 2012)
Estimated Savings: \$14.6 million <sup>11</sup>	
CMS should facilitate access to information necessary to ensure accurate coverage and reimbursement determination.	Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, <u>OEI-07-08-00150</u> (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, <u>OEI-03-09-00510</u> (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.  Estimated Savings: \$97.6 million per year <sup>12</sup>	Nationwide Review of Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005, A-05-07-00077 (April 2009)
CMS should seek legislative authority or administratively require rural health clinic applicants to document need and impact on access to health care in rural underserved areas.	Status of the Rural Health Clinic Program, OEI-05-03-00170 (August 2005)
CMS should evaluate the potential impacts of updating the DRG window policy to include affiliated hospitals, and seek the necessary legislative authority to update the policy as appropriate.	Medicare and Beneficiaries Pay More for Preadmission Services at Affiliated Hospitals Than at Wholly Owned Settings, OEI-05-19-00380 (December 2021)

<sup>&</sup>lt;sup>10</sup> Estimate based on CY 2007 data.

 $<sup>^{\</sup>rm 11}$  Estimate based on CY 2007 data.

<sup>&</sup>lt;sup>12</sup> Estimate based on CY 2005 data.

Recommendation	Relevant Report(s)
CMS should identify and implement an appropriate way to address cybersecurity of networked medical devices in its quality oversight of hospitals, in consultation with HHS partners and others.	Medicare Lacks Consistent Oversight of Cybersecurity for Networked Medical Devices in Hospitals, OEI-01-20-00220 (June 2021)
Top Recommendation #4  CMS should take the following actions for supplier claims for DMEPOS items provided to hospice beneficiaries:  • implement a postpayment edit process to detect claims submitted by suppliers processed before a beneficiary's notice of election of hospice care is processed in the CWF, and instruct the DME Medicare contractors to deny DMEPOS claims identified by the edit process if they do not have the GW modifier;  • direct the DME and hospice Medicare contractors or other contractors as appropriate to:  • conduct prepayment or postpayment reviews of supplier claims for DMEPOS items provided to hospice beneficiaries and billed with the GW modifier, and  • analyze Medicare claims data to probe and educate suppliers that use the GW modifier inappropriately; and  • study the feasibility of including palliative items and services not related to a beneficiary's terminal illness and related conditions within the hospice per diem. Such a requirement would eliminate the need for Medicare to make additional payments for these services consistent with CMS's longstanding position that payments for services unrelated to a beneficiary's terminal illness and related conditions should be exceptional, unusual, and rare given the comprehensive nature of the services covered under the Medicare hospice benefit.	Medicare Improperly Paid Suppliers an Estimated \$117 Million Over 4 Years for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Provided to Hospice Beneficiaries, A-09-20-03026 (November 2021)
Estimated Savings: \$116.9 million from January 2015 through April 2019	

## CMS—Medicare Parts C and D

Recommendation	Relevant Report(s)
Top 25 Recommendation #3	Medicare Part D and Beneficiaries Could Realize Significant Spending
CMS should:	Reductions With Increased Biosimilar
<ul> <li>encourage Part D plans to increase access to and use of biosimilars, and</li> </ul>	<i>Use</i> , <u>OEI-05-20-00480</u> (March 2022)
<ul> <li>monitor Part D plans' submitted formularies to determine whether they discourage beneficiaries from using biosimilars.</li> </ul>	

Recommendation	Relevant Report(s)
<ul> <li>CMS should: <ul> <li>conduct additional outreach to beneficiaries to increase awareness about Medicare coverage for the treatment of opioid use disorder,</li> <li>take steps to increase the number of providers and opioid treatment programs for Medicare beneficiaries with opioid use disorder,</li> <li>assist SAMHSA by providing data about the number of Medicare beneficiaries receiving buprenorphine in office-based settings and the geographic areas where Medicare beneficiaries remain underserved,</li> <li>take steps to increase the utilization of behavioral therapy among beneficiaries receiving medication to treat opioid use disorder,</li> <li>create an action plan and take steps to address disparities in the treatment of opioid use disorder, and</li> <li>collect data on the use of telehealth in opioid treatment programs.</li> </ul> </li> </ul>	Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder, OEI-02-20-00390 (December 2021)
Top 25 Recommendation #10  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)
<ul> <li>Top 25 Recommendation #9</li> <li>With respect to Medicare Advantage payments, CMS should: <ul> <li>require MAOs to flag any MAO-initiated HRAs in MA encounter data,</li> <li>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,</li> <li>provide targeted oversight of the 10 parent organizations that drove most of the risk-adjusted payments resulting from in-home HRAs,</li> <li>require MAOs to implement best practices to ensure care coordination for HRAs, and</li> <li>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.</li> </ul> </li> </ul>	Billions in Estimated Medicare Advantage Payments From Diagnoses Reported Only on Health Risk Assessments Raise Concerns, OEl-03-17-00471 (September 2020)

Recommendation	Relevant Report(s)
Top 25 Recommendation #10  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)
<ul> <li>CMS should:         <ul> <li>provide oversight of the 20 MA companies that had a disproportionate share of the risk-adjusted payments from chart reviews and HRAs;</li> <li>take additional actions to determine the appropriateness of payments and care for the one MA company that substantially drove risk-adjusted payments from chart reviews and HRAs; and</li> <li>perform periodic monitoring to identify MA companies that had a disproportionate share of risk-adjusted payments from chart reviews and HRAs.</li> </ul> </li> </ul>	Some Medicare Advantage Companies Leveraged Chart Reviews and Health Risk Assessments To Disproportionately Drive Payments, OEI-03-17-00474 (September 2021)
<ul> <li>allow revocation of Medicare enrollment for inappropriate billing of Part D,</li> <li>apply the Preclusion List payment prohibitions to pharmacies and other providers that dispense Part D drugs, and</li> <li>include on the Preclusion List pharmacies that inappropriately bill Part D.</li> </ul>	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)
Top 25 Recommendation #9  CMS should:  • 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)
<ul> <li>take action to reduce inappropriate pharmacy rejections;</li> <li>take action to reduce inappropriate coverage denials; and</li> </ul>	Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs, <u>OEI-09-16-00411</u> (September 2019)

Recommendation	Polovant Ponort(s)
	Relevant Report(s)
<ul> <li>provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials.</li> </ul>	
<ul> <li>Top 25 Recommendation #11</li> <li>With respect to Medicare Part D drugs, CMS should: <ul> <li>work directly with hospices to ensure that they are providing drugs covered under the hospice benefit and</li> <li>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.</li> </ul> </li> </ul>	Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit, A-06-17-08004 (August 2019)
Estimated Savings: \$160.8 million a year in Part D total costs	
<ul> <li>CMS should:         <ul> <li>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</li> <li>provide beneficiaries with clear, easily accessible information about serious violations by MAOs.</li> </ul> </li> </ul>	Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials, OEI-09-16-00410 (September 2018)
CMS should:	The MEDIC Produced Some Positive
<ul> <li>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;</li> <li>provide the MEDIC centralized access to all Part C encounter data;</li> <li>require that Part C and Part D providers and pharmacies enroll in Medicare;</li> <li>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;</li> <li>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</li> <li>establish measures to assess the MEDIC's effectiveness.</li> </ul>	Results but More Could be Done to Enhance its Effectiveness, OEI-03-17-00310 (July 2018)
Top 25 Recommendation #10	Medicare Advantage Encounter Data Show Promise for Program Oversight,
<ul> <li>With respect to Medicare Advantage encounter data, CMS should:</li> <li>require MAOs to submit ordering and referring provider identifiers for applicable records;</li> <li>ensure that MAOs submit rendering provider identifiers for applicable records; and</li> <li>track MAOs' responses to reject edits.</li> </ul>	But Improvements Are Needed, OEI-03-15-00060 (January 2018)

Recommendation	Relevant Report(s)
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)
<ul> <li>CMS should:         <ul> <li>determine whether outlier data values submitted by MAOs reflect inaccurate reporting or atypical performance and</li> <li>use appropriate Part C reportingrequirements data as part of its reviews of MAOs' performance.</li> </ul> </li> </ul>	CMS Regularly Reviews Part C Reporting Requirements Data, But Its Followup and Use of the Data Are Limited, OEI-03-11-00720 (March 2014)
<ul> <li>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</li> <li>share Part D plan sponsors' data on potential fraud and abuse with all sponsors and law enforcement.</li> </ul>	Less Than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse, OEI-03-13-00030 (March 2014)
<ul> <li>CMS should:         <ul> <li>define pharmacy benefit managers as entities that could benefit from formulary decisions;</li> <li>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</li> <li>oversee compliance with Federal Pharmacy and Therapeutics committee conflict-of-interest requirements and guidance.</li> </ul> </li> </ul>	Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions, OEI-05-10-00450 (March 2013)
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.	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 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)
<ul> <li>Top 25 Recommendation #13</li> <li>CMS should:         <ul> <li>monitor national EPSDT performance data for blood lead screening tests and target efforts toward low-performing States to develop action plans for increasing tests, according to Medicaid's schedule;</li> <li>ensure consistency across CMS guidance related to actionable blood lead reference values and blood lead screening test definitions; and</li> <li>coordinate with partners to develop and disseminate to State Medicaid agencies educational materials that reaffirm requirements and schedules for blood lead screening tests.</li> </ul> </li> </ul>	More Than One-Third of Medicaid- Enrolled Children in Five States Did Not Receive Required Blood Lead Screening Tests, OEI-07-18-00371 (October 2021)
<ul> <li>Top 25 Recommendation #16</li> <li>CMS should:         <ul> <li>ensure that the three States that are unable to distinguish telehealth from in-person services implement indicators to identify which services are provided via telehealth;</li> <li>conduct evaluations and support State efforts to evaluate the effects of telehealth on access, cost, and quality of behavioral health services; and</li> <li>conduct monitoring for fraud, waste, and abuse, and support State efforts to oversee telehealth for behavioral health services.</li> </ul> </li> </ul>	Opportunities Exist To Strengthen Evaluation and Oversight of Telehealth for Behavioral Health in Medicaid, OEI-02-19-00401 (September 2021)
Top 25 Recommendation #16  CMS should share information to help States address challenges with using telehealth to provide behavioral health services to Medicaid enrollees.	States Reported Multiple Challenges With Using Telehealth To Provide Behavioral Health Services to Medicaid Enrollees, OEI-02-19-00400 (September 2021)
Top 25 Recommendation #12  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)

Recommendation	Relevant Report(s)
Top 25 Recommendation #1  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 or neglect and help ensure compliance with the States' mandatory reporting laws.	Medicaid Data Can Be Used To Identify Instances of Potential Child Abuse or Neglect, A-01-19-00001 (July 2020)
<ul> <li>CMS should:         <ul> <li>collaborate with States to conduct greater oversight of Medicaid MCOs' management of specialty drugs, and this oversight could include a review of contract language that allows States to obtain requested information on specialty drug categorizations, specialty drug reimbursement methodologies, and cost management strategies;</li> <li>provide States with acquisition cost data for a wider range of specialty drugs; and</li> <li>work with States to expand alternative reimbursement models to address rising costs for drugs often categorized as specialty drugs.</li> </ul> </li> </ul>	States Could Do More To Oversee Spending and Contain Medicaid Costs for Specialty Drugs, OEI-03-17-00430 (December 2020)
CMS should 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)
<ul> <li>Top 25 Recommendation #12</li> <li>With respect to preventing terminated providers from serving Medicaid beneficiaries, CMS should:         <ul> <li>recover from States the Federal share of inappropriate feefor-service Medicaid payments associated with terminated providers,</li> <li>implement a method to recover from States the Federal share of inappropriate managed care capitation payments associated with terminated providers, and</li> </ul> </li> </ul>	States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries, OEI-03-19-00070 (March 2020)

Recommendation	Relevant Report(s)
<ul> <li>safeguard Medicaid from inappropriate payments associated with terminated providers.</li> </ul>	
<ul> <li>take steps to disallow Federal reimbursements to States for expenditures associated with unenrolled MCO network providers, including seeking necessary legislative authority;</li> <li>work with States to ensure that unenrolled providers do not participate in Medicaid managed care and assist States in establishing ways to do so;</li> <li>work with States to ensure that they have the controls required to prevent unenrolled ordering, referring, or prescribing providers from participating in Medicaid fee-forservice; and</li> <li>work with States to ensure that they are complying with requirements to collect identifying information and ownership information on Medicaid provider enrollment forms.</li> </ul>	Twenty-Three States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries, OEI-05-19-00060 (March 2020)
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 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 #12  With respect to opioid prescribing in Medicaid, CMS should ensure the correct submission of prescriber National Provider Identifiers.	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 Attention Deficit Hyperactivity Disorder.	Many Medicaid-Enrolled Children Who Were Treated for ADHD Did Not Receive Recommended Followup Care, OEI-07-17-00170 (August 2019)
<ul> <li>CMS should:         <ul> <li>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</li> <li>compare high-risk Medicaid providers' self-reported ownership information to Medicare's provider ownership information to help States identify discrepancies.</li> </ul> </li> </ul>	Problems Remain for Ensuring All High-Risk Medicaid Providers Undergo Criminal Background Checks, OEI-05-18-00070 (July 2019)

Recommendation	Relevant Report(s)
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)
<ul> <li>• 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;</li> <li>• 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</li> <li>• 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.</li> </ul>	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)
<ul> <li>CMS should:         <ul> <li>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);</li> <li>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;</li> <li>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;</li> <li>strengthen guidance to State agencies to clarify who must attest that a correction plan will be implemented by a nursing home;</li> <li>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</li> <li>work with State agencies to address technical issues with the automated survey processing environment system for maintaining supporting documentation.</li> </ul> </li> </ul>	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)
<ul> <li>CMS should:         <ul> <li>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</li> <li>promptly resolve the 140 outstanding audit recommendations that were past due as of September 30, 2016.</li> </ul> </li> </ul>	Although the Centers for Medicare and Medicaid Services 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 a 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 a CMS-64 to improve oversight of the reporting process.	The Centers for Medicare and Medicaid Services Had Not Recovered More Than a Billion Dollars in Medicaid Overpayments Identified by OIG Audits, A-05-17-00013 (December 2018)
CMS should reevaluate 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 #12 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;  • 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)
<ul> <li>CMS should:         <ul> <li>develop a central system by which States can submit and access screening results from other States,</li> <li>strengthen minimum standards for fingerprint-based criminal background checks and site visits, and</li> <li>work with States to develop a plan to complete their revalidation screening in a timely way.</li> </ul> </li> </ul>	Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented, OEI-05-13-00520 (May 2016)
<ul> <li>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;</li> <li>publish regulations that are consistent with Department of the Treasury provisions in 31 CFR part 205 and educate States;</li> </ul>	Opportunities for Program Improvements Related to States' Withdrawals of Federal Medicaid Funds, A-06-14-00068 (March 2016)

Recommendation	Relevant Report(s)
<ul> <li>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</li> <li>require States to reconcile total Federal Medicaid funds withdrawn with the Federal share of net expenditures and issue appropriate reconciliation guidelines.</li> </ul>	
<ul> <li>CMS should:         <ul> <li>develop benchmarks for dental services and require States to create mandatory action plans to meet them,</li> <li>work with States to analyze the effects of Medicaid payments on access to dental providers, and</li> <li>work with States to track children's utilization of required dental services.</li> </ul> </li> </ul>	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)
<ul> <li>CMS should work with States to:         <ul> <li>ensure that plans are complying with State standards and assess whether additional standards are needed,</li> <li>ensure that plans' networks are adequate and meet the needs of their Medicaid managed care enrollees, and</li> </ul> </li> <li>assess the number of providers offering appointments and improve the accuracy of plan information.</li> </ul>	Access to Care: Provider Availability in Medicaid Managed Care, OEI-02-13-00670 (December 2014)
<ul> <li>CMS should:         <ul> <li>strengthen its oversight of State standards and ensure that States develop standards for key providers,</li> <li>strengthen its oversight of States' methods to assess plan compliance and ensure that States conduct direct tests of access standards, and</li> <li>improve States' efforts to identify and address violations of access standards.</li> </ul> </li> </ul>	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)
<ul> <li>CMS should:         <ul> <li>take action against States that do not meet the Deficit</li> <li>Reduction Act of 2005 requirement to collect rebates on physician-administered drugs and</li> </ul> </li> </ul>	States' Collection of Medicaid Rebates for Physician-Administered Drugs, OEI-03-09-00410 (June 2011)

Recommendation	Relevant Report(s)
<ul> <li>ensure that all State agencies are accurately identifying and collecting physician-administered drug rebates owed by manufacturers.</li> </ul>	
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.	Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers, A-03-00-00216 (September 2001)
Estimated Savings: \$3.87 billion over 5 years	

## CMS—General

Recommendation	Relevant Report(s)
<ul> <li>CMS should:         <ul> <li>actively monitor the use and effectiveness of States' corrective action plans and other remedies, with a focus on making the remedies specific and outcome oriented;</li> <li>establish guidelines for progressive enforcement actions, including the use of sanctions, when persistent or egregious performance problems emerge;</li> <li>engage with senior State officials earlier and more frequently to address State performance problems;</li> <li>disseminate results of State performance reviews more widely to ensure that stakeholders become aware of problems; and</li> <li>revise the State Operations Manual to reflect current CMS practices in overseeing State survey performance.</li> </ul> </li> </ul>	CMS Should Take Further Action To Address States With Poor Performance in Conducting Nursing Home Surveys, OEI-06-19-00460 (January 2022)
Top 25 Recommendations #2  CMS should:  • provide training for nursing homes on Federal requirements for facility-initiated discharge notices;  • assess the effectiveness of its enforcement of inappropriate facility-initiated discharges;  • implement its deferred initiatives to address inappropriate facility-initiated discharge; coordinate with ACL to strengthen safeguards to protect nursing home residents from inappropriate facility-initiated discharges; and  • ensure that all State ombudsmen, State agencies, and CMS regional offices (ROs) have an ongoing venue to share information about facility-initiated discharges and potentially other systemic problems in nursing homes.	Facility-Initiated Discharges in Nursing Homes Require Further Attention, OEI-01-18-00250 (November 2021)

#### Recommendation

#### Relevant Report(s)

#### CMS should:

 continue to enhance the data analysis of Medicaid claimslevel 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 lookback analysis on the Medicaid Entitlement Benefits Due and Payable to determine the reasonableness of the methodology utilized for recording the approximately \$52.8 billion accrual;

- enhance the control attributes, including the precision of controls, around the completeness and accuracy of underlying data as it relates to the Medicaid SPA contingencies, and re-evaluate the responsible parties best suited to review the accrual at the balance sheet date particularly when the accrual changes between quarters exceed a specified amount;
- 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 the information security of its IT systems and data, at both headquarters and among CMS Medicare fee-for-service contractors.

Summary of recommendations from CMS Financial Report Fiscal Year 2021, Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2021, A-17-21-53000 (November 2021)

#### CMS should:

- 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:
  - o information related to individuals' premium payments paid during the benefit year and
  - o 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)

Estimated Savings: \$950 million in CY 2018

Recommendation	Relevant Report(s)
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)
<ul> <li>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;</li> <li>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</li> <li>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 a failure to file and reconcile response code from the IRS and who were determined eligible for insurance affordability programs.</li> </ul>	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 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.	Indian Health Service Hospitals: More Monitoring Needed To Ensure Quality Care, OEI-06-14-00010 (October 2016)

## Administration for Children and Families (ACF)

Recommendation	Relevant Report(s)
<ul> <li>ACF should:         <ul> <li>proactively provide technical assistance to States that face challenges in appointing a guardian ad litem for every child victim and</li> <li>proactively identify and address obstacles that States face in reporting complete and accurate guardian ad litem data.</li> </ul> </li> </ul>	ACF Cannot Ensure That All Child Victims of Abuse and Neglect Have Court Representation, OEI-12-16-00120 (March 2021)
Top 25 Recommendation #18  With respect to its incident reporting systems, ORR should:  • track and trend incident report information to better safeguard minors in ORR care;	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,

Recommendation	Relevant Report(s)
<ul> <li>improve ORR's guidance to facilities to help them consistently identify and report significant incidents;</li> <li>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</li> <li>work with care provider facilities to address staffing shortages of youth care workers that impact the ability to prevent, detect, and report incidents.</li> </ul>	<u>OEI-09-18-00430</u> (June 2020)
Top 25 Recommendation #18  With respect to security, ORR should conduct a review to determine whether to enhance 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)
<ul> <li>Top 25 Recommendation #18</li> <li>With respect to the Unaccompanied Children Program, HHS should:         <ul> <li>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;</li> <li>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; and</li> <li>further improve its ability to identify and track separated children by reducing reliance on manual processes.</li> </ul> </li> </ul>	Communication and Management Challenges Impeded HHS's Response to the Zero-Tolerance Policy, OEI-BL-18-00510 (March 2020)
<ul> <li>Top 25 Recommendation #17</li> <li>With respect to the mental health needs of children in HHS custody, ACF's ORR should: <ul> <li>identify and disseminate evidence-based approaches to addressing trauma in short-term therapy,</li> <li>develop and implement strategies to assist care provider facilities in overcoming obstacles to hiring and retaining qualified mental health clinicians,</li> <li>assess whether to establish maximum caseloads for individual mental health clinicians,</li> <li>help care provider facilities improve their access to mental health specialists, and</li> <li>take all reasonable steps to minimize the time that children remain in ORR custody.</li> </ul> </li> </ul>	Care Provider Facilities Described Challenges Addressing Mental Health Needs of Children in HHS Custody, OEI-09-18-00431 (September 2019)

Recommendation	Relevant Report(s)
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)
<ul> <li>Top 25 Recommendation #19</li> <li>With respect to children in foster care, ACF should:         <ul> <li>develop a comprehensive strategy to improve States' compliance with requirements related to treatment planning and medication monitoring for psychotropic medication, and</li> <li>help States strengthen their requirements for oversight of psychotropic medication by incorporating professional practice guidelines for monitoring children at the individual level.</li> </ul> </li> </ul>	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, OEI-07-13-00460 (March 2015)

## Administration for Community Living (ACL)

Recommendation	Relevant Report(s)
<ul> <li>ACL should:         <ul> <li>assist State ombudsman programs in establishing a data-collection system for facility-initiated discharge notices;</li> <li>establish guidance for analysis and reporting of data collected by State ombudsman programs from facility-initiated discharge notices;</li> <li>coordinate with CMS to strengthen safeguards to protect nursing home residents from inappropriate facility-initiated discharges; and</li> <li>ensure that all State ombudsmen, State agencies, and CMS ROs have an ongoing venue to share information about facility-initiated discharges and potentially other systemic problems in nursing homes.</li> </ul> </li> </ul>	Facility-Initiated Discharges in Nursing Homes Require Further Attention, OEI-01-18-00250 (November 2021)

## Food and Drug Administration (FDA)

Recommendation	Relevant Report(s)
<ul> <li>Top 25 Recommendation #22</li> <li>With respect to REMS, FDA should:         <ul> <li>seek additional authority to ensure that manufacturers are held accountable when appropriate;</li> <li>enhance its REMS assessment review process;</li> <li>strengthen REMS for opioid analgesics (the successor to extended-release and long-acting opioids) by requiring prescriber training; and</li> <li>use the new TIRF REMS patient registry to monitor for known areas of risk, such as inappropriate conversions and off-label prescribing.</li> </ul> </li> </ul>	FDA's Risk Evaluation and Mitigation Strategies: Uncertain Effectiveness in Addressing the Opioid Crisis, OEI-01-17-00510 (September 2020)
<ul> <li>DA should:         <ul> <li>build capacity in the Document Archiving, Reporting, and Regulatory Tracking System to support postmarketing requirements oversight; and</li> <li>provide a standardized form for annual status reports, ensure that they are complete, and require sponsors to submit them electronically.</li> </ul> </li> </ul>	FDA is Issuing More Postmarketing Requirements, but Challenges With Oversight Persist, OEI-01-14-00390 (July 2016)
Top 25 Recommendation #22  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, <u>OEI-01-11-00211</u> (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, <u>OEI-05-09-00321</u> (June 2011)

### Indian Health Service (IHS)

Recommendation	Relevant Report(s)
<ul> <li>Top 25 Recommendation #20</li> <li>IHS should:         <ul> <li>solicit feedback from critical care response teams (CCRTs) regarding their observations of potential need for broader, IHS-wide improvements;</li> <li>compile the CCRTs' recommendations to individual facilities and share them across all IHS and Tribal facilities; and</li> <li>assess whether IHS could use the CCRT model to provide support and training to facilities needing assistance with non-COVID-19-related care.</li> </ul> </li> </ul>	Indian Health Service Use of Critical Care Response Teams Has Helped To Meet Facility Needs During the COVID-19 Pandemic, OEI-06-20-00700 (September 2021)
<ul> <li>assess the costs and benefits of updating its electronic health record (EHR) system with tools to support more automated monitoring and</li> <li>request support from States and from Federal partners to address challenges with State-run prescription drug monitoring programs.</li> </ul>	Few Patients Received High Amounts of Opioids from IHS-Run Pharmacies, OEI-05-18-00470 (December 2020)
IHS should 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.	Incidence of Adverse Events in Indian Health Service Hospitals, OEI-06-17-00530 (December 2020)
<ul> <li>improve the process for and timeliness of conducting staff background investigations, and notifying facilities when staff are approved;</li> <li>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</li> <li>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.</li> </ul>	Indian Health Service Facilities Made Progress Incorporating Patient Protection Policies, but Challenges Remain, OEI-06-19-00331 (December 2020)
<ul> <li>encourage and support greater adoption of the Alliance for Innovation on Maternal Health's bundles of maternal-safety best practices;</li> <li>take steps to ensure that IHS providers employ best practices in diagnosing and treating postpartum hemorrhage; and</li> </ul>	Instances of IHS Labor and Delivery Care Not Following National Clinical Guidelines or Best Practices, OEI-06-19-00190 (December 2020)

Recommendation	Relevant Report(s)
<ul> <li>assess its labor and delivery practices and consider practice improvements based on the findings of this assessment.</li> </ul>	
<ul> <li>Top 25 Recommendation #20</li> <li>IHS should: <ul> <li>extend policies to address more types of perpetrators, victims, and abuse;</li> <li>ensure that the new incident reporting system is effective and addresses the risks identified in the current system;</li> <li>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; and</li> <li>continue to actively promote an organizational culture of transparency and work to resolve barriers to staff reporting of abuse.</li> </ul> </li> </ul>	Indian Health Service Has Strengthened Patient Protection Policies but Must Fully Integrate Them Into Practice and Organizational Culture, OEI-06-19-00330 (December 2019)
<ul> <li>Top 25 Recommendation #20</li> <li>With respect to IHS operated hospitals, IHS should:         <ul> <li>as a management priority, develop and implement a staffing program for recruiting, retaining, and transitioning staff and leadership to remote hospitals;</li> <li>enhance training and orientation for new hospital leaders to ensure that they follow IHS directives and continue improvement efforts; and</li> <li>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.</li> </ul> </li> </ul>	Rosebud Hospital, Indian Health Service Management of Emergency Department Closure and Reopening, A Case Study, OEI-06-17-00270 (July 2019)
<ul> <li>IHS should work with hospitals to:         <ul> <li>develop policies and procedures to review 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</li> <li>track all opioids prescribed at the hospital in the patient EHRs, including those being filled at an outside pharmacy.</li> </ul> </li> </ul>	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)

Recommendation	Relevant Report(s)
<ul> <li>implement a quality-focused compliance program to support Federal requirements for health care programs;</li> <li>continue to invest in training for hospital administration and staff, and assess the value and effectiveness of training efforts;</li> <li>establish standards and expectations for how Area Offices and Governing Boards oversee and monitor hospitals and monitor adherence to those standards; and</li> <li>continue to seek new, meaningful ways to monitor hospital quality through the use of outcomes and/or process measures.</li> </ul>	Indian Health Service Hospitals: More Monitoring Needed To Ensure Quality Care, OEI-06-14-00010 (October 2016)
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 #20  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.	Indian Health Service 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)
<ul> <li>NIH should:</li> <li>centrally capture and monitor data on ICs' funding of grant applications out of rank order; and</li> <li>update its policy and guidance to reflect the latest HHS grants policy on justifying funding out of rank order.</li> </ul>	Selected NIH Institutes Met Requirements for Documenting Peer Review But Could Do More To Track and Explain Funding Decisions, OEI-01-19-00140 (June 2021)
<ul> <li>Top 25 Recommendation #21</li> <li>With respect to peer reviewers, NIH should: <ul> <li>conduct targeted, risk-based oversight of peer reviewers using analysis of information about threats to research integrity;</li> <li>update its training materials routinely to include information about breaches of peer reviewer confidentiality and possible undue foreign influence; and</li> <li>require all peer reviewers to attend periodic training about peer review integrity.</li> </ul> </li> </ul>	NIH Has Acted To Protect Confidential Information Handled by Peer Reviewers, But It Could Do More, OEI-05-19-00240 (March 2020)

Recommendation	Relevant Report(s)
Top 25 Recommendation #21  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)
NIH should promulgate regulations that address institutional FCOIs.	Institutional Conflicts of Interest at NIH Grantees, OEI-03-09-00480 (January 2011)

## General Departmental

Recommendation	Relevant Report(s)
<ul> <li>continue to work with OMB and other stakeholders to develop and implement an approach to reporting on Temporary Assistance for Needy Families (TANF) improper payments in FY 2022, as this process will aid in identifying root causes of TANF improper payments and allow HHS to report corrective action plans (CAPs) in the Agency Financial Report;</li> <li>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 these new requirements, including working with States to bring their respective systems into full compliance with the requirements to decrease the improper payment rate percentage below 10 percent, and HHS should work with States to follow up on repeat root causes for errors and enhance the CAPs for implementation;</li> <li>continue to follow up with States during the interim period to verify that corrective actions identified after an improper Payment Error Rate Measurement review are being implemented, and HHS should also consider sharing corrective action best practices across States to help address these issues;</li> </ul>	Department of Health and Human Services Met Many Requirements, but It Did Not Fully Comply With the Payment Integrity Information Act of 2019 and Applicable Improper Payment Guidance for Fiscal Year 2021, A-17-22-52000 (May 2022)

Recommendation	Relevant Report(s)
<ul> <li>improve its recovery audit efforts as required under the Payment Integrity Information Act (PIIA) Section 2(i), to identify and recoup overpayments for Medicare Parts C and D unless not deemed cost-effective, and HHS should also continue to explore alternative vehicles to conduct recovery audits that will fit into the larger Medicare Parts C and D programs in FY 2022 in the event that the Risk Adjustment Data Validation and PPI-MEDIC programs cannot effectively serve as HHS's sole recovery audit strategies;</li> <li>continue to work with OMB and other relevant stakeholders to complete the improper payment measurement program for the federally facilitated exchange in FY 2022, and HHS continues to make progress in the development of an improper payment measurement methodology for the Statebased exchange to report an accurate improper payment estimate;</li> <li>either (1) implement a risk assessment strategy that ensures that all programs with annual outlays greater than \$10 million are risk-assessed at least once every 3 years; or (2) work with OMB to develop an approach and obtain concurrence to perform risk assessments at a level that meets the intent of PIIA, as HHS has 236 programs that exceed the \$10 million threshold in FY 2021 and HHS should consider what additional resources are needed to perform these risk assessments for an organization as large and complex as HHS, or what enhancements can be made to the current process to reduce the time and effort to risk assess each program; and</li> <li>focus on the root causes of the improper payment percentage and evaluate critical and feasible action steps to assist MAOs with compliance efforts, and this would include working with the MAOs—specifically those with repeated noncompliance—to ensure that medical record documentation is sufficient and substantiates clinical diagnoses, as these efforts could reduce medical record discrepancies, which would assist HHS in its efforts to decrease the improper payment rate percentage below 10 perce</li></ul>	
<ul> <li>HHS should:         <ul> <li>continue to develop and refine its financial management systems and processes to improve accounting, analysis, and oversight of financial management activity; and</li> <li>continue to strengthen oversight of remediation activities to limit new deficiencies and improve internal control over financial information systems.</li> </ul> </li> </ul>	Summary of recommendations from OIG Report on the Financial Statement Audit of HHS for Fiscal Year 2021, <u>A-17-21-00001</u> (November 2021)

Recommendation	Relevant Report(s)
Top 25 Recommendation #24  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)
Top 25 Recommendation #25  HHS should ensure that incident response capabilities are fully implemented at all OpDivs and Components.	HHS Should Address Gaps in Incident Response Capabilities Across the Department, A-18-17-04002 (May 2020)
<ul> <li>Top 25 Recommendation #23</li> <li>With respect to HCCs, ASPR should:         <ul> <li>clarify Hospital Preparedness Program guidance that HCC membership should ensure strategic, comprehensive coverage of community gaps in preparedness and response;</li> <li>continue to work with CMS to help health care entities comply with the CMS emergency preparedness CoPs;</li> <li>identify ways to incentivize core member participation in HCCs; and</li> <li>clarify to HPP awardees the flexibility available in meeting cooperative agreement requirements.</li> </ul> </li> </ul>	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)
<ul> <li>Top 25 Recommendation #23</li> <li>With respect to emergency response, HHS should: <ul> <li>develop departmentwide objectives and a strategic framework for responding to international public health emergencies;</li> <li>develop policies and procedures that clearly define HHS components' roles and responsibilities for responding to international public health emergencies;</li> <li>develop large-scale international response plans;</li> <li>develop various means of obtaining and using quality data for decision-making; and</li> <li>work with other Federal Government agencies to develop a flexible, multiagency international response framework.</li> </ul> </li> </ul>	HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts, A-04-16-03567 (August 2019)

Recommendation	Relevant Report(s)
<ul> <li>With respect to security, HHS should ensure that:</li> <li>OpDivs implement properly configured web application firewalls in accordance with an agreed-upon baseline standard established by HHS.</li> </ul>	Summary Report for Office of Inspector General Penetration Testing of Eight HHS Operating Division Networks, <u>A-18-18-08500</u> (March 2019)
HHS should address factors that may limit the Office for Human Research Protection's ability to operate independently.	OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence, OEI-01-15-00350 (July 2017)
HHS should revise its guidance to include specific standards for conducting past performance reviews of companies under consideration during contract procurement.	Federal Marketplace: Inadequacies in Contract Planning and Procurement, 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, <u>OEI-04-11-00530</u> (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 Technology, <u>OEI-01-11-00570</u> (December 2013)

# Appendix C: Implemented and Closed Recommendations Reported in 2021 Edition

This appendix identifies 72 significant recommendations described in the 2021 edition of this publication that were implemented or closed since the edition was issued. <sup>13</sup> OIG may close a recommendation that was 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 listed as relevant for reporting on the 2021 top 25 list. The status of each recommendation is also included. Each hyperlink below provides more information on the report relevant to each recommendation.

#### CMS—Medicare Parts A and B

Recommendation	Relevant Report(s)	Status
CMS should identify any claims for transfers to post-acute-care hospitals 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)	Implemented
<ul> <li>CMS should instruct DME MACs to:         <ul> <li>recover \$36,825 in overpayments for the 39 unallowable claim lines; and</li> <li>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.</li> </ul> </li> </ul>	Medicare Improperly Paid Suppliers an Estimated \$92.5 Million for Inhalation Drugs, A-09-18-03018 (October 2019)	Implemented/Closed
CMS should:  • review the impact of programmatic changes on the ability of Accountable Care Organizations to promote valuebased care,	ACOs' Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program, OEI-02-15-00451 (July 2019)	Implemented

<sup>&</sup>lt;sup>13</sup> OIG, 2021 OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs, Oct. 2021. Available at <a href="https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2021.pdf">https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2021.pdf</a>.

Recommendation	Relevant Report(s)	Status
<ul> <li>adopt outcome-based measures and better align measures across programs, and</li> <li>identify and share information about strategies that encourage patients to share behavioral health data.</li> </ul>		
CMS should educate hospices about common deficiencies and those that pose particular risks to beneficiaries.	Hospice Deficiencies Pose Risks to Medicare Beneficiaries, OEI-02-17-00020 (July 2019)	Implemented
CMS should assess the costs and benefits of improving oversight of no-payment bills submitted by SNFs.	CMS Did Not Detect Some Inappropriate Claims for Durable Medical Equipment in Nursing Facilities, OEI-06-16-00380 (June 2018)	Implemented
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)	Closed
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)	Implemented
CMS should seek legislative authority to expand the DRG window to include other hospital ownership arrangements, such as affiliated hospital groups.	Medicare and Beneficiaries Could Realize Substantial Savings If the DRG Window Were Expanded, OEI-05-12-00480 (February 2014)	Closed
CMS should lower the fee schedule amount for the L0631 back orthosis.	Medicare Supplier Acquisition Costs for L0631 Back Orthoses, OEI-03-11-00600 (December 2012)	Implemented
CMS should revise the requirements in the local coverage determination.	Questionable Billing by Suppliers of Lower Limb Prostheses, OEI-02-10-00170 (August 2011)	Closed
CMS should require that PSCs, ZPICs, and claims processors have controls in their tracking systems to ensure that all overpayment referrals and data related to their collection status can be found.	Collection Status of Medicare Overpayments Identified by Program Safeguard Contractors, OEI-03-08-00030 (May 2010)	Implemented

#### CMS—Medicare Parts C and D

Recommendation	Relevant Report(s)	Status
2021 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)	Implemented
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.	Billions in Estimated Medicare Advantage Payments From Chart Reviews Raise Concerns, OEI-03-17-00470 (December 2019)	Implemented
2021 Top 25 Recommendation #11  CMS should:  • establish and monitor Medicare    Advantage encounter data    performance thresholds related to    each MAO's submission of records    with complete and valid data,  • provide targeted oversight of MAOs    that submitted a higher percentage    of encounter records with potential    errors.	Medicare Advantage Encounter Data Show Promise for Program Oversight, But Improvements Are Needed, OEI-03-15-00060 (January 2018)	Implemented
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, A-07-13-01125 (April 2014)	Closed
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.	Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse, <u>OEI-03-07-00380</u> (October 2008)	Closed

#### CMS—Medicaid

Recommendation	Relevant Report(s)	Status
CMS should assist participating States in addressing the challenge of coordination between State-level departments.	National Background Check Program for Long-Term-Care Providers: Assessment of State Programs Concluded in 2019, OEI-07-20-00180 (September 2020)	Implemented
<ul> <li>2021 Top 25 Recommendation #13</li> <li>With respect to preventing terminated providers from serving Medicaid beneficiaries, CMS should:         <ul> <li>follow up with States to remove terminated providers that OIG identified as inappropriately enrolled in Medicaid, and</li> <li>confirm that States do not continue to have terminated providers enrolled in their Medicaid programs, and</li> <li>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.</li> </ul> </li> </ul>	States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries, OEI-03-19-00070 (March 2020)	Implemented
<ul> <li>CMS should:         <ul> <li>assess the costs and benefits of implementing a targeted process to review certain assumptions; and</li> <li>issue guidance related to the areas identified in the report, specifically value-based purchasing arrangements.</li> </ul> </li> </ul>	Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices, OEI-12-17-00130 (September 2019)	Implemented
2021 Top 25 Recommendations #13  With respect to opioid prescribing in Medicaid, CMS should 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)	Implemented

Recommendation	Relevant Report(s)	Status
CMS should ensure that all States fully implement fingerprint-based criminal background checks for high-risk Medicaid providers.	Problems Remain for Ensuring That All High-Risk Medicaid Providers Undergo Criminal Background Checks, <u>OEI-05-18-00070</u> (July 2019)	Implemented
2021 Top 25 Recommendations #13 and #15  CMS should work with States to clarify the information managed care organizations are required to report regarding providers who are terminated or otherwise leave the managed care organization network.	Weaknesses Exist in Medicaid Managed Care Organizations' Efforts To Identify and Address Fraud and Abuse, OEI-02-15-00260 (July 2018)	Implemented
CMS should assist States in implementing fingerprint-based criminal background checks for all high-risk providers.	Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented, OEI-05-13-00520 (May 2016)	Implemented
CMS should encourage State Medicaid programs to seek further cost savings for disposable incontinence supplies.	State Medicaid Program Efforts to Control Costs for Disposable Incontinence Supplies, OEI-07-12-00710 (January 2014)	Implemented

#### CMS—General

Recommendation	Relevant Report(s)	Status
• work with Treasury and Qualified Health Plan (QHP) 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 the monthly premium; and	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)	Implemented/Closed

Recommendation	Relevant Report(s)	Status
<ul> <li>work with Treasury and QHP 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.</li> </ul>		
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)	Implemented
CMS should require all benefit integrity contractors to report monetary impact, when calculable, in a consistent format.	Addressing Vulnerabilities Reported by Medicare Benefit Integrity Contractors, OEI-03-10-00500 (December 2011)	Implemented

## Administration for Children and Families (ACF)

Recommendation	Relevant Report(s)	Status
Missouri foster care agency should implement improvements to the case management system to enable accurate identification of children who are missing from care.	Case Study: Missouri's Efforts To Protect Children Missing From Foster Care, OEI-07-19-00372 (September 2021)	Implemented
<ul> <li>2021 Top 25 Recommendations #17</li> <li>With respect to contracts, ORR should:         <ul> <li>ORR should establish written policies and procedures for reviewing invoices;</li> <li>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;</li> </ul> </li> </ul>	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)	Implemented

Recommendation	Relevant Report(s)	Status
<ul> <li>work with PSC to document roles and responsibilities for designating a Contracting Officer Representative (COR) and defining contracts in accordance with the Federal Acquisition Regulation (FAR);</li> <li>work with PSC to recoup the \$2,581,157 overpayment of fixed fees from Comprehensive Health Service, LLC.</li> <li>develop plans for upcoming service needs by using all available data and indicators to ensure adherence to FAR competition requirements; and</li> <li>establish a policy and procedure for designating employees to serve as CORs.</li> </ul>		
2021 Top 25 Recommendations #17  With respect to security, ORR should:  • develop and implement methods to ensure that care provider facilities regularly report inspection checklist results to ORR, 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)	Implemented
2021 Top 25 Recommendations #17  HHS should improve communication to care provider facilities regarding interim guidance, operational directives, and other instructions that are not immediately available in published policy documents.	Communication and Management Challenges Impeded HHS's Response to the Zero-Tolerance Policy, OEI-BL-18-00510 (March 2020)	Implemented
2021 Top 25 Recommendations #17  With respect to the mental health needs of children in HHS custody, ACF's ORR should increase therapeutic placement options for children who require more intensive mental health treatment.	Care Provider Facilities Described Challenges Addressing Mental Health Needs of Children in HHS Custody, OEI-09-18-00431 (September 2019)	Implemented

Recommendation	Relevant Report(s)	Status
<ul> <li>reiterate to facilities that ORR requires all background checks be completed prior to an employee's start date and having access to children;</li> <li>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;</li> <li>provide additional guidance to facilities so they can better ensure that case managers and mental health clinicians meet ORR's minimum required education qualifications;</li> <li>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</li> <li>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.</li> </ul>	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)	Implemented

## Agency for Healthcare Research and Quality (AHRQ)

Recommendation	Relevant Report(s)	Status
<ul> <li>AHRQ should:         <ul> <li>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</li> <li>update guidance for patient safety organizations on the initial and continued listing processes.</li> </ul> </li> </ul>	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 provide educational outreach to trading partners about required drug product tracing information and data standardization guidelines.	Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain, OEI-05-17-00460 (February 2020)	Implemented
<ul> <li>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</li> <li>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.</li> </ul>	The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply,  A-01-16-01502 (December 2017)	Implemented

Recommendation	Relevant Report(s)	Status
FDA should provide technical assistance regarding exempt products.	Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information, OEI-05-14-00640 (September 2017)	Implemented
FDA should require standardized electronic clinical trial data and create an internal database.	Challenges To FDA's Ability To Monitor And Inspect Foreign Clinical Trials <u>OEI-01-08-00510</u> (June 2010)	Implemented

## National Institutes of Health (NIH)

Recommendation	Relevant Report(s)	Status
2021 Top 25 Recommendations #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.	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
2021 Top 25 Recommendations #20  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)	Closed
NIH should develop disseminate guidance on methods to verify researchers' financial interests.	How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health, OEI-03-07-00700 (November 2009)	Closed

## Indian Health Service (IHS)

Recommendation	Relevant Report(s)	Status
<ul> <li>IHS should:         <ul> <li>establish patient harm monitoring and reduction as a key priority of the Office of Quality, and</li> </ul> </li> </ul>	Incidence of Adverse Events in Indian Health Service Hospitals, OEI-06-17-00530 (December 2020)	Implemented

Recommendation	Relevant Report(s)	Status
<ul> <li>effectively track and monitor patient harm events using an improved incident reporting system.</li> </ul>		
IHS should 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.	Indian Health Service Facilities Made Progress Incorporating Patient Protection Policies, but Challenges Remain, OEI-06-19-00331 (December 2020)	Implemented
IHS should 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)	Implemented
2021 Top 25 Recommendations #19  With respect to IHS operated hospitals, IHS should continue to take steps to ensure early and effective intervention when IHS identifies problems at hospitals.	Rosebud Hospital, Indian Health Service Management of Emergency Department Closure and Reopening, A Case Study, OEI-06-17-00270 (July 2019)	Implemented

## General Departmental

Recommendation	Relevant Report(s)	Status
2021 Top 25 Recommendations #23  CMS should:  • 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;	CMS Did Not Administer and Manage Strategic Communications Services Contracts in Accordance With Federal Requirements, A-12-19-20003 (July 2020)	Implemented

Recommendation	Relevant Report(s)	Status
<ul> <li>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;</li> <li>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</li> <li>expand the "COR Invoice Approval Operating Guidance" to include a description of acceptable documentation to support contractor payments.</li> </ul>		
OHRP should request that HHS consider the adequacy of whistleblower protections for complainants who make disclosures to OHRP about human subjects protections.	OHRP Should Inform Potential Complainants of How They Can Seek Whistleblower Protections, OEI-01-15-00351 (September 2017)	Implemented
2021 Top 25 Recommendations #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.	Summary Report for Office of Inspector General Penetration Testing of Eight HHS Operating Division Networks, A-18-18-08500 (March 2019)	Implemented

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



