2020

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 August 2020 Edition

The *OIG'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, program effectiveness and efficiency, and public health and safety 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.[1]

The top 25 unimplemented recommendations in this edition derive from audits and evaluations issued through December 31, 2019. As such, these recommendations predate the COVID-19 public health emergency. We recognize that COVID-19 response and recovery efforts are a top priority for HHS, including OIG.

This edition begins with a list of the top 25 unimplemented recommendations, grouped by the cognizant HHS operating division (OpDiv). For each top 25 recommendation, we outline key OIG findings and the OpDiv's reported progress in implementation. In the appendices, we include a list of all unimplemented OIG recommendations that require legislative action. (See Appendix A.) We also include a broader list of OIG's significant unimplemented recommendations issued through June 1, 2020. (See Appendix B.)

Additionally, we include a list of over 50 significant recommendations reported in the 2019 edition of this publication that have since been implemented or closed.[2] (See Appendix C.) This list includes several Top 25 recommendations from the 2019 edition that were implemented by OpDivs in critical areas such as Medicare provider enrollment, questionable billing for Part D drugs, food facility inspections and recalls, and access to genomic data.

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

For more information

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

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

[2] OIG, *Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: OIG's Top Recommendations*, July 2019. Available at https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2019.pdf

[3] OIG, *2019 Top Management and Performance Challenges Facing HHS*, November 2019. Available at https://oig.hhs.gov/reports-and-publications/top-challenges/2019/2019-tmc.pdf.

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Top 25 Unimplemented Recommendations

The top 25 recommendations in this edition derive from audits and evaluations issued through December 31, 2019. As such, these recommendations predate the COVID-19 public health emergency. We recognize that COVID-19 response and recovery efforts are a top priority for the Department of Health and Human Services (HHS), including the Office of Inspector General (OIG).

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

1. CMS should take actions to ensure that incidents of potential abuse or neglect of Medicare beneficiaries are identified and reported.[1]
2. CMS should reevaluate the inpatient rehabilitation facility payment system, which could include seeking legislative authority to make any changes necessary to more closely align inpatient rehabilitation facility payment rates and costs.
3. CMS should seek legislative authority to comprehensively reform the hospital wage index system.[2]
4. CMS should seek legislative authority to implement least costly alternative policies for Part B drugs under appropriate circumstances.
5. CMS should provide consumers with additional information about hospices' performance via Hospice Compare.[1]
6. CMS should continue to work with the Accredited Standards Committee X12 to ensure that medical device-specific information is included on claim forms and require hospitals to use certain condition codes for reporting device replacement procedures.
7. CMS should analyze the potential impacts of counting time spent as an outpatient toward the 3-night requirement for skilled nursing facility (SNF) services so that beneficiaries receiving similar hospital care have similar access to these services.[3]

CMS—Medicare Parts C and D

8. CMS should provide targeted oversight of Medicare Advantage organizations (MAOs) that had risk-adjusted payments resulting from unlinked chart reviews for beneficiaries who had no service records in the 2016 encounter data.[1]
9. CMS should require MAOs to submit ordering and referring provider identifiers for applicable records in the encounter data.
10. 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.[1, 2, 4]

CMS—Medicaid

11. CMS should ensure that States' reporting of national Medicaid data is complete, accurate, and timely.
12. CMS should collaborate with partners to develop strategies for improving rates of followup care for children treated for attention deficit hyperactivity disorder (ADHD).[1]
13. CMS should develop policies and procedures to improve the timeliness of recovering Medicaid overpayments and recover uncollected amounts identified by OIG's audits.
14. CMS should 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.[1]

Administration for Children and Families (ACF)

15. ACF should improve access to appropriate mental health treatment services for unaccompanied children and take reasonable steps to minimize the time that they remain in the Office of Refugee Resettlement's (ORR's) custody.[1]
16. ACF should develop a comprehensive strategy to improve States' compliance with requirements related to treatment planning and medication monitoring for children prescribed psychotropic medication.

Administration for Community Living (ACL)

17. ACL should determine whether it can allocate its funds differently or seek additional department funding or resources to conduct required onsite compliance reviews of independent living programs.[1, 2]

Food and Drug Administration (FDA)

18. FDA should ensure effective and timely processes related to food facility inspections and food recalls.

Indian Health Service (IHS)

19. IHS should develop and implement a staffing program for recruiting, retaining, and transitioning staff and leadership to remote hospitals.[1]
20. IHS should work with hospitals to ensure that they follow the Indian Health Manual when prescribing and dispensing opioids.[1, 2]
21. IHS should increase oversight of information technology (IT) systems by IHS management.[1, 2]

National Institutes of Health (NIH)

22. NIH should continue to build on its efforts to identify and mitigate potential foreign threats to research integrity.[1]

General Departmental

23. HHS should develop departmentwide objectives and a strategic framework for responding to international public health emergencies.[1]
24. HHS should ensure that all future web application developments incorporate security requirements from an industry recognized web application security standard.
25. CMS and the Health Resources and Services Administration (HRSA) should ensure that States can pay correctly for 340B-purchased drugs billed to Medicaid, by requiring claim-level methods to identify 340B drugs and sharing the official 340B ceiling prices.

Table Note:

[1] Top 25 recommendation is new to this edition.

[2] As of the date of this publication, we have not received a Final Management Decision (FMD) for this recommendation, and it is overdue. OpDivs are required to submit an FMD within 6 months of report issuance, which indicate whether they concur with the recommendations and any corrective actions they plan to take to implement recommendations.

[3] Estimated Savings: $84.2 million based on estimates for SNF services that did not meet the 3-day rule from calendar years (CY) 2013 through 2015.

[4] Estimated Savings: $160.8 million a year in Part D total cost that hospice organizations should have paid for under the Part A hospice benefit in 2016.

CMS—Medicare Parts A and B

Approximately 38.6 million beneficiaries were enrolled in Medicare Parts A and B in 2019. In 2018, Medicare Parts A and B program payments reached $403 billion. The 2019 Annual Report by Medicare's Board of Trustees estimates that the Trust Fund for Medicare Part A (hospital insurance) will be depleted by 2026. It also projects that spending for Medicare Part B (medical insurance) will grow over 8.3 percent over the next 5 years, outpacing the U.S. economy. 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 payment policies. OIG's work promotes quality of care for Medicare beneficiaries in various settings. OIG also identifies and offers recommendations to reduce improper payments, prevent and deter fraud, and foster economical payment policies across Medicare Part A and B benefits.

Relevant Top Management and Performance Challenges (TMCs):

- Ensuring the Financial Integrity of HHS Programs
- Working Across Government To Provide Better Service to HHS Beneficiaries
- Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid
- Protecting the Health and Safety of HHS Beneficiaries

Top Unimplemented Recommendations

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

Key OIG Findings

An estimated one in five high-risk hospital emergency room Medicare claims for treatment provided in 2016 were the result of potential abuse or neglect of beneficiaries residing in a SNF. 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. Additionally, CMS does not require all incidents of potential abuse or neglect and related referrals made to law enforcement and other agencies to be recorded and tracked. In another report, we identified 34,664 Medicare claims that contained diagnosis codes indicating the treatment of injuries potentially caused by abuse or neglect of beneficiaries from January 2015 through June 2017; an estimated 30,754 of these claims were supported by medical records that contained evidence of potential abuse or neglect. Further, we found in some cases of beneficiary harm we reviewed that beneficiaries have been seriously harmed when hospices provided poor care or failed to take action 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

CMS stated that it will conduct annual data analysis on Immediate Jeopardy citations in hospice and analyze trends over time, as well as conduct an annual quality assurance study to determine if citations were appropriately cited at standard and condition level. CMS has also analyzed ways that beneficiaries can make complaints about hospice services and is evaluating ways to streamline the complaint process. CMS has not revised its interpretive guidance to add examples of potential abuse or neglect and other clarifications about reporting. However, it has published information on abuse and neglect in hospice and associated reporting requirements in a Medicare Learning Network article.

Relevant Reports: **A-01-16-00509** (June 2019); **A-01-17-00513** (June 2019); **OEI-02-17-00021** (June 2019)

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

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 cost, which may have provided IRFs with a financial incentive to admit patients inappropriately.

Progress in Implementing the Recommendation

CMS stated that it continuously evaluates the IRF payment system on an annual basis.

We note that the President's Fiscal Year (FY) 2021 Budget includes a proposal to establish a unified payment system based on patients' clinical needs rather than site of care. Under this proposal, IRFs will receive a lower annual Medicare payment update from FY 2021 to FY 2025. Beginning in FY 2026, a unified post-acute-care payment system would span four post-acute-care settings and would include a unified quality reporting program across the four settings.

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

3. 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

As of July 15, 2020, we had not received an FMD for this recommendation.

We note that the President's FY 2021 Budget includes a legislative proposal to create a statutory demonstration to test comprehensive wage index reform.

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

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

Key OIG Findings

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

Progress in Implementing the Recommendation

CMS indicated that it would consider including a legislative proposal to address the recommendation when developing legislative proposals for the President's FY 2021 Budget.

We note that the President's FY 2021 Budget did not include a legislative proposal seeking this legislative authority.

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

5. CMS should provide consumers with additional information about hospices' performance via Hospice Compare.

Key OIG Findings

Vulnerabilities exist in the hospice program. For instance, hospices do not always provide needed services to beneficiaries and sometimes provide poor quality care. Additionally, beneficiaries and their families and caregivers do not receive crucial information to make informed decisions about care. We found that over 80 percent of hospices surveyed from 2012 to 2016 had at least one deficiency in the quality of care provided to Medicare beneficiaries. Examples of these deficiencies involved poor care planning, mismanagement of aide services, and inadequate assessments of beneficiaries. Further, one-third of hospices had complaints filed against them. Over 300 hospices were poor performers in that each had at least one serious deficiency or at least one substantiated severe complaint in 2016. The findings make clear the need for CMS to strengthen its oversight of the Medicare hospice program to better protect both the program and its beneficiaries.

Progress in Implementing the Recommendation

CMS has published information from complaint surveys conducted by State agencies on its Quality, Certification, and Oversight Reports website. However, the information will not be posted on its the Hospice Compare website; CMS currently requires statutory authority to make public information from accrediting organizations on its websites.

We note that the President's FY 2021 Budget includes a legislative proposal to allow CMS to make public survey results from accrediting organizations.

Relevant Reports: **OEI-02-17-00020** (July 2019); **OEI-02-16-00570** (July 2018)

6. CMS should continue to work with the Accredited Standards Committee X12 to ensure that medical device-specific information is included on claim forms and require hospitals to use certain condition codes on claim forms for reporting device replacement procedures.

Key OIG Findings

As a result of the limitations of claim forms, CMS would not be able to determine from claim data alone the specific device implanted and whether the device was replaced because of a recall, a premature failure, or a necessary upgrade. It is difficult to identify and track Medicare's replacement costs for recalled or prematurely failed medical devices due to the lack of medical device-specific information and certain condition codes on claim forms.

Progress in Implementing the Recommendation

CMS is reviewing its claims policy to determine whether ensuring that device identifiers are included on the next version of claim forms would impose any unnecessary burden on physicians. The Accredited Standards Committee X12, which is the standards-setting organization for claims transactions, issued a draft proposal to add device identifiers to claims.

Relevant Reports: A-05-16-00059 (March 2018); A-01-15-00504 (September 2017)

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

Key OIG Findings

Beneficiaries with similar post-hospital care needs have different access to and cost sharing for SNF services depending on whether they were hospital outpatients or inpatients. Additionally, our review of a sample of SNF claims found that many SNFs incorrectly used a combination of inpatient and non-inpatient hospital days to determine whether the 3-night requirement was met, leading to CMS improperly paying an estimated $84.2 million between 2013 and 2015.

Progress in Implementing the Recommendation

In 2019, CMS's Office of the Actuary analyzed counting time spent as an outpatient toward the 3-day inpatient hospital stay requirement for SNF Medicare coverage; its analysis identified potential impacts of a 20-percent uptake in SNF admissions and an increase in Medicare SNF expenditures of $65 billion from 2021 to 2030. CMS still needs to conduct updated analysis about whether, and to what extent, the problem of beneficiaries failing to qualify for Medicare coverage of their SNF services, because some or all of their time spent in the hospital was as an outpatient, continues, as well as reanalyze the potential impacts of counting time spent as an outpatient toward the 3-night requirement for SNF Medicare coverage.

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

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

CMS—Medicare Parts C and D

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

Relevant TMC:

- Protecting the Health and Safety of HHS Beneficiaries

Top Unimplemented Recommendations

8. 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.

Key OIG Findings

Billions of estimated Medicare Advantage risk-adjusted payments supported solely through chart reviews raise potential concerns about the completeness of payment data submitted to CMS, the validity of diagnoses on chart reviews, and the quality of care provided to beneficiaries. Diagnoses that MAOs reported only on chart reviews—and not on any service records—resulted in an estimated $6.7 billion in risk-adjusted payments for 2017. CMS based an estimated $2.7 billion in risk-adjusted payments on chart review diagnoses that MAOs did not link to a specific service provided to the beneficiary—much less a face to-face visit. Although limited to a small number of beneficiaries, almost half of MAOs reviewed had payments from unlinked chart reviews where there was not a single record of a service being provided to the beneficiary in all of 2016.

Progress in Implementing the Recommendation

CMS stated that in February 2020, it reviewed the data OIG provided to CMS related to the beneficiaries who had unlinked chart reviews but no service records. CMS plans to release Encounter Data Exchange Reports in the third quarter of CY 2020 to the respective MAOs for these beneficiaries. These reports will require the MAOs to provide written explanations for detected errors and describe actions that the MAO has planned or in progress to prevent and correct errors.

Relevant Report: OEI-03-17-00470 (December 2019)

9. CMS should require MAOs to include ordering and referring provider identifiers for applicable records in the encounter data.

Key OIG Findings

Ordering and referring provider identifiers are not required in, and were frequently absent from, Medicare Advantage encounter data for records of durable medical equipment (DME), prosthetics, orthotics, and supplies, clinical laboratory, imaging, and home health services. The lack of ordering and referring provider identifiers limits the use of these data for vital program oversight and enforcement activities. For example, these provider identifiers are critical for identifying questionable billing patterns and pursuing fraud investigations for ordering and referring providers. National Provider Identifiers are an important tool for assessing whether ordering or referring providers have determined that services were appropriate for patients.

Progress in Implementing the Recommendation

CMS stated that MAOs establish their own billing requirements with providers and may or may not require referrals or orders for the same set of services for which Medicare fee-for-service requires referrals. CMS also stated that it will explore whether ordering or referring provider identifiers are necessary for program integrity purposes and will consider requiring their inclusion in the future.

Relevant Reports: OEI-03-15-00060 (January 2018)

10. 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 hospices should have paid for under the Part A hospice benefit. The estimated Part D total cost was $160.8 million for the sample of drugs that hospice organizations should have paid for. Additionally, although hospices told us they should not have paid for the drugs associated with the remaining total cost, a review of CMS communications with hospices and sponsors between 2012 and 2016 indicates otherwise. Hospice organizations or hospice beneficiaries—not Part D—likely should have paid for many of these drugs. Further, other OIG work has found that Medicare sometimes paid twice for drugs because they were paid for under Part D when payment for these drugs should have been provided by the hospice under the hospice daily payment rate.

Progress in Implementing the Recommendation

Since the audit report was issued in August 2019, no progress has been reported in implementing the recommendations. As of July 15, 2020, we had not received an FMD for this recommendation. However, in its agency comments to the report, CMS stated that its current efforts will address this issue and ensure that no disruption occurs in beneficiary access. For instance, CMS will continue to engage in meaningful activities to reduce duplicate payment in this area, such as 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. Furthermore, CMS does not have any planned actions to work directly with hospices to ensure that they are providing drugs covered under the hospice benefit.

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

CMS—Medicaid

Medicaid serves more enrollees than any other Federal health care program, and Medicaid spending represents one-sixth of the national health care economy. In FY 2020, HHS projects the Federal share of Medicaid expenditures will be $447 billion. As of December 2019, Medicaid served 70.6 million individuals, including in the Children's Health Insurance Program (CHIP). OIG's work has identified substantial improper payments to providers across a variety of Medicaid services and on behalf of ineligible individuals. OIG has also identified concerns with the completeness and reliability of national Medicaid data. Medicaid has experienced longstanding program integrity vulnerabilities and challenges in ensuring that beneficiaries have access to and receive high-quality care.

Relevant TMCs:

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

Top Unimplemented Recommendations

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

Key OIG Findings

Data are essential for detecting fraud, waste, and abuse. However, national Medicaid data have deficiencies that hinder timely and accurate detection. Additionally, problems with Medicaid data have hindered program integrity, research, budgeting, and policy.

Progress in Implementing the Recommendation

All States, the District of Columbia, Puerto Rico, and the Virgin Islands are submitting Transformed Medicaid Statistical Information System (T-MSIS) data. CMS has shifted its T-MSIS efforts to assessing and improving the quality of T-MSIS data. Through one-on-one technical assistance efforts, CMS reviews States' data quality issues in 23 top-priority areas and works with States on addressing them. In November 2019, CMS released research-ready data files, known as T-MSIS Analytic Files, which contain research identifiable files with beneficiary-level data and currently include data from CYs 2014, 2015, and 2016. In 2019, CMS also released the Substance Use Disorder Data Book and used T-MSIS data to calculate per capita Medicaid expenditures for 12 States.

Relevant Reports: **OEI-05-18-00480** (August 2019); **OEI-02-15-00260** (July 2018); **OEI-05-15-00050** (June 2017); **OEI-05-12-00610** (September 2013)

12. CMS should collaborate with partners to develop strategies for improving rates of followup care for children treated for ADHD.

Key OIG Findings

Many Medicaid-enrolled children who receive treatment for ADHD are not receiving followup care within the timeframes outlined in national quality measures and professional guidelines. Specifically, over 500,000 Medicaid-enrolled children who were newly prescribed an ADHD medication and over 3,500 children who were hospitalized with a primary diagnosis of ADHD did not receive timely followup care within the timeframes outlined in HHS's national quality measures. Additionally, over 54,000 children did not receive any behavioral therapy as recommended by professional guidelines. Followup care is an important part of children's treatment for ADHD, as the disorder can affect all aspects of a child's academic and health outcomes (e.g., increased risk of dropping out of school, substance abuse).

Progress in Implementing the Recommendation

CMS stated that it hosted a meeting with Federal partners, including HRSA, the Substance Abuse and Mental Health Services Administration (SAMHSA), and ACF, to identify activities in progress and best practices regarding followup care for children who receive treatment for ADHD. In addition, CMS plans to continue to collaborate with Federal partners to finalize the list of activities and best practices that will be shared with States by December 2020. Finally, CMS stated that it will encourage States to learn about activities currently underway within States and to consider implementing the identified best practices.

Relevant Report: OEI-07-17-00170 (August 2019)

13 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 2, 2018, CMS had recovered about $909.2 million of the $2.7 billion in Medicaid overpayments identified in the current and prior periods. However, CMS did not collect the remaining $1.8 billion for 84 OIG audit reports. Specifically, CMS had not collected about $1.6 billion in overpayments identified in 77 current period audits and $188.6 million in overpayments identified in 7 prior period audits.

Progress in Implementing the Recommendation

CMS indicated that it has issued or is 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 guides to make its processes more efficient to allow for more timely resolution of identified overpayments. Under this realignment, CMS created an Audit and Review Branch for audit resolution, 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)

14. CMS should 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.

Key OIG Findings

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

Progress in Implementing the Recommendation

CMS stated that it completed a "secret shopper" initiative for six States on the availability of behavioral health providers and hosted three forums that addressed topics identified from the initiative. The initiative also resulted in a Recommendations Memo. Finally, CMS stated that it anticipates publishing a Behavioral Health Access Toolkit by the end of 2020.

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

IMPLEMENTED: Top 25 Recommendations From 2019

CMS should require States to either enroll personal care services (PCS) attendants as providers or require PCS attendants to register with their State Medicaid agencies and assign each attendant a unique identifier. (OIG-12-12-01)

Update: Section 12006 of the 21st Century Cures Act (P.L. No. 114-255) requires States to implement an electronic visit verification system for personal care and home health services under Medicaid. It also requires that the electronic visit verification system collect information on the beneficiary receiving the service and individual providing the service, service performed, start and stop time, and the date and location of the service. CMS indicated that this system must be able to electronically verify the individual providing the service or a mandated Federal Medical Assistance Percentage penalty will be applied. Additionally, CMS provided guidance and training on system requirements and developed a compliance assessment survey released to States in November 2019.

IMPLEMENTED: Top 25 Recommendations From 2019

CMS should facilitate State Medicaid agencies' efforts to screen new and existing providers by ensuring the accessibility and quality of Medicare's enrollment data. (OEI-05-13-00520)

Update: With respect to the accessibility of the data, CMS stated that it worked with States to facilitate access to Medicare data in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS), updated CMS guidance on how States can access and use Medicare's data, and offered the option for States to submit their provider enrollment data to CMS to match against Medicare data. With respect to the quality of the data, CMS also reviews the quality, completeness, and accuracy of PECOS data through the Quality Assurance Surveillance Program. Additionally, CMS has analyzed PECOS data to ensure that the proper risk level designations were assigned to enrolling providers and suppliers. When CMS's analysis identified risk-level data that were not complete or accurate, CMS stated that it took action to ensure that the data related to risk level were corrected to be complete and accurate. Further, CMS conducts monthly reviews of PECOS data to identify data anomalies. Finally, CMS uses the Advanced Provider Screening system to continuously monitor all current providers and suppliers to identify providers for whom administrative action may be appropriate.

Administration for Children and Families (ACF)

ACF programs focus on promoting the economic and social well-being of families, children, individuals, and communities. Among ACF's vital programs, the Child Care and Development Fund (CCDF)—the third-largest block grant program administered by the Federal Government—provides subsidies to approximately 1.3 million children to receive child care every month. Head Start—the largest Federal investment in early childhood education—promotes school readiness to more than 1 million low-income children through education, health, social, and other services. Safeguarding funds for these programs is crucial to ensure that they are used efficiently, effectively, and for intended purposes. OIG's work focuses on ensuring program integrity, quality of care, and safety of grants programs that provide critical health and human services to children, families, and communities. ACF's ORR program has provided care and found sponsors for almost 407,000 unaccompanied children. OIG's work continues to focus on examining the health and safety of children in ORR care provider facilities.

Relevant TMCs:

- Working Across Government To Provide Better Service to HHS Beneficiaries
- Protecting the Health and Safety of HHS Beneficiaries

Top Unimplemented Recommendations

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

Key OIG Findings

Care provider facilities that care for unaccompanied children in ORR custody struggled to address the mental health needs of children who had experienced intense trauma and had difficulty accessing specialized treatment for children who needed it. Facilities reported challenges that included employing mental health clinicians, 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. Further, policy changes in 2018 exacerbated these challenges and resulted in longer stays in ORR custody, which led to deteriorating mental health for some children and increased demands on staff.

Progress in Implementing the Recommendation

ORR has taken steps to improve access to mental health treatment services for unaccompanied children. For instance, it collaborated with the National Child Traumatic Stress Network to develop a four-part webinar series on addressing trauma in unaccompanied children. ORR also requires that care provider staff have training in trauma-informed care to better understand and identify unaccompanied children with significant mental health needs. According to ORR, its current staff were required to complete this training by May 1, 2020; all incoming staff must also complete the training within 30 days of onboarding.

ORR is also taking actions to hire and retain qualified mental health clinicians, including making funding available for continuing education for licensed clinicians. For instance, its Division for Health of Unaccompanied Children was granted approval to hire additional medical and public health professionals; this staff expansion has allowed for the Division to create focused teams to support ongoing efforts to ensure proper and timely heath care delivery to children. ORR is also considering further changes to policies and other requirements to mentor future clinicians (e.g., through partnerships with universities that provide internships within ORR).

Among its other actions, ORR plans to evaluate its 1-to-12 ratio of mental health clinicians to children in consultation with experts. ORR also developed a Discharge Rate Improvement Plan to improve its ability to accelerate discharges to appropriate sponsors and limit the amount of time children remain in custody. Further, ORR reported it is working to expand access to telepsychology services and in-network therapeutic group homes.

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

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

Key OIG Findings

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

Progress in Implementing the Recommendation

ACF plans to undertake several actions to improve States' compliance, including requesting that States report on successes and challenges in addressing psychotropic medication use requirements in their Child and Family Services Plans, as well as assessing related findings in its State Child and Family Services Reviews. Additionally, ACF stated that the topic of oversight of psychotropic medications will be addressed with its constituency group of State foster care managers.

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

Administration for Community Living (ACL)

ACL's mission is to maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers. With an annual budget of $2.2 billion in FY 2020, ACL invests in services, research, education, training, and innovation. The number of individuals served by ACL is growing at an unprecedented rate. Specifically, the number of adults in the U.S. who are age 65 or older is projected to increase from 49 million to nearly 78 million between 2016 and 2035. The number of individuals with disabilities is also growing, in part due to their increasing lifespans. Among ACL's programs, the Aging and Disability Networks provide tools, resources, and supports to community-based centers that provide services to support independent living. OIG's work has included examining ACL's oversight on independent living programs and whether its funds were allocated sufficiently to maximize program implementation.

Relevant TMC:

- Ensuring the Financial Integrity of HHS Programs

Top Unimplemented Recommendations

17. ACL should determine whether it can allocate its funds differently or seek additional department funding or resources to conduct required onsite compliance reviews of independent living programs.

Key OIG Findings

ACL did not appropriately oversee the activities of the Centers for Independent Living program. Specifically, it had not conducted any onsite compliance reviews since beginning its oversight of the programs in May 2015. Although ACL conducted some monitoring activities, its desk reviews did not include any onsite compliance reviews as of December 2018. ACL was appropriated over $156 million for independent living program services during the audit period; however, it did not allocate sufficient funds to support onsite compliance reviews. Additionally, ACL officials were unable to conduct onsite compliance reviews because of limited travel funding. Without these required onsite reviews, there is less assurance that these programs are effectively working to maximize the independence, well-being, and health of older adults, people with disabilities, and the families and caregivers of both.

Progress in Implementing the Recommendation

As of July 15, 2020, we had not received an FMD for this recommendation. ACL previously indicated that it was moving forward with the risk-based, three-tiered oversight protocol (i.e., Compliance and Outcome Monitoring Protocol). The program oversees the quality assurance of independent living program grantees' programs through a review of program compliance, outcomes, fiscal operations, and the provision of technical assistance incorporated into a three-tiered model. ACL stated that it conducted three onsite reviews in late 2019, but its current onsite reviews are on hold due to the COVID-19 public health emergency.

Relevant Report: A-05-18-00034 (August 2019)

Food and Drug Administration (FDA)

FDA is tasked with protecting the 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 supplements and products that give off radiation. With an annual budget of approximately $5.7 billion in FY 2019, FDA is responsible for the oversight of more than $2.6 trillion in consumption of food, medical products, and tobacco. FDA-regulated products account for approximately 20 percent of all U.S. consumer spending. FDA regulates about 77 percent of the U.S. food supply. OIG has a long history of FDA work focused on topics related to food safety, drug products, and medical devices. OIG's work on food safety has highlighted systemic and persistent public health and safety issues.

Relevant TMC:

- Safeguarding Public Health

Top Unimplemented Recommendations

18. FDA should ensure effective and timely processes related to food facility inspections and food recalls.

Key OIG Findings

OIG's audit of voluntary food recalls identified deficiencies in FDA's oversight of recall initiation, monitoring of recalls, and the information captured and maintained in FDA's electronic recall data system. For instance, FDA could not always ensure that firms initiated recalls promptly. It did not always evaluate health hazards in a timely manner, issue audit check assignments at the appropriate level, complete audit checks in accordance with its procedures, and collect timely and complete status reports from firms that have issued recalls. Additionally, it did not always track key and maintain accurate recall data in its electronic recall data system. In regard to food facility inspections, FDA did not take advisory or enforcement action in response to 22 percent of significant inspection violations identified from 2011 to 2015. When it took action, it commonly relied on facilities to voluntarily correct violations and rarely used administrative tools provided by the Food Safety Modernization Act. Moreover, FDA did not issue warning letters within expected timeframes to almost half of the facilities it inspected from 2011 to 2015. In some cases, its inaction led to facilities continuing to operate under conditions harmful to public health. Furthermore, FDA consistently failed to conduct timely followup inspections to ensure that facilities corrected significant inspection violations.

Progress in Implementing the Recommendation

In addition to establishing the Strategic Coordinated Oversight of Recall Execution (SCORE) team and implementing plans to audit and monitor its recall program, FDA has taken additional actions to improve its oversight. FDA established a workgroup to make system improvements to its Recall Enterprise System to enable functionality to record dates it learns of potentially hazardous products. FDA will also establish performance measures to track the time between when a firm learns of potentially hazardous food and when it initiates voluntary recalls. Once the measures are established, FDA will monitor performance and refine operating procedures as needed.

In regard to food facility inspections, FDA's actions include publicly tracking performance goals for followup after significant inspection violations; implementing additional training courses and webinars to provide tools for regulatory evidence development; and implementing an IT system to record facility operation dates.

Relevant Reports: **A-01-16-01502** (December 2017); **OEI-02-14-00420** (September 2017)

IMPLEMENTED: Top 25 Recommendations From 2019

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

Update: FDA began publicly tracking performance goals for followup after significant inspection violations, which includes the proportion of significant inspection violations that receive appropriate followup after regulatory action was taken, as well as the proportion of followup inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. FDA also developed and implemented training courses and webinars to educate staff and provide the necessary tools for regulatory evidence development.

Additionally, FDA conducted several important actions to shorten recall timeframes and remove hazardous products from the market faster. In 2016, FDA created the SCORE team to help determine the right course of action in complex situations, including actions to shorten recall timeframes and get products off the market faster. FDA also created procedural timeframes to address potential Class I human food recall situations, which are for products that could cause serious injury or death. Further, FDA formalized procedures, within its Regulatory Procedures Manual, with timeframes to be followed by agency staff to recommend a voluntary recall to a firm. When a firm is not willing to voluntarily conduct a recall, FDA's procedures include exercising authority to mandate a recall or take other regulatory action once FDA has determined that the legal threshold for doing so is met.

Indian Health Service (IHS)

IHS, with an estimated annual budget of $5.8 billion in FY 2019, 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 573 federally recognized Tribes in 37 States. IHS services are administered through a system of 12 Area offices and 170 IHS and tribally managed service units. IHS faces longstanding challenges that hinder 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.

Relevant TMCs:

- Protecting the Health and Safety of HHS Beneficiaries
- Working Across Government To Provide Better Service to HHS Beneficiaries

Top Unimplemented Recommendations

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

Key OIG Findings

IHS closed the Rosebud Hospital emergency department in December 2015 due to Immediate Jeopardy deficiencies and staffing shortages. IHS reopened the hospital's emergency department in July 2016, but it was again cited with an Immediate Jeopardy deficiency in July 2018. Longstanding problems at Rosebud Hospital remain a concern, including difficulty 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. Additionally, in early 2019, IHS updated its policies to prevent and address child sexual abuse by health care providers. Although IHS policies are consistent with other health care organizations, the policies have coverage gaps and are still early in implementation.

Progress in Implementing the Recommendation

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

Prior to the COVID-19 public health emergency, in February 2019, IHS published a 5-year Strategic Plan for FY 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, in July 2020 the IHS Deputy Director for Management Operations initiated the development of a multidisciplinary, senior-level working group to develop a comprehensive workforce plan to address the recruitment, training, and placement of staff into hospital leadership positions, particularly in remote locations. The target date for completion of the workgroup charge, with the final version of the comprehensive workforce plan and recommendations submitted to the IHS Director, is September 30, 2020.

Relevant Reports: **OEI-06-19-00330** (December 2019); **OEI-06-17-00270** (July 2019)

20. IHS should work with hospitals to ensure that they follow the Indian Health Manual when prescribing and dispensing opioids.

Key OIG Findings

The IHS hospitals that we reviewed did not always follow the Indian Health Manual when prescribing and dispensing opioids. Through patient record review, we found that hospitals did not always review the course of patient treatment and causes of pain within required timeframes, perform the required urine drug screenings within recommended time intervals, review patient health records before filling a prescription from a non-IHS provider, or maintain pain management documents to support that provider responsibilities had been performed. Additionally, these IHS hospitals did not fully use the States' prescription drug monitoring programs when prescribing or dispensing opioids.

Progress in Implementing the Recommendation

As of July 15, 2020, we had not received an FMD for this recommendation. IHS stated that it is committed to providing its FMD to OIG no later than September 30, 2020. To ensure that all opioids are in a locked cabinet, safe, drawer, or other appropriate secure container at all times, IHS revised the Indian Health Manual to include requirements for locking prescriptions awaiting pickup and for the Area Pharmacy Consultants to review this for compliance during their annual audits. IHS also reported on other actions they planned to take related to prescribing and dispensing opioids. These actions include, for example, revising the Indian Health Manual to reinforce requirement to review and document the results of electronic health records (EHRs) of patients with opioid prescriptions from non-IHS providers; issuing a directive that IHS prescribers track all opioids prescribed at IHS facilities in EHRs; designing and testing IT updates to ensure facilities' compliance with pain management and related documentation; creating software programming to automate reporting of controlled substance prescribing data to State-based Prescription Drug Monitoring Programs (software was completed and released in May 2019); and implementing the IHS Safe Opioid Monitoring tool, a facility-level report submitted monthly to all IHS facilities and Area leadership that includes percentage of opioid prescriptions and co-prescribing of opioids with benzodiazepines. IHS is also developing an opioid stewardship quality assurance program that includes evaluating opioid-related data on national, regional, and local levels.

Relevant Report: **A-18-17-11400** (July 2019)

21. IHS should increase oversight of IT systems by IHS management.

Key OIG Findings

IHS's decentralized IT management structure led to vulnerabilities and weaknesses in implementing security controls at all five hospitals. IHS's controls were not effective at preventing or detecting our penetration test cyberattacks. In addition, the hospitals implemented IT security controls to protect health information and patient safety differently. As a result, IHS hospital operations and delivery of patient care could have been significantly affected.

Progress in Implementing the Recommendation

As of July 15, 2020, we had not received an FMD for this recommendation. IHS stated that it is committed to providing an FMD to OIG no later than September 30, 2020. In its response to the report, IHS stated that it will coordinate resources with the support of IHS Area and Service Unit staff, including resources to replace necessary infrastructure and establish cybersecurity controls to ensure that compliance is maintained. IHS's FY 2021 budget request included a justification for additional resources to ensure successful coordination and oversight of all IT infrastructure in IHS.

IHS stated that it is seeking to implement stronger, more centralized security controls through the implementation of Department of Homeland Security Continuous Diagnostics and Mitigation tools and technologies. IHS IT Security and Operations staff plans to implement these tools and provide oversight for their use at IHS hospitals and clinics; according to IHS, implementation of these tools through IHS Headquarters should allow for centralized use and monitoring. In addition, IHS continues to undertake efforts to centralize systems. Most notably, it is completing a consolidation of all mobile device contracts throughout the organization with plans for additional technology centralizations to follow. IHS is also developing professional IT positions within its organization, who will consolidate other acquisitions of hardware and software for enterprisewide use.

Furthermore, IHS continues to develop stronger justifications for centralized resources to address its infrastructure requirements.

Relevant Report: A-18-17-11400 (July 2019)

National Institutes of Health (NIH)

NIH, the Nation's medical research agency, is the largest grant-making agency in HHS. It is made up of 27 different Institutes and Centers, each with its own specific research agenda. It invests about $41.7 billion in medical research, and more than 80 percent of its funding is awarded to extramural research projects. Recently, numerous congressional committees have expressed concerns about potential threats to the integrity of taxpayer-funded research and intellectual property, including intellectual property theft and its diversion to foreign entities. OIG's work is focused 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.

Relevant TMC:

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

Top Unimplemented Recommendations

22. 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. Additionally, although NIH has made progress in overseeing financial conflicts that extramural grantee institutions report in the past decade, it could do more to ensure the adequacy and consistency of reviews. For instance, NIH cannot identify—and does not plan to identify—whether investigators' financial conflicts of interest (FCOIs) involve foreign interests. We also found that NIH has limited policies, procedures, and controls in place to ensure institutions report all sources of research support, financial interests, and affiliations.

Progress in Implementing the Recommendation

NIH is coordinating with Federal partners to update its peer-reviewer nominee guidance. For instance, it is working with the Office of National Security to develop a risk-based approach to identify peer reviewers who may pose a threat to integrity and with other Federal agencies to develop a systematic, risk-based, data-driven approach to vetting nominees. Additionally, NIH performs quarterly quality assurance reviews of pending FCOI reports and the information exchange between NIH staff and grantee institutions. NIH is also developing procedures to document the FCOI quality assurance review process as well as whether FCOI processes should be revised to address foreign influence concerns. Further, NIH is reviewing the 1,013 institutions that OIG identified as not having FCOI policies on their websites and ensuring that each of the institutions that are subject to FCOI regulatory requirements post these policies. It is also developing enhancements to its electronic research administration Commons Institutional Profile and FCOI Module.

Relevant Reports: OEI-01-19-00160 (September 2019); OEI-03-19-00150 (September 2019); A-03-19-03003 (September 2019)

IMPLEMENTED: Top 25 Recommendation From 2019

NIH should require security training and security plans for principal investigators and entities and verify that they have fulfilled these requirements before granting them access to genomic data. (A-18-18-09350)

Update: NIH's Office of Extramural Research is identified as the responsible office for systemwide oversight and implementation of the Genomic Data Sharing Policy and provide dedicated resources to support such oversight, which includes the development of comprehensive information, education, and training resources in the areas of Genomic Data Sharing compliance. The "NIH Information Security and Information Management Training" is available to the public.

General Departmental

In FY 2019, HHS reported a total of approximately $1.2 trillion in expenditures and awarded $109 billion in grants (excluding CMS). HHS is the largest grant-making agency in the Federal government. It administers more than 100 programs that protect the health and provide essential human services for all individuals. Ensuring program integrity and responsible stewardship across HHS programs is vital, and operating an infrastructure that minimizes risk and provides oversight for the protection of resources remains a challenge. OIG has examined the operation of financial management and administrative infrastructure (including IT) across HHS. OIG's work also promotes public health and safety by recommending improvements to address public health and safety and emergency preparedness.

Relevant TMCs:

- Harnessing Data to Improve Health and Well-Being of Individuals
- Working Across Government To Provide Better Service to HHS Beneficiaries
- Protecting the Health and Safety of HHS Beneficiaries

Top Unimplemented Recommendations

23. HHS should develop departmentwide objectives and a strategic framework for responding to international public health emergencies.

Key OIG Findings

As part of a global effort, HHS was ultimately effective in making significant contributions to controlling the Ebola crisis and accomplishing its mission to help stop the spread of the Ebola virus in 2014 and 2015. However, HHS's response efforts could have been more efficient and effective. Specifically, its response was hindered by having no strategic framework in place to coordinate global health security at the international or departmental levels before the Ebola outbreak in West Africa. During the Ebola epidemic, HHS's strategic plan emphasized the need to maintain a strong public health and response system abroad to prevent the spread of infectious disease and for working with global health partners to eradicate certain diseases. However, the strategic plan did not include a departmentwide framework for responding to an international event. Instead some HHS components relied on their own domestic incident response plans, domestic-focused policies, and procedures during their response efforts.

Progress in Implementing the Recommendation

CDC stated in its FMD that HHS continues to coordinate on these efforts and will provide additional updates in the coming months.

Relevant Report: A-04-16-03567 (August 2019)

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

Key OIG Findings

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

Progress in Implementing the Recommendation

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

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

25. CMS and HRSA should ensure that States can pay correctly for 340B-purchased drugs billed to Medicaid, by requiring claim-level methods to identify 340B drugs and sharing the official 340B ceiling prices.

Key OIG Findings

A lack of transparency regarding both 340B ceiling prices and Medicaid claims associated with 340B-purchased drugs limits State Medicaid agencies' ability to correctly apply their 340B payment policies. Specifically, State Medicaid agencies do not have access to 340B ceiling prices and so cannot create prepay edits for 340B-purchased drugs to prevent overpayments. Moreover, many States are not able to accurately identify specific claims for 340B-purchased drugs because they use methods (e.g., HRSA's Medicaid Exclusion File) that operate at the broader, provider level. State Medicaid agencies need to know 340B ceiling prices and which Medicaid claims are associated with 340B drugs to ensure that they are correctly paying claims.

Progress in Implementing the Recommendation

CMS stated that it does not have statutory authority to require claim-level methods to identify 340B drugs. However, it issued a best practices document to States in January 2020, which outlines voluntary methods States can use to identify specific claims for 340B-purchased drugs. HRSA stated that it would need new legislative authority to share 340B ceiling prices directly with States. HRSA also stated that it has explored an approach of sharing ceiling prices with CMS, which in turn would share them with States. However, it determined that such an approach would also require new legislative authority.

Relevant Reports: OEI-05-14-00430 (June 2016); OEI-05-09-00321 (June 2011)

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 [indicated below]. The recommendations are grouped by OpDivs. Some recommendations also include estimated cost savings that we believe would be generated if the specific recommendation(s) were implemented.

Centers for Medicare & Medicaid Services (CMS)

Recommendation	Relevant Report(s)
CMS should take steps to disallow Federal reimbursements to States for expenditures associated with unenrolled managed care organization (MCO) network providers, including seeking necessary legislative authority.	*Twenty-Three States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries*, OEI-05-19-00060 (March 2020)
CMS should seek legislative authority to align Medicare allowable amounts for these items with payments made by select non-Medicare payers. **Estimated Savings: $337,547,542**	*Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers*, A-05-17-00033 (October 2019)
Top 25 Recommendation #5 CMS should: • include on Hospice Compare the survey reports from accrediting organizations, once authority is obtained; and • take the steps necessary to seek statutory authority to include information from accrediting organizations on Hospice Compare.	*Hospice Deficiencies Pose Risks to Medicare Beneficiaries*, OEI-02-17-00020 (July 2019)
Top 25 Recommendation #3 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. **Estimated Savings: $223.1 million**	*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)

Recommendation	Relevant Report(s)
Top 25 Recommendations #5 and #10 CMS should: • seek statutory authority to establish additional remedies for hospices with poor performance and • modify the payments for hospice care in nursing facilities.	*Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio*, OEI-02-16-00570 (July 2018)
CMS should seek a legislative change that would provide the agency flexibility to determine when noncovered versions of a drug should be included in Part B payment amount calculations.	*Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and Its Beneficiaries*, OEI-12-17-00260 (November 2017)
CMS should set firm deadlines for marketplaces to fully develop system functionality for verifying applicants' eligibility and resolving inconsistencies, assess potential enforcement mechanisms to ensure that marketplaces meet those deadlines, and, if such mechanisms are identified, seek legislative authority to establish them.	*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*, A-05-15-00020 (May 2017)
Top 25 Recommendation #7 CMS should explore ways of protecting beneficiaries in outpatient stays from paying more than they would have paid as inpatients.	*Vulnerabilities Remain Under Medicare's 2-Midnight Hospital Policy*, OEI-02-15-00020 (December 2016)
Top 25 Recommendation #25 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 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**	*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 seek legislation that would exempt the reduced expenditures as a result of 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**	*Medicare and Beneficiaries Could Save Billions if CMS Reduces the Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates*, **A-05-12-00020** (April 2014)
CMS should seek legislative authority to expand the diagnosis-related group window to include: • additional days prior to the inpatient admission and other hospital ownership arrangements, such as affiliated hospital groups; and • other hospital ownership arrangements, such as affiliated hospital groups. **Estimated Savings: $318 million**[4]	*Medicare and Beneficiaries Could Realize Substantial Savings if the Diagnosis Related Group Window Were Expanded*, **OEI-05-12-00480** (February 2014)
CMS should seek legislative authority to: • remove Necessary Provider CAHs' permanent exemption from the distance requirement, allowing CMS to reassess these CAHs; and • revise the CAH Conditions of Participation to include alternative location-related requirements. **Estimated Savings: $449 million in 2011**[5]	*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 seek legislative change to prevent States from using State Supplementary Payments to shift Medicare Part B premium costs for full-benefit dual eligibles to the Federal Government.	*Iowa Has Shifted Medicare Cost-Sharing for Dual Eligibles to the Federal Government*, **OEI-07-13-00480** (April 2013)
Top 25 Recommendation #4 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)

[4] The estimated $318 million in savings is based on OIG's analysis of claims for services provided just prior to the window or provided at affiliated hospitals during the window in 2011.

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

Recommendation	Relevant Report(s)
CMS and the Office of Medicare Hearings and Appeals should improve handling of appeals from appellants who are also under fraud investigation and seek statutory authority to postpone these appeals when necessary.	*Improvements Are Needed at the Administrative Law Judge Level of Medicare Appeals*, OEI-02-10-00340 (November 2012)
CMS should work with Congress to require manufacturers of first generics to submit monthly average sales price data during initial generic availability.	*Medicare Payments for Newly Available Generic Drugs*, OEI-03-09-00510 (January 2011)
CMS should 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)

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)
FDA should seek legislative authority to enforce FDA assessment plans.	*FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety*, OEI-04-11-00510 (February 2013)
FDA should seek statutory authority to impose civil monetary penalties on companies that do not comply with registration requirements.	*Dietary Supplements: Companies May Be Difficult To Locate in an Emergency*, OEI-01-11-00211 (October 2012)
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)
Top 25 Recommendation #25 HRSA should share 340B ceiling prices with States.	*State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321 (June 2011)

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 of program beneficiaries.

This appendix includes significant recommendations issued from audits and evaluations issued through June 1, 2020. The recommendations describe problems, abuses, or deficiencies for which corrective action has not been completed. The recommendations are generally grouped by OpDivs. It includes OIG's top 25 unimplemented recommendations [indicated below]. Note that the recommendations in this appendix include the exact wording from the associated audits or evaluations, some of which is paraphrased in the top 25 recommendation summaries. Some recommendations also include estimated cost savings that we believe would be generated if the specific recommendation(s) were implemented. The hyperlinks below provide more information on the report(s) relevant to each recommendation.

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

Recommendation	Relevant Report(s)
CMS should: • attempt recovery of the $93,591,531 in estimated incorrect net incentive payments made during our audit period and ensure that all final and nonfinal payments made after our audit period are correct; and • to address the 50 incorrect net incentive payments in our sample, recover from acute-care hospitals, in accordance with CMS policies, the portion of the $1,266,111 in incorrect net incentive payments that are within the reopening period.	*CMS Made an Estimated $93.6 Million in Incorrect Medicare Electronic Health Record Incentive Payments to Acute-Care Hospitals, or Less Than 1 Percent of $10.8 Billion in Total Incentive Payments*, A-09-18-03020 (December 2019)
CMS should require reconciliation of all hospital cost reports with outlier payments during a cost-reporting period.	*Hospitals Received Millions in Excessive Outlier Payments Because CMS Limits the Reconciliation Process*, A-05-16-00060 (November 2019)
CMS should: • direct the Medicare contractors to recover the $54,372,337 in identified overpayments in accordance with CMS's policies and procedures; • identify any claims for transfers to post-acute care in which incorrect patient discharge status codes were used, and direct the Medicare contractors to recover any overpayments after our audit period; and • ensure that the Medicare contractors are receiving the postpayment edit's automatic notifications of improperly billed claims and are taking action by adjusting the original inpatient claims to initiate recovery of the overpayments.	*Medicare Improperly Paid Acute-Care Hospitals $54.4 Million for Inpatient Claims Subject to the Post-Acute-Care Transfer Policy*, A-09-19-03007 (November 2019)

Recommendation	Relevant Report(s)
CMS should: • recoup $640,452 from providers, and instruct providers to refund overcharges totaling up to $173,495 to beneficiaries, consisting of: ○ $436,877 in overpayments to providers that billed for the same chronic care management services for the same beneficiaries and up to $121,573 in overcharges to these beneficiaries and ○ $203,575 in overpayments to providers that billed for both CCM services and overlapping care management services for the same beneficiaries and up to $51,922 in overcharges to these beneficiaries; • 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 to recoup any overpayments from outpatient facilities and ○ recoup any overpayments from outpatient facilities and ○ instruct the outpatient facilities to refund corresponding overcharges to beneficiaries; and • implement claim processing controls, including system edits, to prevent and detect overpayments for chronic care management services.	*Medicare Made Hundreds of Thousands of Dollars in Overpayments for Chronic Care Management Services*, **A-07-17-05101** (November 2019)
CMS should: • review Medicare allowable amounts for 161 orthotic device HCPCS codes for which Medicare and beneficiaries paid an estimated $337,547,542 more than select non-Medicare payers and: ○ adjust the allowable amounts, as appropriate, using regulations promulgated under existing legislative authority, or ○ if the allowable amounts cannot be adjusted using regulations promulgated under existing legislative authority, seek legislative authority to align Medicare allowable amounts for these items with payments made by select non-Medicare payers; and • routinely review Medicare allowable amounts for new and preexisting orthotic devices to ensure that Medicare allowable amounts are in alignment with payments made by select non-Medicare payers or pricing trends. **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)
CMS should instruct the DME MACs to: • recover $36,825 in overpayments for the 39 unallowable claim lines and • notify the 22 suppliers associated with the 39 claim lines with potential overpayments of $36,825 so that those suppliers can exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation.	*Medicare Improperly Paid Suppliers an Estimated $92.5 Million for Inhalation Drugs*, **A-09-18-03018** (October 2019)

Recommendation	Relevant Report(s)
CMS should also work with the DME MACs to: • expand their review of suppliers' claims to include additional inhalation drugs (e.g., those with the highest reimbursement rates); • provide additional training to suppliers on Medicare documentation requirements for inhalation drugs; and • identify suppliers that consistently bill for inhalation drugs that do not comply with Medicare documentation requirements, perform reviews of those suppliers, collect the amount overpaid for unallowable claims, and educate them on Medicare requirements for inhalation drugs. **Estimated Savings: $92,471,272 for CY 2017**	
CMS should: • continue to work with the Contractors and the MACs to develop strategies that improve timely coordination to give the MACs a better opportunity to recover overpayments, • establish a uniform methodology for the Contractors to use when reporting estimates for the value of law enforcement referrals, and • update the Fraud Prevention System's law enforcement referral adjustment factor.	*CMS Could Improve Its Processes for Evaluating and Reporting Payment Recovery Savings Associated With the Fraud Prevention System*, **A-01-15-00510** (October 2019)
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)
CMS should: • review the impact of programmatic changes on Accountable Care Organizations' (ACOs) ability to promote value-based care; • adopt outcome-based measures and better align measures across programs; • identify and share information about strategies that encourage patients to share behavioral health data; • identify and share information about strategies that integrate physical and behavioral health services and address social determinants of health; • assess and share information about ACOs' use of the 3-day waiver and apply these results when making changes to the Shared Savings Program or other programs; and • prioritize ACO referrals of potential fraud, waste, and abuse.	*ACOs' Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program*, **OEI-02-15-00451** (July 2019)

Recommendation	Relevant Report(s)
CMS should instruct the MACs to: • recover the portion of the $56,668 in identified net overpayments that are within the 4-year reopening period and • notify the 117 providers associated with 147 claims (83 beneficiaries with 150 corresponding lines of service) with potential overpayments of $56,668 so that those providers can exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and identify and track any returned overpayments as having been made in accordance with this recommendation. CMS should also work with the MACs to: • conduct data analysis allowing for targeted reviews of claims for polysomnography services and • educate providers on properly billing for polysomnography services. **Estimated Savings: $269,768,285 over the 2-year audit period January 1, 2014, through December 31, 2015**	*Medicare Payments to Providers for Polysomnography Services Did Not Always Meet Medicare Billing Requirements*, **A-04-17-07069** (July 2019)
Top 25 Recommendation #5 CMS should: • expand the deficiency data that accrediting organizations report to CMS and use these data to strengthen its oversight of hospices; • take the steps necessary to seek statutory authority to include information from accrediting organizations on Hospice Compare; • include on Hospice Compare the survey reports from State agencies; • include on Hospice Compare the survey reports from accrediting organizations, once authority is obtained; • educate hospices about common deficiencies and those that pose particular risks to beneficiaries; and • increase oversight of hospices with a history of serious deficiencies.	*Hospice Deficiencies Pose Risks to Medicare Beneficiaries*, **OEI-02-17-00020** (July 2019)
Top 25 Recommendation #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 Immediate Jeopardy citation; and • improve and make user-friendly the process for beneficiaries and caregivers to make complaints.	*Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm*, **OEI-02-17-00021** (July 2019)

Recommendation	Relevant Report(s)
Top 25 Recommendation #1 CMS should: • work with the Survey Agencies to improve training for staff of SNFs on how to identify and report incidents of potential abuse or neglect of Medicare beneficiaries, • require the Survey Agencies to record and track all incidents of potential abuse or neglect in SNFs and referrals made to local law enforcement and other agencies, • monitor the Survey Agencies' reporting of findings of substantiated abuse to local law enforcement, and • clarify guidance to clearly define and provide examples of incidents of potential abuse or neglect.	*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 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 the 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)
Top 25 Recommendation #7 CMS should: • ensure that when SNF claims are being processed for payment, the Common Working File (CWF) qualifying inpatient hospital stay edit for SNF claims is enabled and operating properly to identify SNF claims ineligible for Medicare reimbursement; • 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 has been met (if necessary, CMS should seek statutory authority to do so);	*CMS Improperly Paid Millions of Dollars for Skilled Nursing Facilities When the Medicare 3-Day Inpatient Hospital Stay Requirement Was Not Met*, **A-05-16-00043** (February 2019)

Recommendation	Relevant Report(s)
• 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 (if necessary, CMS should seek statutory authority to do so); • require SNFs to provide written notice to beneficiaries if Medicare is expected to deny payment for the SNF stay when the 3-day rule is not met (if necessary, CMS should seek statutory authority to do so); • educate hospitals about the importance of explicitly communicating the correct number of inpatient days to beneficiaries and whether the inpatient days qualify subsequent SNF care for Medicare reimbursement so that beneficiaries understand their potential financial liability related to SNF care; and • educate SNFs about their responsibility to submit accurate and valid claims for payment that are supported with documentation that clearly shows that the SNF services qualify for reimbursement. **Estimated Savings: $84.2 million based on estimates from CYs 2013 through 2015**	
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. **Estimated Savings: $223.1 million based on estimates from CYs 2008 through 2017**	*Medicare Improperly Paid Suppliers for Durable Medical Equipment Prosthetics, Orthotics, and Supplies Provided to Beneficiaries During Inpatient Stays*, **A-09-17-03035** (November 2018)
Top 25 Recommendation #3 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 steps to ensure that no resident is counted as more than one full-time employee. This could include implementing policies and procedures to analyze Intern and Resident Information System data or requiring MACs to determine whether residents claimed by hospitals in their jurisdiction were claimed as more than one full-time employee.	*CMS Did Not Always Ensure Hospitals Complied With Medicare Reimbursement Requirements for Graduate Medical Education*, **A-02-17-01017** (November 2018)
Top 25 Recommendation #2 CMS should reevaluate the IRF payment system, which could include considering the high error rate found in this report and Comprehensive Error Rate Testing reviews in future acute inpatient rehabilitation service payment reform, which may be a component of a unified post-acute-care PPS system.	*Many Inpatient Rehabilitation Facilities Stays Did Not Meet Medicare Requirements*, **A-01-15-00500** (September 2018)

Recommendation	Relevant Report(s)
CMS should expand the price-substitution policy. **Estimated Savings: $2.7 million**[6]	*Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2016 Average Sales Prices*, **OEI-03-18-00120** (August 2018)
Top 25 Recommendations #5 and #10 CMS should: • seek statutory authority to establish additional, intermediate remedies for poor hospice performance; • develop other claims-based information and include it on Hospice Compare; • include on Hospice Compare deficiency data from surveys, including information about complaints filed and resulting deficiencies; • work with its partners, such as hospitals and caregiver groups, to make available consumer-friendly information explaining the hospice benefit to beneficiaries and their families and caregivers; • ensure that a physician is involved in the decisions to start and continue general inpatient care; • analyze claims data to identify hospices that engage in practices or have characteristics that raise concerns; • take appropriate actions to follow up with hospices that engage in practices or have characteristics that raise concerns; • increase oversight of general inpatient care claims and focus particularly on general inpatient care provided in SNFs, given the higher rate at which these stays were inappropriate; • implement a comprehensive prepayment review strategy to address lengthy general inpatient care stays so that beneficiaries do not have to endure unnecessarily long periods of time in which their pain and symptoms are not controlled; • 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 cost of drugs covered under the benefit are not inappropriately shifted to Part D; • assess the current payment system to determine what changes may be needed to tie payments to beneficiaries' care needs and quality of care to ensure that services rendered adequately serve beneficiaries' needs; • adjust payments based on these analyses, if appropriate, to ensure that the payment system is aligned with beneficiary needs and quality of care; and • modify the payments for hospice care in nursing facilities.	*Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio*, **OEI-02-16-00570** (July 2018)

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

Recommendation	Relevant Report(s)
CMS should work with Medicare contractors to establish periodic reviews of claims for replacement positive airway pressure device supplies and take remedial action for suppliers that the contractors find consistently bill claims that do not meet Medicare requirements. **Estimated Savings: $631.2 million during CYs 2014 and 2015**	*Most Medicare Claims for Replacement Positive Airway Pressure Device Supplies Did Not Comply With Medicare Requirements*, A-04-17-04056 (June 2018)
CMS should conduct periodic postpayment reviews for telehealth claim edits that cannot be implemented and implement all telehealth claim edits.	*CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements*, A-05-16-00058 (April 2018)
Top 25 Recommendation #6 CMS should: • (assuming the OIG recommendation requiring the use of condition codes 49 and 50 is implemented) instruct its Medicare contractors to implement a postpayment process to follow up with any hospital that submits a claim for certain cardiac device replacement procedures with condition code 49 or 50 but no value code FD (a credit of 50 percent or greater received from a manufacturer for a replaced medical device) to determine whether an adjustment claim should be submitted; and • consider studying alternatives to implementing edits to eliminate the current Medicare requirements for reporting device credits, for instance, by reducing inpatient PPS and outpatient PPS payments for device-intensive procedures.	*Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits*, A-05-16-00059 (March 2018)
CMS should: • direct the Medicare contractors to recover the $66,309,751 in identified improper payments; and • strengthen its system edits to prevent improper payments for specimen validity tests and instruct the Medicare contractors to educate providers on properly billing for specimen validity and urine drug tests, which could result in savings of an estimated $12,146,760 over a 5-year period. **Estimated Savings: $12.1 million over a 5-year period**	*Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination With Urine Drug Tests*, A-09-16-02034 (February 2018)
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)

Recommendation	Relevant Report(s)
CMS should: • identify strategies to increase MACs' collection of Zone Program Integrity Contractors and Unified Program Integrity Contractors referred overpayments and • implement the surety bond requirement for home health providers and consider the feasibility of implementing surety bonds for other providers based on their level of risk.	*Enhancements Needed in the Tracking and Collection of Medicare Overpayments Identified by Zone Program Integrity Contractors and Program Safeguard Contractors,* **OEI-03-13-00630** (September 2017)
Top 25 Recommendation #6 CMS should: • continue to work with the Accredited Standards Committee to ensure that the device identifier is included on the next version of claim forms and • require hospitals to use condition codes 49 or 50 on claims for reporting a device replacement procedure if the procedure resulted from a recall or premature failure independent of whether there was a device provided at no cost or with a credit.	*Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices,* **A-01-15-00504** (September 2017)
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. **Estimated Savings: $10.2 million**	*Medicare Could Save Millions by Eliminating the Lump-Sum Purchase Option for All Power Mobility Devices,* **A-05-15-00020** (May 2017)
Top 25 Recommendation #7 CMS should: • conduct routine analysis of hospital billing and target for review the hospitals with high or increasing numbers of short inpatient stays that are potentially inappropriate under the 2-midnight policy, • identify and target for review the short inpatient stays that are potentially inappropriate under the 2-midnight policy, • analyze the potential impacts of counting time spent as an outpatient toward the 3-night requirement for SNF services so that beneficiaries receiving similar hospital care have similar access to these services, and • explore ways of protecting beneficiaries in outpatient stays from paying more than they would have paid as inpatients.	*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,* **OEI-02-10-00492** (September 2016)

Recommendation	Relevant Report(s)
CMS should: • raise awareness of adverse events in rehabilitation hospitals and work to reduce harm to patients, • collaborate with the Agency for Healthcare Research and Quality (AHRQ) to create and promote a list of potential rehabilitation hospital events, and • 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)
CMS should: • take appropriate action against hospitals and their off-campus provider-based facilities that we identified as not meeting requirements and • require hospitals to submit attestations for all their provider-based facilities.	*CMS Is Taking Steps To Improve Oversight of Provider-Based Facilities, but Vulnerabilities Remain*, **OEI-04-12-00380** (June 2016)
CMS should revise and clarify site visit forms so that they can be more easily used by inspectors to determine whether a facility is operational.	*Enhanced Enrollment Screening of Medicare Providers: Early Implementation Results*, **OEI-03-13-00050** (April 2016)
CMS should: • evaluate the extent to which Medicare payment rates for therapy should be reduced, • change the method for paying for therapy, and • adjust Medicare payments to eliminate any increases that are unrelated to beneficiary characteristics.	*The Medicare Payment System for Skilled Nursing Facilities Needs To Be Reevaluated*, **OEI-02-13-00610** (September 2015)
CMS should seek legislation to adjust CAH swing-bed reimbursement rates to the lower SNF PPS rates paid for similar services at alternative facilities. **Estimated Savings: $4.1 billion over a 6-year period from CYs 2005 through 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 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: Over $100 million**[7]	*Medicare Part B Prescription Drug Dispensing and Supplying Fee Payment Rates Are Considerably Higher Than the Rates Paid by Other Government Programs*, **A-06-12-00038** (September 2014)

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

Recommendation	Relevant Report(s)
CMS should finalize the implementation of automated average sales price-related procedures by using average manufacturer price-related processes as a model, and subsequently require all manufacturers to submit average sales prices through the automated system.	*Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs,* **OEI-12-13-00040** (July 2014)
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)
CMS should: • explore the possibility of requiring providers to identify on the Part B claim the pharmacy that produced the compounded drug; and • explore the possibility of conducting descriptive analyses of Part B claims for compounded drugs.	*Compounded Drugs Under Medicare Part B: Payment and Oversight*, **OEI-03-13-00270** (April 2014)
CMS should implement policies and procedures to detect and recoup improper payments when entitlement termination information is received on previously paid Medicare claims, and identify improper payments after our audit period but before implementation of policies and procedures and ensure that Medicare contractors recoup the improper payments.	*Medicare Improperly Paid Providers Millions of Dollars for Entitlement-Terminated Beneficiaries Who Received Services During 2010 Through 2012*, **A-07-13-01127** (April 2014)
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 the reduced expenditures as a result of lower outpatient PPS payment rates from budget neutrality adjustments for ASC-approved procedures. **Estimated Savings: Up to $15 billion over a 6-year period from CYs 2012 through 2017**	*Medicare and Beneficiaries Could Save Billions if CMS Reduces the Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates*, **A-05-12-00020** (April 2014)
CMS should distinguish payments in the end-stage renal disease (ESRD) base rate between independent and hospital-based dialysis facilities.	*Update: Medicare Payments for End Stage Renal Disease Drugs*, **OEI-03-12-00550** (March 2014)
CMS should seek legislative authority to expand the diagnosis-related group window to include: • additional days prior to the inpatient admission and other hospital ownership arrangements, such as affiliated hospital groups; and • other hospital ownership arrangements, such as affiliated hospital groups. **Estimated Savings: $318 million[8]**	*Medicare and Beneficiaries Could Realize Substantial Savings if the Diagnosis Related Group Window Were Expanded*, **OEI-05-12-00480** (February 2014)

[8] The estimated $318 million in savings is based on OIG's analysis of claims for services provided just prior to the window or provided at affiliated hospitals during the window in 2011.

Recommendation	Relevant Report(s)
CMS should work with AHRQ to add a question to the Consumer Assessment of Healthcare Providers and Systems to assess beneficiaries' fear of reprisal.	*The ESRD Beneficiary Grievance Process*, OEI-01-11-00550 (December 2013)
CMS should instruct Medicare contractors to increase monitoring of outlier payments.	*Medicare Hospital Outlier Payments Warrant Increased Scrutiny*, OEI-06-10-00520 (November 2013)
CMS should use the Medicare Appeals System to monitor Medicare contractor performance.	*The First Level of the Medicare Appeals Process, 2008–2012: Volume, Outcomes, and Timeliness*, OEI-01-12-00150 (October 2013)
CMS should examine the additional potential impacts of establishing a prescription drug rebate program under Medicare Part B and, if appropriate, seek legislative change.	*Medicare Could Collect Billions if Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs*, OEI-12-12-00260 (September 2013)
CMS should seek legislative authority to: • remove Necessary Provider CAHs' permanent exemption from the distance requirement, allowing CMS to reassess these CAHs; and • revise the CAH Conditions of Participation to include alternative location-related requirements. **Estimated Savings: $449 million in 2011**[9]	*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 #4 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: • standardize case files and make them electronic and • improve the handling of appeals from appellants who are also under fraud investigation and seek statutory authority to postpone these appeals when necessary.	*Improvements Are Needed at the Administrative Law Judge Level of Medicare Appeals*, OEI-02-10-00340 (November 2012)
CMS should 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)

[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 adjust the estimated number of evaluation and management (E&M) services within musculoskeletal global surgery fees to reflect the actual number of E&M services being provided to beneficiaries, which would have reduced payments in CY 2007 alone by an estimated $49 million, or use the results of this audit during the annual update of the physician fee schedule. **Estimated Savings: $49 million**[10]	*Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided*, **A-05-09-00053** (May 2012)
CMS should adjust the estimated number of E&M services within cardiovascular global surgery fees to reflect the actual number of E&M services being provided to beneficiaries, which would have reduced payments in CY 2007 alone by an estimated $14.6 million, or use the results of this audit during the annual update of the physician fee schedule. **Estimated Savings: $14.6 million**[11]	*Cardiovascular Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided*, **A-05-09-00054** (May 2012)
CMS should facilitate access to information necessary to ensure accurate coverage and reimbursement determination.	*Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, **OEI-07-08-00150** (May 2011)
CMS should work with Congress to require manufacturers of first generics to submit monthly average sales price data during initial generic availability.	*Medicare Payments for Newly Available Generic Drugs*, **OEI-03-09-00510** (January 2011)
CMS should adjust the estimated number of E&M services within eye global surgery fees to reflect the number of E&M services actually being provided to beneficiaries, or use the financial results of the audit, in conjunction with other information, during the annual updates of the physician fee schedule. **Estimated Savings: $97.6 million per year**[12]	*Nationwide Review of E&M 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)

[10] Estimate based on CY 2007 data.
[11] Estimate based on CY 2007 data.
[12] Estimate based on CY 2005 data.

CMS—Medicare Parts C and D

Recommendation	Relevant Report(s)
CMS should educate Part D beneficiaries about access to medication-assisted drugs and naloxone.	*Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look,* OEI-02-19-00130 (May 2020)
CMS should: • allow revocation of Medicare enrollment for inappropriate billing of Part D, • apply the Preclusion List payment prohibitions to pharmacies and other providers that dispense Part D drugs, and • include on the Preclusion List pharmacies that inappropriately bill Part D.	*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)
CMS should: • continue to monitor providers submitting a high number of E1 transactions relative to prescriptions processed, • issue guidance that clearly states that E1 transactions should not be used for marketing purposes, • ensure that only pharmacies and other authorized entities submit E1 transactions, and • take appropriate enforcement action when abuse is identified.	*The Majority of Providers Reviewed Used Medicare Part D Eligibility Verification Transactions for Potentially Inappropriate Purposes,* A-05-17-00020 (February 2020)
CMS should research the remaining records for which we estimated missed Coverage Gap discounts totaling $406,755 and instruct Part D sponsors to validate and adjust PDE records accordingly and remit applicable amounts to the beneficiaries.	*CMS's Implementation of a 2014 Policy Change Resulted in Improvements in the Reporting of Coverage Gap Discounts Under Medicare Part D,* A-07-16-06067 (January 2020)
Top 25 Recommendation #8 CMS should: • provide targeted oversight of MAOs that had risk-adjusted payments resulting from unlinked chart reviews for beneficiaries who had no service records in the 2016 encounter data, • conduct audits that validate diagnoses reported on chart reviews in the Medicare Advantage encounter data, and • reassess the risks and benefits of allowing chart reviews that are not linked to service records to be used as sources of diagnoses for risk adjustment.	*Billions in Estimated Medicare Advantage Payments From Chart Reviews Raise Concerns,* OEI-03-17-00470 (December 2019)
CMS should: • take additional steps to improve electronic communication between Part D sponsors and prescribers to reduce avoidable pharmacy rejections and coverage denials; • take action to reduce inappropriate pharmacy rejections; • take action to reduce inappropriate coverage denials; and	*Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs,* OEI-09-16-00411 (September 2019)

Recommendation	Relevant Report(s)
• provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those relate to inappropriate pharmacy rejections and coverage denials.	
Top 25 Recommendation #10 As OIG has previously recommended, CMS should: • work directly with hospices to ensure that they are providing drugs covered under the hospice benefit and • develop and execute a strategy to ensure that Part D does not pay for drugs that should be covered by the Part A hospice benefit. **Estimated Savings: $160.8 million a year in Part D total cost**	*Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit*, A-06-17-08004 (August 2019)
CMS should: • enhance its oversight of MAO contracts, including those with extremely high overturn rates and/or low appeal rates, and take corrective action as appropriate; and • provide beneficiaries with clear, easily accessible information about serious violations by MAOs.	*Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials*, OEI-09-16-00410 (September 2018)
CMS should: • require plan sponsors to report Part C and Part D fraud and abuse incidents and the corrective actions taken to address them to a centralized system; • provide the MEDIC centralized access to all Part C encounter data; • require that Part C and Part D providers and pharmacies enroll in Medicare; • clarify the MEDIC's authority to require records from pharmacies, pharmacy benefit managers, and other entities under contract with Part C and Part D plan sponsors; • ensure that the 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; and • establish measures to assess the MEDIC's effectiveness.	*The MEDIC Produced Some Positive Results but More Could Be Done to Enhance Its Effectiveness*, OEI-03-17-00310 (July 2018)
Top 25 Recommendation #9 CMS should: • require MAOs to submit ordering and referring provider identifiers for applicable records; and • ensure that MAOs submit rendering provider identifiers for applicable records.	*Medicare Advantage Encounter Data Show Promise for Program Oversight, but Improvements Are Needed*, OEI-03-15-00060 (January 2018)
CMS should: • evaluate the cost-effectiveness of edits and medical reviews that are designed to ensure appropriate payments for covered uses on Part B drug claims and • assign a single entity to assist MACs in making coverage determinations.	*MACs Continue To Use Different Methods To Determine Drug Coverage*, OEI-03-13-00450 (August 2016)

Recommendation	Relevant Report(s)
CMS should: • determine whether outlier data values submitted by MAOs reflect inaccurate reporting or atypical performance and • use appropriate Part C reporting requirements data as part of its reviews of MAOs' performance.	*CMS Regularly Reviews Part C Reporting Requirements Data, but Its Followup and Use of the Data Are Limited*, OEI-03-11-00720 (March 2014)
CMS should: • provide Part D plan sponsors with specific guidelines on how to define and count incidents of potential fraud and abuse, related inquiries, and corrective actions; • review data from Part D plan sponsors to determine why certain sponsors reported especially high or low numbers of incidents of potential fraud and abuse, related inquiries, and corrective actions; and • share Part D plan sponsors' data on potential fraud and abuse with all sponsors and law enforcement.	*Less Than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse*, OEI-03-13-00030 (March 2014)
CMS should: • implement policies and procedures to notify MAOs of unlawful-presence information and thereby prevent their enrollment in MAOs, prevent enrollment of unlawfully present beneficiaries in Part D, disenroll such beneficiaries already enrolled, automatically reject such prescription drug event records, and recoup any improper payments; • identify and recoup improper payments made to MAOs for unlawfully present beneficiaries after our audit period and until policies and procedures have been implemented; and • recoup $26 million in improper payments in accordance with legal requirements.	*Medicare Improperly Paid Millions of Dollars for Prescription Drugs Provided to Unlawfully Present Beneficiaries During 2010 Through 2012*, A-07-13-01125 (April 2014) *Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2009 Through 2011*, A-07-12-06038 (October 2013)
CMS should: • define pharmacy benefit managers as entities that could benefit from formulary decisions; • establish minimum standards requiring sponsors to ensure that safeguards are established to prevent improprieties related to employment by the entity that maintains the Medicare Part D Pharmacy and Therapeutics committee; and • oversee compliance with Federal Pharmacy and Therapeutics committee conflict-of-interest requirements and guidance.	*Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions*, OEI-05-10-00450 (March 2013)
CMS should: • define pharmacy benefit managers as entities that could benefit from formulary decisions; and • 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	*Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions*, OEI-05-10-00450 (March 2013)

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

CMS—Medicaid

Recommendation	Relevant Report(s)
CMS should: • take steps to disallow Federal reimbursements to States for expenditures associated with unenrolled MCO network providers, including seeking necessary legislative authority; • work with States to ensure that unenrolled providers do not participate in Medicaid managed care and assist States in establishing ways to do so; • work with States to ensure that they have the controls required to prevent unenrolled ordering, referring, or prescribing providers from participating in Medicaid fee-for-service; and • work with States to ensure that they are complying with requirements to collect identifying information and ownership information on Medicaid provider enrollment forms.	*Twenty-Three States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries*, **OEI-05-19-00060** (March 2020)
CMS should: • recover from States the Federal share of inappropriate fee-for-service Medicaid payments associated with terminated providers,	*States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries,* **OEI-03-19-00070** (March 2020)

Recommendation	Relevant Report(s)
• implement a method to recover from States the Federal share of inappropriate managed care capitation payments associated with terminated providers, • follow up with States to remove terminated providers that OIG identified as inappropriately enrolled in Medicaid, • confirm that States do not continue to have terminated providers enrolled in their Medicaid programs, • safeguard Medicaid from inappropriate payments associated with terminated providers, and • review States' contracts with MCOs to ensure that they specifically include the required provision that prohibits terminated providers from participating in Medicaid managed care networks.	
CMS should verify that all State plans comply with Federal requirements prohibiting payments for provider-preventable conditions and issue clarifying guidance to States in specific areas (e.g., to help ensure that States identify provider-preventable conditions on inpatient claims from all inpatient hospitals).	*CMS Could Take Actions to Help States Comply With Federal Requirements Prohibiting Medicaid Payments for Inpatient Hospital Services Related to Provider-Preventable Conditions,* **A-09-18-02004** (March 2020)
Top 25 Recommendation #14 CMS should 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.	*Provider Shortages and Limited Availability of Behavioral Health Services in New Mexico's Medicaid Managed Care*, **OEI-02-17-00490** (September 2019)
CMS should: • assess the costs and benefits of implementing a targeted process to review certain assumptions; • issue guidance related to the areas identified in the report, specifically value based purchasing arrangements; and • implement a system to share responses to manufacturer inquiries for technical assistance.	*Reasonable Assumptions in Manufacturer Reporting of Average Manufacturer Prices and Best Prices*, **OEI-12-17-00130** (September 2019)
Top 25 Recommendation #11 CMS should: • ensure the correct submission of prescriber National Provider Identifiers, and • work to ensure that individual beneficiaries can be uniquely identified at a national level using T-MSIS.	*National Review of Opioid Prescribing in Medicaid Is Not Yet Possible*, **OEI-05-18-00480** (August 2019)

Recommendation	Relevant Report(s)
Top 25 Recommendation #12 CMS should: • collaborate with partners to develop strategies for improving rates of followup care for children treated for ADHD, • provide technical assistance to States to implement strategies for improving rates of followup care for children treated for ADHD, and • analyze the effectiveness of strategies for improving rates of followup care for children treated for ADHD.	*Many Medicaid-Enrolled Children Who Were Treated for Attention Deficit Hyperactivity Disorder Did Not Receive Recommended Followup Care*, **OEI-07-17-00170** (August 2019)
CMS should: • ensure that all States fully implement fingerprint-based criminal background checks for high-risk Medicaid providers, • amend its guidance so that States cannot forgo conducting criminal background checks on high-risk providers applying for Medicaid that have already enrolled in Medicare unless Medicare has conducted the checks, and • compare high-risk Medicaid providers' self-reported ownership information to Medicare's provider ownership information to help States identify discrepancies.	*Problems Remain for Ensuring All High Risk Medicaid Providers Undergo Criminal Background Checks*, **OEI-05-18-00070** (July 2019)
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 and • work with States to ensure that they prevent inappropriate reimbursement for drugs that are not FDA-approved and do not meet the criteria for an exception.	*One Percent of Drugs With Medicaid Reimbursement Were Not FDA-Approved*, **OEI-03-17-00120** (May 2019)
CMS should: • work with the States reviewed to ensure that the instances of noncompliance with health and safety and administrative requirements identified in this report are corrected; • assist all States to ensure the health and safety of vulnerable adults by offering technical assistance to look at staffing models in centers, homes, and other home and community-based service settings; • work with all States to review current training the States provide to centers and homes; and • assist all States to ensure the health and safety of vulnerable adults by offering technical assistance to look at possible templates for administrative records in centers, homes, and other home and community-based service settings.	*Four States Did Not Comply With Federal Waiver and State Requirements in Overseeing Adult Day Care Centers and Foster Care Homes*, **A-05-19-00005** (May 2019)

Recommendation	Relevant Report(s)
CMS should: • reconsider its position on permitting State agencies to certify nursing homes' substantial compliance on the basis of correction plans without obtaining evidence of correction for less serious deficiencies (deficiencies with ratings of *D, E,* and *F* without substandard quality of care); • revise guidance to State agencies to provide specific information on how State agencies should verify and document their verification of nursing homes' correction of less serious deficiencies before certifying nursing homes' substantial compliance with Federal participation requirements; • revise guidance to State agencies to clarify the type of supporting evidence of correction that should be provided by nursing homes with or in addition to correction plans; • strengthen guidance to State agencies to clarify who must attest that a correction plan will be implemented by a nursing home; • consider improving its forms related to the survey and certification process, such as the Forms CMS-2567, CMS-2567B, and CMS-1539, so that surveyors can explicitly indicate how a State agency verified correction of deficiencies and what evidence was reviewed; and • work with State agencies to address technical issues with the ASPEN system for maintaining supporting documentation.	*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)
CMS should: • continue to follow its policies and procedures related to the audit resolution process, and enhance them where possible, to ensure that all management decisions are issued within the required 6-month resolution period; and • promptly resolve the 140 outstanding audit recommendations that were past due as of September 30, 2016.	*Although CMS Has Made Progress, It Did Not Always Resolve Audit Recommendations in Accordance With Federal Requirements*, **A-07-18-03228** (January 2019)
CMS should instruct all State agencies to review, revise, develop, and implement policies and procedures to monitor the 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 #13 CMS should develop policies and procedures to improve the timeliness of recovering Medicaid overpayments, and recover uncollected amounts identified during OIG's audit.	*CMS Had Not Recovered More Than a Billion Dollars in Medicaid Overpayments Identified by OIG Audits*, **A-05-17-00013** (December 2018)

Recommendation	Relevant Report(s)
CMS should re-evaluate the effects of the health care-related tax safe-harbor threshold and the associated 75/75 requirement to determine whether modifications are needed.	*Although Hospital Tax Programs in Seven States Complied With Hold-Harmless Requirements, the Tax Burden on Hospitals Was Significantly Mitigated*, A-03-16-00202 (November 2018)
Top 25 Recommendation #11 CMS should: • improve MCO identification and referral of cases of suspected fraud or abuse; • increase MCO reporting of corrective actions taken against providers suspected of fraud or abuse to the State; • clarify the information MCOs are required to report regarding providers that are or otherwise leave the MCO network; • identify and share best practices about payment retention policies and incentives to increase recoveries; • improve coordination between MCOs and other State program integrity entities; • standardize reporting of referrals across all MCOs in the 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 Organization's Efforts To Identify and Address Fraud and Abuse*, OEI-02-15-00260 (July 2018)
CMS should provide additional technical assistance to help Medicaid agencies fully utilize Medicaid payment suspensions as a program integrity tool.	*Challenges Appear To Limit States' Use of Medicaid Payment Suspensions*, OEI-09-14-00020 (September 2017)
Top 25 Recommendation #25 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)

Recommendation	Relevant Report(s)
CMS should: • help States implement fingerprint-based criminal background checks for all high-risk providers, • help States overcome challenges in conducting site visits, • develop a central system by which States can submit and access screening results from other States, • strengthen minimum standards for fingerprint-based criminal background checks and site visits, and • work with States to develop a plan to complete their revalidation screening in a timely way.	*Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented*, **OEI-05-13-00520** (May 2016)
CMS should take appropriate action to ensure that States fully implement National Correct Coding Initiative edits.	*Inconsistencies in State Implementation of Correct Coding Edits May Allow Improper Medicaid Payments*, **OEI-09-14-00440** (April 2016)
CMS should: • issue guidance that clarifies requirements and provides further interpretation of the" as needed" language in 42 CFR § 430.30(d)(3) as it relates to the withdrawal of Medicaid funds; • publish regulations that are consistent with the U.S. Department of the Treasury provisions in 31 CFR part 205 and educate States; • publish and enforce formal guidance based on CMS's instructional email from November 8, 2011, so that States are aware of the appropriate Payment Management System account from which to withdraw or return funds; and • require States to reconcile total Federal Medicaid funds withdrawn with the Federal share of net expenditures and issue appropriate reconciliation guidelines.	*Opportunities for Program Improvements Related to States' Withdrawals of Federal Medicaid Funds*, **A-06-14-00068** (March 2016)
CMS should: • develop benchmarks for dental services and require States to create mandatory action plans to meet them, • work with States to analyze the effects of Medicaid payments on access to dental providers, and • work with States to track children's utilization of required dental services.	*Most Children With Medicaid in Four States Are Not Receiving Required Dental Services*, **OEI-02-14-00490** (January 2016)
CMS should issue Medicaid regulations to clarify the requirements of the Affordable Care Act that parallel its proposed Medicare rules and require that States ensure that providers exercise reasonable diligence to identify, report, and return overpayments.	*Providers Did Not Always Reconcile Patient Records With Credit Balances and Report and Return the Associated Medicaid Overpayments to State Agencies*, **A-04-14-04029** (August 2015)
CMS should work with States to: • ensure that plans are complying with State standards and assess whether additional standards are needed,	*Access to Care: Provide Availability in Medicaid Managed Care*, **OEI-02-13-00670**

Recommendation	Relevant Report(s)
• ensure that plans' networks are adequate and meet the needs of their Medicaid managed care enrollees, and • assess the number of providers offering appointments and improve the accuracy of plan information.	(December 2014)
CMS should: • strengthen its oversight of State standards and ensure that States develop standards for key providers, • strengthen its oversight of States' methods to assess plan compliance and ensure that States conduct direct tests of access standards, and • improve States' efforts to identify and address violations of access standards.	*State Standards for Access to Care in Medicaid Managed Care*, OEI-02-11-00320 (September 2014)
Top 25 Recommendation #11 CMS should establish a deadline for when national T-MSIS data will be available.	*Early Outcomes Show Limited Progress for the Transformed Medicaid Statistical Information System*, OEI-05-12-00610 (September 2013)
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)
CMS should: • take action against States that do not meet the Deficit Reduction Act of 2005 requirement to collect rebates on physician-administered drugs and • ensure that all State agencies are accurately identifying and collecting physician-administered drug rebates owed by manufacturers.	*States' Collection of Medicaid Rebates for Physician-Administered Drugs*, OEI-03-09-00410 (June 2011)
CMS should provide States with definitive guidance for calculating the Medicaid upper payment limit, which should include using facility-specific upper payment limits that are based on actual cost report data. **Estimated Savings: $3.87 billion over 5 years**	*Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers*, A-03-00-00216 (September 2001)

CMS—General

Recommendation	Relevant Report(s)
CMS should: • continue to enhance the data analysis on Medicaid claims-level data to develop robust analytical procedures and measures against benchmarks to monitor and identify risks associated with the Medicaid program;	Summary of recommendations from the *Report on the Financial Statement Audit of CMS for Fiscal Year 2019* (**A-17-19-53000**), CMS Financial Report Fiscal Year 2019 (November 2019)

Recommendation	Relevant Report(s)
• establish a process to perform a claims-level detailed look-back analysis on the Medicaid Entitlement Benefits Due and Payable to determine the reasonableness of the methodology utilized to record the approximately $37.1 billion accrual; • consider whether there are portions of the manual journal voucher process to record MAC data at the Central Office that should be configured as routine systemic entries within the system; • 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 which are consistent with the organization's objectives of improving payment accuracy levels; and • continually assess the governance and oversight across its organizational units charged with responsibility for configuration management and information security of its IT systems and data, at both the Central Office and the CMS Medicare fee-for-service contractors.	
CMS should: • work with Treasury and Qualified Health Plan issuers to collect improper financial assistance payments, which we estimate to be $434,398,168, for policies for which the payments were not authorized in accordance with Federal requirements; and • work with Treasury and Qualified Health Plan issuers to resolve the potentially improper financial assistance payments, which we estimate to be $504,889,518, for policies for which there was no documentation provided to verify enrollees had paid their premiums.	*CMS Did Not Always Accurately Authorize Financial Assistance Payments to Qualified Health Plan Issuers in Accordance With Federal Requirements During the 2014 Benefit Year*, **A-02-15-02013** (August 2018)
CMS should ensure that critical security updates are applied to Internet-facing systems regularly and follow vendor-provided security recommendations for configuring software.	*OIG Penetration Test of CMS's Network*, **A-18-17-08200** (April 2018)
CMS should 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, if such mechanisms are identified, seek legislative authority to establish them.	*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.	*IHS Hospitals: More Monitoring Needed To Ensure Quality Care*, **OEI-06-14-00010** (October 2016)

Administration for Children and Families (ACF)

Recommendation	Relevant Report(s)
HHS should: • take steps to ensure that children's interests are prioritized and represented in decisions affecting the unaccompanied children Program, both internally and when engaging with interagency partners; • modify or pursue formal agreements with the Department of Homeland Security and Department of Justice to ensure that it is receiving information that supports its operation of and ability to provide care for children in the unaccompanied children Program; • improve communication to care provider facilities regarding interim guidance, operational directives, and other instructions that are not immediately available in published policy documents; and • further improve its ability to identify and track separated children by reducing reliance on manual processes.	*Communication and Management Challenges Impeded HHS's Response to the Zero-Tolerance Policy*, **OEI-BL-18-00510** (March 2020)
Top 25 Recommendation #15 ACF's ORR should: • identify and disseminate evidence-based approaches to addressing trauma in short-term therapy, • develop and implement strategies to assist care provider facilities in overcoming obstacles to hiring and retaining qualified mental health clinicians, • assess whether to establish maximum caseloads for individual mental health clinicians, • help care provider facilities improve their access to mental health specialists, • increase therapeutic placement options for children who require more intensive mental health treatment, and • take all reasonable steps to minimize the time that children remain in ORR custody.	*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: • reiterate to facilities that ORR requires all background checks be completed prior to the employee's start date and access to children; • require facilities to ensure that Child Protective Services (CPS) checks are completed for all employees who lived outside of their current State of residence in the past 5 years and where necessary, ORR should work with facilities to ensure that CPS checks are completed; • provide additional guidance to facilities so they can better ensure that case managers and mental health clinicians meet ORR's minimum required education qualifications; • reiterate to all facilities the ORR policy requiring facilities to obtain ORR written approval prior to hiring a case manager or mental health clinician who does not meet minimum requirements and require a supervision plan or additional training for the potential employee as needed; and • work with facilities to develop a process for facilities to report when case manager or mental health clinician staffing ratios are not met, so that ORR can use this information when making placement decisions and ensuring the children's needs are met.	*Unaccompanied Alien Children Care Provider Facilities Generally Conduced Required Background Checks but Faced Challenges in Hiring, Screening, and Retaining Employees,* **A-12-19-20001** (September 2019)
ACF should establish a forum for States to share strategies regarding how they set payment rates to ensure equal access for eligible families while balancing competing program priorities.	*States' Payment Rates Under the Child Care and Development Fund Program Could Limit Access to Child Care Providers*, **OEI-03-15-00170** (August 2019)
Top 25 Recommendation #16 ACF should: • develop a comprehensive strategy to improve States' compliance with requirements related to treatment planning and medication monitoring for psychotropic medication and • help States strengthen their requirements for oversight of psychotropic medication by incorporating professional practice guidelines for monitoring children at the individual level.	*Treatment Planning and Medication Monitoring Were Lacking for Children in Foster Care Receiving Psychotropic Medication*, **OEI-07-15-00380** (September 2018)
ACF should proactively monitor Head Start grantee performance results to verify that those grantees designated for automatic, noncompetitive renewal perform better than their peers.	*Head Start Grant Recompetition: Early Implementation Results Suggest Opportunities for Improvement*, **OEI-12-14-00650** (August 2016)
ACF should expand the scope of the 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)
Top 25 Recommendation #17 ACL should: • determine whether it can allocate its funds differently to enable onsite compliance reviews, • seek additional department funding or resources to conduct the onsite compliance reviews, and • perform the required onsite compliance reviews of independent living programs.	*ACL Failed To Conduct Any of the Required Onsite Compliance Reviews of Independent Living Programs*, **A-05-18-00034** (August 2019)

Agency for Healthcare Research and Quality (AHRQ)

Recommendation	Relevant Report(s)
AHRQ should: • take steps to encourage patient safety organizations to participate 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; • update guidance for patient safety organizations on the initial and continued listing processes; and • develop and execute a communications strategy to increase hospitals' awareness of the program and its value to participants.	*Patient Safety Organizations: Hospital Participation, Value, and Challenges*, **OEI-01-17-00420** (September 2019)

Food and Drug Administration (FDA)

Recommendation	Relevant Report(s)
FDA should: • provide educational outreach to trading partners about required drug product tracing information and data standardization guidelines and • seek legislative authority to include information about a drug product's complete physical path through the supply chain 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)
FDA should implement more effective tools and methods, such as application whitelisting, to detect and prevent execution of unauthorized commands or programs on FDA systems.	*FDA Continues To Mature Its Preventative and Detective Controls To More Effectively Mitigate the Risk of Compromise*, **A-18-18-08300**[13] (October 2019)

[13] This report is not publicly available.

Recommendation	Relevant Report(s)
Top 25 Recommendation #18 FDA should: • develop a policy for defining and a procedure for identifying retrospectively the date that FDA learns of a potentially hazardous product and consider adding a field for the date to the RES or another FDA system so that FDA staff involved in managing a recall have access to this information; and • establish performance measures for the amount of time between the date FDA learns of a potentially hazardous product and the date a firm initiates a voluntary recall, monitor performance, and refine operating procedures, as needed.	*FDA's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply*, A-01-16-01502 (December 2017)
FDA should provide technical assistance regarding exempt products.	*Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information*, OEI-05-14-00640 (September 2017)
FDA should: • build capacity in the Document Archiving, Reporting, and Regulatory Tracking System to support postmarketing requirements oversight; and • provide a standardized form for annual status reports, ensure that they are complete, and require sponsors to submit them electronically.	*FDA Is Issuing More Postmarketing Requirements, but Challenges With Oversight Persist*, OEI-01-14-00390 (July 2016)
FDA should: • identify risk evaluation and mitigation strategies that are not meeting their goals and take appropriate actions to protect the public health, • seek legislative authority to enforce FDA assessment plans, and • ensure that assessment reviews are timely.	*FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety*, OEI-04-11-00510 (February 2013)
FDA should seek statutory authority to review substantiation for structure/function claims to determine whether claims are truthful and not misleading.	*Dietary Supplements: Structure/Function Claims Fail To Meet Federal Requirements*, OEI-01-11-00210 (October 2012)
FDA should seek statutory authority to impose civil monetary penalties on companies that do not comply with registration requirements.	*Dietary Supplements: Companies May Be Difficult To Locate in an Emergency*, OEI-01-11-00211 (October 2012)
FDA should consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements.	*FDA Inspections of Domestic Food Facilities*, OEI-02-08-00080 (April 2010)

Health Resources and Services Administration (HRSA)

Recommendation	Relevant Report(s)
Top 25 Recommendation #25 HRSA should share 340B ceiling prices with States.	*State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321 (June 2011)

Indian Health Service (IHS)

Recommendation	Relevant Report(s)
Top 25 Recommendation #19 IHS should: • extend policies to address more types of perpetrators, victims, and abuse; • ensure that the new incident reporting system is effective and addresses the risks identified in the current system; • designate a central owner in IHS headquarters to ensure clear roles and responsibilities for shared ownership in implementing patient protection policies, and managing and responding to abuse reports; • continue to actively promote an organizational culture of transparency and work to resolve barriers to staff reporting of abuse; and • conduct additional outreach to Tribal communities to inform them of patient rights, solicit community concerns, and address barriers to reporting of patient abuse.	*IHS Has Strengthened Patient Protection Policies but Must Fully Integrate Them Into Practice and Organizational Culture*, OEI-06-19-00330 (December 2019)
Top 25 Recommendation #19 IHS should: • as a management priority, develop and implement a staffing program for recruiting, retaining, and transitioning staff and leadership to remote hospitals; • enhance training and orientation for new hospital leaders to ensure that they follow IHS directives and continue improvement efforts; • continue to take steps to ensure early and effective intervention when IHS identifies problems at hospitals; and • develop procedures for temporary emergency department closures and communicate those procedures with receiving hospitals and emergency medical services to ensure that they are adequately prepared to receive diverted patients during such events.	*Case Study: IHS Management of Rosebud Hospital Emergency Department Closure and Reopening*, OEI-06-17-00270 (July 2019)

Recommendation	Relevant Report(s)
Top 25 Recommendations #20 and #21 IHS should: • increase oversight of IT systems by IHS management; • present findings and cost savings analysis to Tribal leadership and the IHS user community to get buy-in for any significant IT enterprise changes; and • implement a strategic and phased approach to centralization of IT systems, services, and cybersecurity functions. IHS should work with hospitals to: • ensure that they follow the Indian Health Manual when prescribing and dispensing opioids; • develop policies and procedures to review the 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; • ensure that opioid dispensing data are complete, accurate, and submitted in a timely manner to the State Prescription Drug Monitoring Program for use by providers and pharmacists; and • track all opioids prescribed at the hospital in the patient EHRs, including those being filled at an outside pharmacy.	*IHS Needs To Improve Oversight of Its Hospitals' Opioid Prescribing and Dispensing Practices and Consider Centralizing Its Information Technology Functions*, **A-18-17-11400** (July 2019)
IHS should: • implement a quality-focused compliance program to support Federal requirements for health care programs; • continue to invest in training for hospital administration and staff, and assess the value and effectiveness of training efforts; • establish standards and expectations for how Area Offices and Governing Boards oversee and monitor hospitals and monitor adherence to those standards; and • continue to seek new meaningful ways to monitor hospital quality through the use of outcomes and/or process measures.	*IHS Hospitals: More Monitoring Needed To Ensure Quality Care*, **OEI-06-14-00010** (October 2016)
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)
IHS should conduct a needs assessment culminating in an agencywide strategic plan with actionable initiatives and target dates.	*IHS Hospitals: Longstanding Challenges Warrant Focused Attention To Support Quality Care*, **OEI-06-14-00011** (October 2016)

National Institutes of Health (NIH)

Recommendation	Relevant Report(s)
Top 25 Recommendation #22 NIH should: • update its guidance on vetting peer reviewer nominees to identify potential foreign threats to research integrity, in consultation with national security experts, as needed; and • work with the HHS Office of National Security to develop a risk-based approach for identifying those peer reviewer nominees who warrant extra scrutiny.	*Vetting Peer Reviewers at NIH's Center for Scientific Review: Strengths and Limitations*, **OEI-01-19-00160** (September 2019)
Top 25 Recommendation #22 NIH should: • perform periodic quality assurance reviews of information in the FCOI module to ensure the adequacy of oversight regarding FCOIs and • 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)
Top 25 Recommendation #22 NIH should: • ensure that the 1,013 institutions identified by this review as not having FCOI policies on their website post these policies as required and • implement procedures to ensure that all institutions that are required to have FCOI policies have FCOI policies.	*NIH Has Limited Policies, Procedures, and Controls in Place for Helping To Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations*, **A-03-19-03003** (September 2019)
NIH should promulgate regulations that address institutional FCOIs.	*Institutional Conflicts of Interest at NIH Grantees,* **OEI-03-09-00480** (January 2011)
NIH should develop and disseminate guidance on methods to verify researchers' financial interests.	*How Grantees Manage Financial Conflicts of Interest in Research Funded by the NIH,* **OEI-03-07-00700** (November 2009)

Substance Abuse and Mental Health Services Administration (SAMHSA)

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

General Departmental

Recommendation	Relevant Report(s)
HHS should: • continue to work with the Office of Management and Budget and other stakeholders to develop and implement an approach to reporting on TANF improper payments in FY 2020; • continue to focus on developing and implementing an approach to reporting on TANF improper payments, as this process will aid in identifying root causes of TANF improper payments; • develop and publish corrective action plans after implementing an approach; • focus on the root causes of the improper payment percentage and evaluate critical and feasible action steps to assist States with their compliance efforts for new requirements of the Medicaid and CHIP programs; • continue to follow up with States during the interim period to verify that corrective actions identified after the improper payment error rate measurement review for the Medicaid and CHIP programs are being implemented[14]; and • continue to explore a vehicle to conduct recovery audits that will fit into the larger Medicare Part C program in FY 2019.	*HHS Met Many Requirements of the Improper Payments Information Act of 2002 but Did Not Fully Comply for Fiscal Year 2019,* **A-17-20-52000** (May 2020)
HHS should: • continue to develop and refine their financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity; and • continue to strengthen oversight of remediation activities to limit new deficiencies and improve internal control over financial information systems.	Summary of recommendations from *OIG Report on the Financial Statement Audit of HHS for Fiscal Year 2019* (**A-17-19-00001**), **HHS Fiscal Year 2019 Agency Financial Report** (November 2019)
Top 25 Recommendation #23 HHS should: • develop departmentwide objectives and a strategic framework for responding to international public health emergencies; • develop policies and procedures that clearly define HHS components' roles and responsibilities for responding to international public health emergencies; • develop large-scale international response plans; • develop various means of obtaining and using quality data for decision making, and • work with other U.S. Government agencies to develop a flexible multiagency international response framework.	*HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts,* **A-04-16-03567** (August 2019)

[14] Note: The current COVID-19 public health emergency may impact States' ability to analyze and follow up on corrective action plans. Similarly, this will impact the information reported to CMS.

Recommendation	Relevant Report(s)
Top 25 Recommendation #24 HHS should ensure that: • all future web application developments incorporate security requirements from an industry-recognized web application security standard and • OpDivs implement properly configured web application firewalls in accordance with an agreed-upon baseline standard established by HHS.	*Summary Report for OIG Penetration Testing of Eight HHS Operating Division Networks*, **A-18-18-08500** (March 2019)
HHS should address factors that may limit the Office for Human Research Protection's (OHRP) 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*, **OEI-04-11-00530** (April 2014)
The Office of the National Coordinator for Health Information Technology and CMS should strengthen their collaborative efforts to develop a comprehensive plan to address fraud vulnerabilities in EHRs.	*Not All Recommended Fraud Safeguards Have Been Implemented in Hospital Electronic Health Record Technology*, **OEI-01-11-00570** (December 2013)

Appendix C: Implemented and Closed Recommendations Reported in 2019 Edition

This appendix identifies over 50 significant recommendations described in the 2019 edition of this publication that were implemented or closed for other reasons since the publication was issued.[15] OIG may close recommendations that were not implemented for a range of reasons; for example, the underlying problem may have been solved in a different way, a program change may make a recommendation no longer relevant, or OIG may conduct new work on the same issue and make a new, "superseding" recommendation to address the problem. The recommendations listed below are generally grouped by OpDiv. We have indicated which recommendations below were on the 2019 Top 25 list and legislative recommendations. The status of each recommendation is also included. The hyperlinks below provide more information on the report(s) relevant to each recommendation.

CMS—Medicare Parts A and B

Recommendation	Relevant Report(s)	Status
CMS should direct the DME MACs to correct the Common Working File edits to fully prevent or detect overpayments to suppliers for DME, prosthetics, orthotics, and supplies items provided during inpatient stays.	*Medicare Improperly Paid Suppliers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Provided to Beneficiaries During Inpatient Stays,* **A-09-17-03035** (November 2018)	Implemented
CMS should analyze deficiency data to inform the survey process.	*Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio,* **OEI-02-16-00570** (July 2018)	Implemented
CMS should offer education and training to practitioners on Medicare telehealth requirements.	*CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements,* **A-05-16-00058** (April 2018)	Implemented
CMS should work with its contractors to educate chiropractors on the training materials that are available to them.	*Medicare Needs Better Controls to Prevent Fraud, Waste, and Abuse Related to Chiropractic Services,* **A-09-16-02042** (February 2018)	Implemented
CMS should recover $2,344,680 in overpayments made to eligible professionals after they switched programs and recover $291,222 in payments made to the sampled eligible professionals who did not meet meaningful use requirements.	*Medicare Paid Hundreds of Millions in Electronic Health Record Incentive Payments That Did Not Comply With Federal Requirements,* **A-05-14-00047** (June 2017)	Implemented

[15] OIG, *Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: OIG's Top Recommendations*, July 2019. Available at https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2019.pdf.

Recommendation	Relevant Report(s)	Status
CMS should make better use of data analytics to ensure the integrity of hospital quality data and the resulting payment adjustments.	*CMS Validated Hospital Inpatient Quality Reporting Program Data, but Should Use Additional Tools To Identify Gaming*, OEI-01-15-00320 (April 2017)	Implemented
2019 Top 25 Recommendation #15 CMS should ensure that PECOS contains the complete and accurate data needed to execute and evaluate CMS's enrollment-screening enhancements.	*Enhanced Enrollment Screening of Medicare Providers: Early Implementation Results*, OEI-03-13-00050 (April 2016)	Implemented
CMS should follow up on inappropriate general inpatient care stays, inappropriate Part D payments, and hospices that provided poor-quality care.	*Hospices Inappropriately Billed Medicare Over $250 Million for General Inpatient Care*, OEI-02-10-00491 (March 2016)	Implemented
CMS should continue working with participating States to fully implement their background check programs.	*National Background Check Program for Long-Term-Care Employees: Interim Report*, OEI-07-10-00420 (January 2016)	Implemented
CMS should strengthen oversight of SNF billing.	*The Medicare Payment System for Skilled Nursing Facilities Needs To Be Reevaluated*, OEI-02-13-00610 (September 2015)	Implemented
CMS should: • reduce the financial incentive for SNFs to use assessments differently when decreasing therapy than when increasing it and • strengthen the oversight of SNF billing for changes in therapy.	*Skilled Nursing Facility Billing for Changes in Therapy: Improvements Are Needed*, OEI-02-13-00611 (June 2015)	First recommendation closed: CMS conducted an analysis that included claims for SNFs that billed for changes in therapy and frequently used therapy assessments incorrectly, and OIG agreed to close the recommendation. Second recommendation implemented.
CMS should implement additional claims processing edits or improve edits to ensure that claims are paid appropriately.	*Medicare Paid $22 Million in 2012 for Potentially Inappropriate Ophthalmology Claims*, OEI-04-12-00281 (December 2014)	Implemented
2019 Legislative Recommendation	*Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2011*, OEI-03-12-00670 (January 2013)	Implemented

Recommendation	Relevant Report(s)	Status
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.		
CMS should: • define "grievance" for facilities, • provide guidance to facilities on what constitutes a robust process for anonymous grievances, and • provide networks with better technical support for the Contact Utility database.	*The ESRD Beneficiary Grievance Process*, OEI-01-11-00550 (December 2013)	All three recommendations implemented.
CMS should monitor compliance with the new therapy assessments.	*Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than $1 Billion in 2009*, OEI-02-09-00200 (November 2012)	Implemented
CMS should require that all Immediate Jeopardy complaint surveys evaluate compliance with the Conditions of Participation on quality assurance and performance improvement.	*Adverse Events in Hospitals: Medicare's Responses to Alleged Serious Events*, OEI-01-08-00590 (October 2011)	Closed. CMS took action toward achieving the goal of the recommendation. OIG closed the recommendation in recognition that CMS would not be taking further action to implement the recommendation.

CMS—Medicare Parts C and D

Recommendation	Relevant Report(s)	Status
CMS should address persistent problems related to inappropriate denials and insufficient denial letters in Medicare Advantage.	*Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials,* OEI-09-16-00410 (September 2018)	Implemented
2019 Top 25 Recommendation #11 CMS should: • conduct additional analysis on compounded topical drugs;	*Questionable Billing for Compounded Topical Drugs in Medicare Part D*, OEI-02-16-00440 (August 2018)	All three recommendations implemented.

Recommendation	Relevant Report(s)	Status
• conduct training for Part D sponsors on fraud schemes and safety concerns related to compounded topical drugs; and • follow up on pharmacies with questionable Part D billing and the prescribers associated with these pharmacies.		
CMS should improve coordination and collaboration with NIH.	*CMS Has Not Performed Required Closeouts of Contracts Worth Billions*, OEI-03-12-00680 (December 2015)	Implemented
CMS should ensure that all MAOs are responding appropriately to potential fraud and abuse incidents.	*MAOs' Identification of Potential Fraud and Abuse*, OEI-03-10-00310 (February 2012)	Implemented
CMS should: • require sponsors to use methods CMS deems reasonable to allocate rebates across plans and • ensure that sponsors appropriately report the fees that pharmacy benefit managers collect from manufacturers.	*Concerns With Rebates in the Medicare Part D Program*, OEI-02-08-00050 (March 2011)	Both recommendations implemented.

CMS—Medicaid

Recommendation	Relevant Report(s)	Status
CMS should continue to improve its reporting system to prevent inappropriate reimbursement for drugs that are not FDA-approved.	*One Percent of Drugs With Medicaid Reimbursement Were Not FDA-Approved*, OEI-03-17-00120 (May 2019)	Implemented
CMS should improve its Drug Data Reporting for Medicaid System to minimize inconsistent data submissions and track potential classification errors for followup.	*Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates*, OEI-03-17-00100 (December 2017)	Implemented
2019 Top 25 Recommendation #15 CMS should enable States to substitute Medicare screening data by ensuring the accessibility and quality of Medicare data.	*Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented,* OEI-05-13-00520 (May 2016)	Implemented
CMS should ensure that States pay for services in accordance with their periodicity schedules.	*Most Children With Medicaid in Four States Are Not Receiving Required Dental Services*, OEI-02-14-00490 (January 2016)	Implemented

Recommendation	Relevant Report(s)	Status
CMS should monitor encounter data to ensure that States report data for all managed care entities.	*Not All States Reported Medicaid Managed Care Encounter Data as Required*, OEI-07-13-00120 (July 2015)	Closed: superseded by recommendation in OEI-02-15-00260.
CMS should require each State Medicaid agency to report all terminated providers.	*CMS Process for Sharing Information About Terminated Providers Needs Improvement*, OEI-06-12-00031 (March 2014)	Implemented
2019 Top 25 Recommendation #14 CMS should improve CMS's and States' ability to monitor billing and care quality by requiring States to either enroll all PCS attendants as providers or require all PCS attendants to register with their State Medicaid agencies and assign each attendant a unique identifier.	*Personal Care Services: Trends, Vulnerabilities, and Recommendations for Improvement*, OIG-12-12-01 (November 2012)	Implemented

CMS—General

Recommendation	Relevant Report(s)	Status
CMS should: • correct internal control deficiencies by implementing computerized systems to maintain confirmed enrollee and payment information so that CMS does not have to rely on qualified health plan issuers' attestations in calculating payments and • correct internal control deficiencies by implementing a computerized system so that State marketplaces can submit enrollee eligibility data.	*CMS's Internal Controls Did Not Effectively Ensure the Accuracy of Aggregate Financial Assistance Payments Made to Qualified Health Plan Issuers Under the Affordable Care Act*, A-02-14-02006 (June 2015)	Both recommendations implemented.
CMS should ensure that all contracts that are subject to its Contract Review Board requirements undergo these reviews.	*Federal Marketplace: Inadequacies in Contract Planning and Procurement*, OEI-03-14-00230 (January 2015)	Implemented

Administration for Children and Families (ACF)

Recommendation	Relevant Report(s)	Status
ACF should examine with States the benefit of expanding program integrity and fraud-fighting activities.	*More Effort Is Needed To Protect the Integrity of the Child Care and Development Fund Block Grant Program*, OEI-03-16-00150 (July 2016)	Implemented

Food and Drug Administration (FDA)

Recommendation	Relevant Report(s)	Status
2019 Top 25 Recommendation #20 FDA should establish set timeframes, through its SCORE initiative, to: • discuss the possibility of a voluntary recall with a firm and • initiate use of its mandatory recall authority after it has made the determination that the legal standard for use of that authority has been met and a firm is not willing to voluntarily conduct a recall.	*FDA's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply*, A-01-16-01502 (December 2017)	Both recommendations implemented.
FDA should provide technical assistance: • on requirements regarding direct purchase statements and • regarding the exchange of drug product tracing information for sales to 340B-covered entities that use 340B contract pharmacies.	*Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information*, OEI-05-14-00640 (September 2017)	Both recommendations implemented.
2019 Top 25 Recommendation #20 FDA should take appropriate action against all facilities with significant inspection violations.	*Challenges Remain in FDA's Inspections of Domestic Food Facilities*, OEI-02-14-00420 (September 2017)	Implemented
FDA should: • develop and implement a plan to identify, develop, validate, and assess risk evaluation and mitigation strategy components; and • clarify expectations for sponsors' assessments in FDA assessment plans.	*FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety*, OEI-04-11-00510 (February 2013)	Both recommendations implemented.

Health Resources and Services Administration (HRSA)

Recommendation	Relevant Report(s)	Status
HRSA should clarify its guidance on preventing duplicate discounts for MCO drugs.	*State Efforts To Exclude 340B Drugs From Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016)	Implemented

Indian Health Service (IHS)

Recommendation	Relevant Report(s)	Status
2019 Top 25 Recommendation #22 IHS should deem a risk of the lack of continuity of operations to be unacceptable and take immediate action to assess all IHS facilities and ensure that each facility has a tested and viable continuity of operations program to respond to and recover from a range of disasters.	*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)	Implemented
IHS should, as part of the Office of the Secretary's newly formed Executive Council, lead an examination of the quality of care delivered in IHS hospitals and use the findings to identify and implement innovative strategies to mitigate IHS's longstanding challenges.	*IHS Hospitals: Longstanding Challenges Warrant Focused Attention To Support Quality Care*, OEI-06-14-00011 (October 2016)	Implemented

National Institutes of Health (NIH)

Recommendation	Relevant Report(s)	Status
2019 Top 25 Recommendation #23 NIH should: • work with an organization with national security expertise and knowledge of international risk areas to assess the impact of the potential misuse of genomic data provided to foreign principal investigators; • develop and implement mechanisms to ensure that the Genomic Data Sharing Policy keeps current with emerging threats to national security; and	*Opportunities Exist for the NIH To Strengthen Controls in Place To Permit and Monitor Access to Its Sensitive Data*, A-18-18-09350 (February 2019)	All three recommendations implemented.

Recommendation	Relevant Report(s)	Status
• make security training and security plans a requirement that principal investigators and entities must fulfill before being permitted access to genomic data, and develop additional internal controls to verify that foreign principal investigators and entities have fulfilled those requirements.		

General Departmental

Recommendation	Relevant Report(s)	Status
The Office of the Assistant Secretary for Preparedness and Response, Centers for Disease Control and Prevention, and CMS should continue to help hospitals sustain preparedness for emerging infectious diseases by coordinating guidance and providing practical advice for all hospitals.	*Hospitals Reported Improved Preparedness for Emerging Infectious Diseases After the Ebola Outbreak*, **OEI-06-15-00230** (October 2018)	Implemented

U.S. Department of Health and Human Services

Office of Inspector General