

HHS/OIG Compendium of Unimplemented Recommendations

About the April 2016 Edition

This document, entitled the *Compendium of Unimplemented Recommendations (Compendium)*, is a core publication of the Department of Health and Human Services (HHS or Department) Office of Inspector General (OIG). In this edition we focus on the top 25 unimplemented recommendations that, on the basis of OIG's professional opinion, would most positively impact HHS programs in terms of cost savings and/or quality improvements and should, therefore, be prioritized for implementation. The recommendations come from OIG audits and evaluations, performed pursuant to the Inspector General Act of 1978 (IG Act), as amended. The Appendix of the *Compendium* includes a comprehensive list of significant unimplemented recommendations from OIG.

The *Compendium* constitutes OIG's response to a specific requirement of the Inspector General Act of 1978, as amended (section 5(a)(3)). It identifies significant recommendations described in previous *Semiannual Reports to Congress* with respect to problems, abuses, or deficiencies for which corrective actions have not been completed. The 2016 edition also responds to a requirement associated with the Consolidated Appropriations Act of 2014, directing OIG to report its top unimplemented recommendations that, on the basis of the professional opinion of OIG, would best protect the integrity of HHS programs if implemented.¹

The recommendations represent opportunities to achieve expected impact through improvements in program effectiveness and efficiency and to better ensure quality of care and safety of beneficiaries in fiscal year (FY) 2016 and beyond.² Each of the top 25 unimplemented recommendations is linked to our Top Management and Performance Challenges. Annually, OIG prepares a summary of the most significant management and performance challenges facing HHS, including challenges that reflect continuing vulnerabilities that OIG has identified for HHS over recent years as well as new and emerging issues.

In this publication, the top 25 unimplemented recommendations are generally grouped by the underlying program or operation area or area of legislation/regulation. However, they are not internally ranked and do not reflect relative priority among the 25.

Implementation of OIG's Recommendations

Implementing OIG's recommendations generally requires one of three types of actions: legislative, regulatory, or administrative. Some issues involve more than one type of corrective action. The expected impact of OIG's recommendations varies from direct cost savings to improvements in payment

¹ Explanatory statement submitted by Mr. Rogers of Kentucky, chairman of the House Committee on Appropriations, regarding the House amendment to the Senate amendment on H.R. 3547 Consolidated Appropriations Act, 2014; Division H – Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2014; Title II, Department of Health and Human Services, Office of Inspector General, p. 63.

² The *Compendium* does not include all unimplemented OIG recommendations. For example, it does not include recommendations that are only to collect improper payments or those that are addressed to specific non-Federal entities. It also does not include recommendations that are significant but involve sensitive security issues.

efficiency, program operations, and/or quality and safety. These improvements may not result in direct monetary recoveries, but their impact on ensuring the integrity of HHS programs and the health and welfare of program beneficiaries is just as crucial.

The IG Act provides OIG the responsibility to make recommendations related to HHS programs and operations. In response, HHS and its operating and staff divisions have the responsibility to respond to those recommendations, including whether recommendations should be implemented. Although many OIG recommendations are directly implemented by organizations within HHS, some are acted upon by States that collaborate with HHS to administer, operate, and/or oversee designated Federally funded programs, such as Medicaid.

Other policymakers, such as the Administration and Congress, may also take actions to address our recommendations and any additional steps to achieve optimal outcomes. For example, Congress has previously incorporated OIG's recommendations into legislative actions in order to achieve substantial savings; put public funds to better use; and/or improve quality of care, program integrity, or information systems and processes.

Some of the recommendations in the *Compendium* require HHS to seek additional statutory authority or other legislative change; to be considered implemented, these recommendations ultimately require legislative action by Congress. The *Compendium* includes two recommendations (CMS should restrict certain beneficiaries to a limited number of pharmacies or prescribers; CMS should seek legislative authority to limit State Medicaid durable medical equipment prosthetics, orthotics, and supplies reimbursement rates to Medicare program rates and encourage further reduction of Medicaid reimbursement rates through competitive bidding or manufacturer rebates) where CMS has sought legislative authority, but additional Congressional action is needed. These recommendations will remain unimplemented until legislation is enacted.

Many of the recommendations in this *Compendium* have seen some progress. However, as of April 2016, the month of publication, OIG has reason to believe that more should be achieved.

If more information is needed on any report listed in this publication, the report numbers are hyperlinked to the full text of the reports on our website. The full reports can also be located by entering the report numbers into any major Internet search engine or into the search field on our website. Questions about the Compendium or other publications should be directed to OIG's Office of External Affairs at (202) 619-1343.

Find Us on the Web

- OIG's website, which provides a full range of OIG output, includes the Compendium and other key publications, such as the *OIG Work Plan*, *Semiannual Report to Congress*, and *Top Management and Performance Challenges*. The website is at <http://oig.hhs.gov>.
- You may report potential instances of waste, fraud, or abuse related to HHS's programs via phone at 1-800-HHS-TIPS or on our website at <https://forms.oig.hhs.gov/hotlineoperations>.

Emerging Issues, the OIG Work Plan, and OIG's Top Management and Performance Challenges

The significant unimplemented recommendations described in the body of this report reflect OIG's past and recently issued final reports. As such, the recommendations do not reflect the totality of work we have underway on many emerging issues.

Brief descriptions of our FY 2016 work in progress and planned new starts are presented in the OIG Work Plan (<http://oig.hhs.gov/reports-and-publications/workplan/index.asp>) for FY 2016, which is available on our website. Once reviews are complete and final reports are issued, we publish them on our website (<http://www.oig.hhs.gov/>) under What's New. Summaries of our reports and legal and investigative activities are in our Semiannual Reports to Congress (<http://oig.hhs.gov/reports-and-publications/semiannual/index.asp>). Many of our unimplemented recommendations coincide with either the previous or current Top Management & Performance Challenges (TMC). A list of the most significant management and performance challenges facing HHS is annually prepared by OIG. These TMCs, and the Department's progress toward addressing them, reflect continuing vulnerabilities that OIG has identified for HHS over recent years. TMCs also forecast new and emerging issues that HHS will face in FY 2016 and beyond. Each TMC is accompanied by an in-depth look at the issues at hand, why they are a challenge for HHS, and how the challenges are being or should be addressed and resolved. For each top unimplemented recommendation, we provide a link to the TMC that the issue best falls under.

To view the top challenges facing HHS programs, visit: <http://oig.hhs.gov/reports-and-publications/top-challenges/2015/>.

The 2015 HHS Top Management & Performance Challenges

- Protecting an Expanding Medicaid Program from Fraud, Waste, and Abuse (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge01.asp>)
- Fighting Fraud, Waste, and Abuse in Medicare Parts A and B (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge02.asp>)
- The Meaningful and Secure Exchange and Use of Electronic Information and Health Information Technology B (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge03.asp>)
- Administration of Grants, Contracts, and Financial and Administrative Management Systems B (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge04.asp>)
- Ensuring Appropriate Use of Prescription Drugs B (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge05.asp>)
- Ensuring Quality in Nursing Home, Hospice, and Home- and Community-Based Care B (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge06.asp>)
- Implementing, Operating, and Overseeing the Health Insurance Marketplaces B (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge07.asp>)
- Reforming Delivery and Payment in Health Care Programs B (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge08.asp>)
- Effectively Operating Public Health and Human Services Programs B (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge09.asp>)
- Ensuring the Safety of Food, Drugs, and Medical Devices B (<http://oig.hhs.gov/reports-and-publications/top-challenges/2015/challenge10.asp>)

To view OIG's TMC website, visit this page: <http://oig.hhs.gov/reports-and-publications/top-challenges/2015/>

Quick Links to the Top 25 Recommendations

Medicare Parts A and B

- CMS should seek legislation that would exempt the reduced expenditures as a result of lower outpatient prospective payment system payment rates from budget neutrality adjustments for ambulatory surgical center approved procedures.
- CMS should change regulations or pursue a legislative change, if necessary, to establish a hospital transfer payment policy for early discharges to hospice care.
- CMS should ensure that all claims with exception codes are processed consistently and pursuant to Federal requirements.
- CMS should enhance efforts to identify adverse events to ensure quality of care and safety.
- CMS should reform payments to reduce the incentive for hospices to target beneficiaries with certain diagnoses and those likely to have long stays.
- CMS should seek legislative authority to modify how coinsurance is calculated for outpatient services received at Critical Access Hospitals.
- CMS should consider pursuing rulemaking to expand the price substitution policy.
- CMS should reevaluate and reform the way Medicare pays skilled nursing facilities for therapy services.

Medicare Parts C and D

- CMS should implement policies and procedures to notify Medicare Advantage (MA) organizations of unlawful-presence information and thereby prevent enrollment in MA organizations, prevent enrollment of unlawfully present beneficiaries in Part D, disenroll beneficiaries already enrolled, automatically reject prescription drug event records, and recoup any improper payments.
- CMS should restrict certain beneficiaries to a limited number of pharmacies or prescribers. CMS should require plan sponsors to report all potential fraud and abuse to CMS and/or the Medicare Drug Integrity Contractor.
- CMS should require plan sponsors to report all potential fraud and abuse to CMS and/or the Medicare Drug Integrity Contractor.

Human Services Programs

- ACF should amend current policy and regulations to require that any prospective or current employee be disqualified for or terminated from employment with a Head Start grantee if the individual has been convicted of sexual abuse of a child, other forms of child abuse and neglect, or a violent felony.
- 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.

Food and Drug Safety

- FDA should seek statutory authority to review substantiation for structure/function claims to determine whether claims are truthful and not misleading.

Medicaid

- CMS should work with State Medicaid programs to perform utilization reviews of second-generation antipsychotic drugs prescribed to children.
- CMS should seek legislative authority to limit State Medicaid durable medical equipment prosthetics, orthotics, and supplies reimbursement rates to Medicare program rates and encourage further reduction of Medicaid reimbursement rates through competitive bidding or manufacturer rebates.
- CMS should provide States with definitive guidance for calculating the Medicaid upper payment limit (UPL), which should include using facility-specific UPLs that are based on actual cost report data.

- CMS should require each State Medicaid agency to report all terminated providers.
- CMS should promulgate regulations to reduce significant variation in States' personal care services laws and regulations by creating or expanding Federal requirements and issuing operational guidance for claims documentation, beneficiary assessments, plans of care, and supervision of attendants.
- CMS should ensure that Medicaid data are complete, accurate, and timely. This can be achieved through CMS's monitoring of State-submitted managed care encounter data and by implementing the national Transformed Medicaid Statistical Information System.

Affordable Care Act: Marketplaces

- CMS should implement 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.
- CMS should take action to improve the Federal marketplace's internal controls related to verifying applicants' eligibility and resolving and expiring inconsistencies to address the specific deficiencies we identified.
- HHS should improve acquisition planning and oversight, including completing acquisition strategies, as required by regulation.

Improper Payments Information

- HHS should: (1) report an improper payment estimate for Temporary Assistance for Needy Families, and (2) reduce the Medicare Fee-for-Service program's error rates below 10 percent.

Health Information Technology

- ONC and CMS should collaborate to develop a comprehensive plan to address fraud vulnerabilities in electronic health records.

Selected Acronyms and Abbreviations

- **ACA** Patient Protection and Affordable Care Act
- **ACF** Administration for Children and Families
- **ALF** assisted living facility
- **ASFR** Assistant Secretary for Financial Resources
- **ASC** ambulatory surgical center
- **CAH** critical access hospital
- **CMS** Centers for Medicare & Medicaid Services
- **CY** calendar year
- **DMEPOS** durable medical equipment, prosthetics, orthotics, and supplies
- **EHR** electronic health records
- **FDA** Food and Drug Administration
- **FFS** fee for service
- **FY** fiscal year
- **HHA** home health agency
- **HHS** Department of Health and Human Services
- **MUE** medically unlikely edits
- **MSIS** Medicaid Statistical Information System
- **NIH** National Institutes of Health
- **OIG** Office of Inspector General
- **OMB** Office of Management and Budget
- **OPPS** outpatient prospective payment system
- **PCS** personal care services
- **P&T** pharmacy and therapeutics (committee)
- **QHP** qualified health plan
- **SGA** second-generation antipsychotic drugs
- **SNF** skilled nursing facility
- **SSA** Social Security Administration
- **TANF** Temporary Assistance for Needy Families
- **T-MSIS** Transformed MSIS
- **UPL** upper payment limit
- **ZPIC** zone program integrity contractor

Centers for Medicare and Medicaid Services

The programs of the Centers for Medicare & Medicaid Services (CMS), which include Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), account for over 80 percent of HHS's budget. The programs provide medical coverage for adults and children in certain statutorily defined categories. CMS is also responsible within HHS for the health insurance marketplaces and related programs under the Affordable Care Act.

Total Federal program spending for Medicare, Medicaid, and CHIP was close to \$985 billion for FY 2015.³ The amount spent on Medicare for this time period was approximately \$615 billion, which includes health information technology payments.⁴

Medicare Parts A and B

Medicare Part A covers certain inpatient services in hospitals and skilled nursing facilities (SNFs) and some home health services. Medicare Part B covers designated practitioners' services; outpatient care; and certain other medical services, equipment, supplies, and drugs that Part A does not cover. CMS uses Medicare Administrative Contractors (MACs) to administer Medicare Part A and Medicare Part B and to process claims for both parts. In calendar year (CY) 2014, Medicare Parts A and B served approximately 34 million people and provided approximately \$350 billion in program payments.⁵

With regard to Medicare A and B, OIG has focused its efforts on identifying and offering recommendations to reduce improper payments, prevent and deter fraud, ensure quality of care, and foster economical payment policies.

³ Source: CMS.gov Fast Facts

⁴ Ibid

⁵ Ibid

Medicare and Beneficiaries Could Save Billions If CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates

Recommendation

CMS should seek legislation that would exempt the reduced expenditures as a result of lower outpatient prospective payment system (OPPS) payment rates from budget neutrality adjustments for ambulatory surgical center (ASC) approved procedures.

Companion Recommendations

- CMS should reduce OPPS payment rates for ASC-approved procedures on beneficiaries with no-risk or low-risk clinical needs in outpatient departments.
- CMS should develop and implement a payment strategy in which outpatient departments would continue to receive the standard OPPS payment rate for ASC-approved procedures that must be provided in an outpatient department because of a beneficiary's individual clinical needs.

Our objectives were to determine how much Medicare has saved as a result of procedures being performed in ASCs instead of outpatient departments and how much Medicare could save if payment rates for the outpatient departments were reduced to the same level as ASC payment rates. We found that, on the basis of current payment differentials and 2011 utilization data, Medicare saved almost \$7 billion during CYs 2007 through 2011 and could potentially save \$12 billion from CYs 2012 through 2017 because ASC rates are frequently lower than outpatient department rates for surgical procedures. In addition, Medicare could generate savings up to \$15 billion for CYs 2012 through 2017 if CMS reduces outpatient department payment rates for ASC-approved procedures to ASC payment levels for procedures performed on beneficiaries with low-risk and no-risk clinical needs. ASCs provide surgical services in less intensive and less costly settings to patients who do not require an overnight stay. Medicare ASC payment rates are frequently lower than outpatient department payment rates. Medicare generally saves when outpatient surgical procedures that do not pose significant risk to patients are performed in an ASC instead of an outpatient department. Currently, OPPS rates for ASC-approved procedures are determined in a budget-neutral manner—in which the rates for some procedures would result in higher rates for others—negating the potential savings in reducing OPPS rates.

We found that, in addition to the Medicare savings, beneficiaries could have saved approximately \$2 billion during CYs 2007 through 2011 through reduced cost sharing. Beneficiaries could also potentially save an additional \$3 billion over the next 6 years because the ASC rates are frequently lower than outpatient department rates. In addition, beneficiaries could potentially save as much as \$2 billion to \$4 billion more during the 6 years through CY 2017 if CMS reduces outpatient department payment rates for ASC-approved procedures to ASC payment levels. Furthermore, if legislation passes allowing the OPPS rates for ASC-approved procedures to be determined in a non-budget-neutral manner, Medicare could generate up to \$15 billion in potential savings for CYs 2012 through 2017.

Implementation Status

In response to our report, CMS stated that adopting the recommendations would require legislation and that such a proposal is not currently included in the President's Budget. CMS also noted that

the recommended changes “...may raise circularity concerns with respect to the rate calculation process” because most ASC payment rates are based on the OPPS payment rates that we are recommending that CMS reduce and that we did not provide specific clinical criteria to distinguish patients’ risk levels. We continue to recommend changes to Hospital Outpatient Prospective Payment Systems and will monitor CMS’s progress in implementing our recommendations.

Report: A-05-12-00020 – April 2014

Expected Impact: Estimated Savings - \$15 billion, Improved payment efficiency

TMC: This recommendation relates to HHS’s Top Management Challenge: Fighting Fraud, Waste, and Abuse in Medicare Parts A and B

Medicare Could Save Millions by Implementing a Hospital Transfer Payment Policy for Early Discharges to Hospice Care

Recommendation

CMS should change regulations or pursue a legislative change, if necessary, to establish a hospital transfer payment policy for early discharges to hospice care.

Our objective was to determine how a hospital transfer payment policy for early discharges to hospice care would financially affect Medicare Part A and hospitals. We found that, for CYs 2009 and 2010, Medicare would have saved approximately \$602.5 million by implementing a hospital transfer payment policy for early discharges to hospice care. Medicare has two “transfer payment policies” that (a) adjust payments for discharges from hospitals to other hospitals, and (b) adjust payments for early discharges from hospitals to postacute-care facilities for continued treatment. Instead of paying the full amount for an early discharge, Medicare pays hospitals a per diem rate. However, Medicare does not have a transfer payment policy to adjust the payment when a beneficiary is discharged early from a hospital to hospice care.

From our sample results, we determined that approximately 30 percent of all hospital discharges to hospice care were early discharges, which would have received per diem payments rather than full payments under a hospital transfer payment policy. Implementing a hospital transfer payment policy for early discharges to hospice care would be similar to Medicare’s transfer payment policy for early discharges to other postacute-care facilities. We found that this reform would not cause hospitals a significant financial disadvantage or disproportionately affect any hospital.

Implementation Status

CMS indicated that it would like to study our recommendation further. It questioned the savings estimates, stating that adopting a policy for transfers to the hospice setting may produce lower than estimated savings by discouraging hospitals from making transfers to more appropriate and cost-effective care settings “until a patient’s length of stay would not result in a reduction of payment to hospitals.” We continue to recommend changes to the hospital transfer payment policy and will monitor CMS’s progress in implementing our recommendations.

Report: A-01-12-00507 – May 2013

Expected Impact: Estimated Savings - \$602.5 million, Improved payment efficiency

TMC: This recommendation relates to HHS’s Top Management Challenge: Fighting Fraud, Waste, and Abuse in Medicare Parts A and B

Medicare Improperly Paid Providers Millions of Dollars for Incarcerated Beneficiaries Who Received Services During 2009 through 2011

Recommendation

CMS should ensure that all claims with exception codes are processed consistently and pursuant to Federal requirements.

Our objective was to determine whether CMS had adequate controls to prevent and detect improper payments for Medicare services rendered to incarcerated beneficiaries. We found that Medicare payments totaling \$33,587,634 were made to providers for services rendered to 11,619 incarcerated beneficiaries from CYs 2009 through 2011. Medicare generally does not pay for services rendered to individuals who are incarcerated in correctional facilities (incarcerated beneficiaries). Federal requirements, however, allow Medicare payment if State or local law requires incarcerated beneficiaries to repay the cost of medical services. Health care providers indicate this exception by placing a specific code, or exception code, on the claims submitted for payment. The Social Security Administration (SSA) is CMS's primary source of information about incarcerated beneficiaries. CMS's Enrollment Database interfaces with SSA's systems to identify incarcerated individuals. Several applications, including CMS's Common Working File, can be used by the Medicare contractors to access the dates of incarceration for processing and post-payment reviews.

CMS did not have policies and procedures to review incarceration information on a post-payment basis that would have detected improper payments that the prepayment edit could not prevent. Consequently, CMS did not notify the contractors to recoup any of the \$33,587,634 in improper payments.

Implementation Status

CMS concurred with our recommendation to work with other entities to identify ways to improve timelines, although it did not concur with our recommendation to work with Medicare contractors to ensure that all claims with exception codes are processed properly. CMS noted that it was not able to fully understand the issue in order to evaluate this recommendation and requested greater specificity regarding inconsistencies on contractor policies on processing claims with exception codes, which we provided. We continue to monitor CMS's progress in implementing our recommendations.

Report: A-07-12-01113 – January 2013

Expected Impact: Estimated Savings - \$33.6 million, Improved payment efficiency

TMC: This recommendation relates to HHS's Top Management Challenge: Fighting Fraud, Waste, and Abuse in Medicare Parts A and B

Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries

Recommendation

CMS should enhance efforts to identify adverse events to ensure quality of care and safety.

Our objective was to estimate the national incidence of adverse events for Medicare beneficiaries in skilled nursing facilities (SNFs), assess the preventability of such events, and estimate associated costs to Medicare. We found that more than one in five Medicare beneficiaries experienced adverse events during their SNF stays, and that many of these adverse events were preventable. This finding confirms the need and opportunity for hospitals to significantly reduce the incidence of events, and the Agency for Healthcare Research and Quality (AHRQ) and CMS share the responsibility for addressing this issue. The term “adverse event” describes harm to a patient as a result of medical care. An adverse event can either be preventable or non-preventable and includes never events (an event that should never occur in a health care setting); conditions acquired in the health care setting; events that required life-sustaining intervention; and events that caused prolonged hospital stays, permanent harm, or death.

Using a random sample of Medicare beneficiaries discharged from hospitals to SNFs for post-acute care, we found that 22 percent of Medicare beneficiaries experienced adverse events during their SNF stays. An additional 11 percent of Medicare beneficiaries experienced temporary harm during their SNF stays. Physician reviewers determined that 59 percent of these adverse events and temporary harm events were clearly or likely preventable. They attributed much of the preventable harm to substandard treatment, inadequate resident monitoring, and failure or delay of necessary care. Over half of the beneficiaries who experienced harm returned to a hospital for treatment, with an estimated cost to Medicare of \$208 million in August 2011. This equates to \$2.8 billion spent on hospital treatment for harm caused in SNFs in FY 2011.

Implementation Status

CMS concurred with the recommendation and continues to create and promote a list of potential nursing home events. In July 2015, CMS released draft guidance and training materials to nursing homes regarding medication-related events, and disseminated this guidance through a revision of its Quality Assurance & Performance Improvement website. CMS is in the process of developing a list for the remaining categories of adverse events identified by OIG, patient care events, and infection events. All lists and related guidance are planned for final release in 2017. Guidance will include trigger tools for nursing homes to identify events in periodic medical record reviews, as utilized by OIG for this report. OIG believes that CMS’s planned actions, when completed, would implement this recommendation. OIG will consider this recommendation implemented when CMS develops and disseminates lists, guidance, and trigger tools for all three event types to nursing homes and stakeholders.

AHRQ also concurred with the report recommendations. AHRQ worked with CMS to create and promote lists of potential nursing home events and encouraged nursing homes and other providers to participate in patient safety organizations. AHRQ also issued guidance to patient safety organizations on the appropriate definitions of patient safety work products and protections and convened annual patient safety meetings from 2011-2015. OIG considers AHRQ’s portion of the recommendation implemented.

Report: OEI-06-11-00370 – February 2014

Expected Impact: Improved quality, Improved safety

TMC: This recommendation relates to HHS’s Top Management Challenge: Ensuring Quality in Nursing Home, Hospice, and Home and Community Based Care

Medicare Hospices Have Financial Incentives to Provide Care in Assisted Living Facilities

Recommendation

CMS should reform payments to reduce the incentive for hospices to target beneficiaries with certain diagnoses and those likely to have long stays.

Our objective was to determine the trends in Medicare payments for hospice care provided in assisted living facilities (ALFs). We found that Medicare payments for hospice care in ALFs more than doubled in 5 years, totaling \$2.1 billion in 2012. Hospices provided care much longer and received much higher Medicare payments for beneficiaries in ALFs than for beneficiaries in other settings. Medicare hospice care is intended to help terminally ill beneficiaries continue life with minimal disruption and to support families and caregivers. Care may be provided in various settings, including a private home or other places of residence, such as an ALF. Pursuant to the Patient Protection and Affordable Care Act (ACA), CMS must reform the hospice payment system, collect data relevant to revising payments, and develop quality measures.

This report raised concerns about the financial incentives created by the current payment system and the potential for hospices to target beneficiaries in ALFs because they may offer hospices the greatest financial gain. Hospice beneficiaries in ALFs often had diagnoses that usually requires less complex care. Hospices typically provided fewer than 5 hours of visits and were paid about \$1,100 per week for each beneficiary receiving routine home care in ALFs. Also, for-profit hospices received much higher Medicare payments per beneficiary than nonprofit hospices. The findings in this and previous OIG reports show that payment reform and more accountability are needed to reduce incentives for hospices to focus solely on certain types of diagnoses or settings.

Implementation Status

CMS concurred with the recommendation. CMS stated that it is analyzing possible reform options that focus on new payment models and has issued a final rule that will differentiate payments for routine home care based on the beneficiary's length of stay. However, OIG questioned whether changing the payment structure, as outlined in the final rule, was the best way to align payment to costs and address financial incentives for hospices to target beneficiaries likely to have long lengths of stay.

Report: OEI-02-14-00070 – January 2015

Expected Impact: Improved program integrity, Improved payment efficiency

TMC: This recommendation relates to HHS's Top Management Challenge: Ensuring Quality in Nursing Home, Hospice, and Home and Community Based Care

Medicare Beneficiaries Paid Nearly Half of the Costs for Outpatient Services at Critical Access Hospitals

Recommendation

CMS should seek legislative authority to modify how coinsurance is calculated for outpatient services received at Critical Access Hospitals (CAHs)

Our objective was to examine the differences between the amounts beneficiaries paid in coinsurance for outpatient services at CAHs and the amounts they would have paid in coinsurance for outpatient services at acute-care hospitals. We found that, because coinsurance amounts were based on charges and not costs or predetermined rates, Medicare beneficiaries paid nearly half the costs for outpatient services at CAHs, as compared to 22 percent at acute care hospitals paid under the Outpatient Prospective Payment System (OPPS). The system that Medicare uses to calculate outpatient coinsurance amounts for beneficiaries who receive services at CAHs differs from that used for beneficiaries who receive services at acute-care hospitals. Medicare reimburses CAHs at 101 percent of their “reasonable costs,” rather than at the predetermined rates set by OPPS. Beneficiaries who receive services at CAHs pay coinsurance amounts based on CAH charges, whereas beneficiaries who receive services at acute care hospitals pay coinsurance amounts based on OPPS rates. CAH charges are typically higher than the reasonable costs associated with CAH services or the OPPS rates that acute-care hospitals receive.

In 2012, beneficiaries paid approximately \$1.5 billion of the estimated \$3.2 billion cost for CAH outpatient services. Additionally, the average percentage of costs that beneficiaries paid in coinsurance for these services increased 2 percentage points between 2009 and 2012. Finally, for 10 outpatient services that were frequently provided at CAHs, beneficiaries paid between 2 and 6 times the amount in coinsurance than they would have for the same services at acute-care hospitals.

Implementation Status

CMS neither concurred or nonconcurred with the recommendation. OIG continues to recommend that CMS seek legislative authority to modify how coinsurance is calculated for outpatient services received at CAHs. Without this legislative change, beneficiaries who receive outpatient services at CAHs will continue to typically pay more—in terms of both the percentage of final costs and the total amounts—than beneficiaries who receive outpatient services at hospitals paid under the OPPS. CMS should include in its proposal for legislative change a modification that would alter the method for calculating coinsurance from a figure based on charges to a figure that more closely represents costs.

Report: OEI-05-12-00085 – October 2014

Expected Impact: Improved payment efficiency, savings for beneficiaries

TMC: This recommendation relates to HHS’s Top Management Challenge: Fighting Fraud, Waste, and Abuse in Medicare Parts A and B

Comparing Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2013

Recommendation

CMS should consider pursuing rulemaking to expand the price substitution policy.

When Congress established average sales prices as the primary basis for Medicare Part B drug reimbursement, it also mandated that OIG compare average sales prices with average manufacturer prices and directed CMS to substitute payment amounts for drugs with average sales prices that exceed average manufacturer prices by a threshold of 5 percent. To comply with its statutory mandate, OIG has completed over 30 quarterly pricing comparisons. In April 2013, CMS began substituting payment amounts in accordance with its published price substitution policy, which, among other criteria, applies

to drug codes that (1) exceed the 5-percent threshold in two consecutive quarters or three of the previous four quarters, and (2) have complete average manufacturer prices data in those quarters.

Under CMS's price substitution policy, 15 drug codes were subject to reimbursement reductions on the basis of data from 2013, saving Medicare and its beneficiaries an estimated \$13 million from the fourth quarter of 2013 through the third quarter of 2014. We estimate that if CMS had expanded its price substitution criteria to include drug codes with complete average manufacturer prices data in a single quarter or certain codes with partial average manufacturer prices data, the agency could have generated almost \$6 million in additional savings.

Implementation Status

CMS did not concur with the recommendation. CMS does not concur with expanding its current price substitution policy and believes that more experience with this policy is needed before it can be expanded. CMS stated that by continuing to take a cautious approach regarding the price substitution policy, it minimizes the risk of affecting physician and beneficiary access to drugs. We believe that CMS can achieve a better balance between safeguarding access to drugs and ensuring that Medicare and its beneficiaries do not overpay for drugs.

Report: OEI-03-14-00520 – February 2015

Expected Impact: Improved payment efficiency, estimated savings

TMC: This recommendation relates to HHS's Top Management Challenge: Reforming Delivery and Payment in Health Care Programs

The Medicare Payment System for Skilled Nursing Facilities Needs to be Reevaluated

Recommendation

CMS should reevaluate and reform the way Medicare pays skilled nursing facilities (SNFs) for therapy services

Companion Recommendations

- Evaluate the extent to which Medicare payment rates for therapy should be reduced.
- Change the method of paying for therapy.

Our objective was to compare Medicare payments to SNF costs for therapy. The findings of this and prior OIG reports demonstrate the need for CMS to reevaluate the Medicare SNF payment system. Payment reform could save Medicare billions of dollars and encourage SNFs to provide services that are better aligned with beneficiaries' care needs. OIG, the Medicare Payment Advisory Commission, and other entities have raised longstanding concerns regarding Medicare's SNF payment system. These concerns focus on SNF billing, the method of paying for therapy, and the extent to which Medicare payments exceed SNFs' costs. Medicare pays SNFs a daily rate for nursing, therapy, and other services. The daily rate for therapy is primarily based on the amount of therapy provided, regardless of the specific beneficiary characteristics or care needs.

We found that Medicare payments for therapy greatly exceeded SNFs' costs for therapy. Combined with the current method of paying for therapy, this large difference between therapy payments and costs creates a strong financial incentive for SNFs to bill for higher levels of therapy than necessary.

Under this system, SNFs increasingly billed for the highest level of therapy even though key beneficiary characteristics remained largely the same. Increases in SNF billing, particularly for the highest level of therapy, resulted in \$1.1 billion in Medicare payments in FYs 2012 and 2013.

Implementation Status

CMS concurred with our recommendation to evaluate the extent to which Medicare payment rates for therapy should be reduced. CMS stated that additional statutory authority would be required for CMS to address this recommendation. CMS also concurred with our recommendation to change the method of paying for therapy. CMS stated that it is conducting a project to study and evaluate SNF therapy payment options. It will use the results of this project to inform changes to the method of paying for therapy.

Report: OEI-02-13-00610 – September 2014

Expected Impact: Improved payment efficiency, improved quality of care

TMC: This recommendation relates to HHS's Top Management Challenge: Ensuring Quality in Nursing Home, Hospice, and Home and Community Based Care

Medicare Parts C and D

Medicare beneficiaries must be enrolled in both Part A and Part B to join one of the Part C Medicare Advantage (MA) plans, which are administered by MA organizations. MA plans are public or private organizations licensed by States as risk-bearing entities under contract with CMS to provide covered services. MA organizations may offer one or more plans. MA plans provide all Part A and Part B services and generally provide additional services not covered by traditional Medicare. Beneficiaries usually pay monthly premiums and copayments that are often less than the coinsurance and deductibles under the original Medicare Part A and Part B.

Medicare Part D, also called the Medicare prescription drug benefit, is a Federal program to subsidize the costs of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries. Medicare expended over \$77 billion in Part D benefit payments in CY 2014, serving over 37 million beneficiaries.⁶ Part D administration depends on extensive coordination and information sharing between Federal and State Government agencies, drug plan sponsors, contractors, health care providers, and third-party payers. CMS and drug plan sponsors share responsibility for protecting the Part D program from fraud, waste, and abuse. Payments to drug plan sponsors, made on the basis of bids, risk adjustments, and reconciliations, add to the complexities and challenges of the benefit. HHS faces numerous challenges in managing its Part D program, including oversight, drug abuse and diversion, and questionable and inappropriate utilization.

⁶ CMS.gov Fast Facts

Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2010 through 2012 and Medicare Improperly Paid Millions of Dollars for Prescription Drugs Provided to Unlawfully Present Beneficiaries during 2009 through 2011

Recommendation

CMS should implement policies and procedures to notify Medicare Advantage (MA) organizations of unlawful-presence information and thereby prevent enrollment in MA organizations, prevent enrollment of unlawfully present beneficiaries in Part D, disenroll beneficiaries already enrolled, automatically reject prescription drug event records, and recoup any improper payments.

Companion Recommendations

- CMS should identify and recoup improper payments made to MA organizations for unlawfully present beneficiaries after our audit period and until policies and procedures have been implemented.
- CMS should recoup \$26 million in improper payments in accordance with legal requirements.
- CMS should prevent enrollment of unlawfully present beneficiaries, disenroll any currently enrolled unlawful beneficiaries, and automatically reject prescription drug event records submitted by sponsors for prescription drugs provided to this population.
- CMS should reopen and revise final payment determinations for CYs 2009 through 2011 to remove prescription drug costs for unlawfully present beneficiaries.

Our objectives were to determine whether CMS made payments to MA organizations for unlawfully present beneficiaries, and whether CMS accepted prescription drug event records submitted by sponsors on behalf of unlawfully present beneficiaries. We found that CMS made improper payments to MA organizations totaling more than \$26 million for unlawfully present beneficiaries for CYs 2010 through 2012, and CMS accepted prescription drug event records totaling almost \$29 million in unallowable gross drug costs on behalf of unlawfully present beneficiaries during CYs 2009 and 2011. Federal law generally prohibits the payment of Federal public benefits, including Federal health care benefits such as MA and Part D, on behalf of unlawfully present aliens.

CMS did not have policies and procedures to notify the MA organizations of the unlawful-presence information in its data systems. Also, CMS did not have a policy for Part D that included internal controls to identify and disenroll unlawfully present beneficiaries and automatically reject prescription drug event records associated with them.

Implementation Status

CMS stated that it was unable to concur with the specific payment amount identified in the Part C review. In the Part D review, CMS stated there was no effective way to fully recover the improper payments in question without first implementing the appropriate policies and procedures, including the relevant system changes. We acknowledge that CMS is developing and implementing policies and procedures that would address enrollment of unlawful beneficiaries. We continue to monitor CMS's progress in implementing our recommendations.

Reports: A-07-12-06038 — October 2013 / A-07-13-01125 – April 2014

Expected Impact: Improved payment efficiency, improved program management

TMC: This recommendation relates to HHS's Top Management Challenge: Reforming Delivery and Payment in Health Care Programs

Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs

Recommendation

CMS should restrict certain beneficiaries to a limited number of pharmacies or prescribers.

Action for Implementation: CMS has sought legislative authority to address the unimplemented recommendation

Companion Recommendations

- Expand sponsors' drug utilization review programs.
- Expand sponsors' use of beneficiary-specific controls.
- Expand the Overutilization Monitoring System to include additional drugs susceptible to fraud, waste, and abuse.
- Limit the ability of certain beneficiaries to switch plans.
- Increase monitoring of beneficiaries' utilization patterns.

Our objective was to determine the extent to which beneficiaries had questionable utilization patterns for human immunodeficiency virus (HIV) drugs. OIG found that almost 1,600 Part D beneficiaries who received HIV drugs had questionable utilization patterns in 2012. Medicare Part D prescription drug coverage is vulnerable to fraud, waste, and abuse, and limited safeguards exist. OIG work has focused on questionable practices by pharmacies and prescribers and beneficiary utilization patterns. Although CMS has placed limited restrictions on specific beneficiaries, most of these restrictions have focused on opioids. Other Part D drugs, such as those that treat HIV, are vulnerable because of their expense and psychoactive effects.

All of the 1,600 Part D beneficiaries with questionable utilization patterns for HIV warrant further scrutiny. These patterns may indicate that beneficiaries may be receiving inappropriate or unnecessary drugs. Other possibilities include that the pharmacy submitted claims for drugs never dispensed or that the beneficiary's identification was stolen. Almost 900 of the 1,600 beneficiaries had no indication of HIV in their Medicare histories. Others received an excessive dose or excessive supply of HIV drugs, obtained HIV drugs from a high number of pharmacies, had a high number of prescribers, or received contraindicated HIV drugs (i.e., HIV drugs that should not be used in combination with one another).

Implementation Status

Restricting certain beneficiaries to a limited number of pharmacies or prescribers could reduce inappropriate utilization. This practice, known as "lock-in," is currently used by most State Medicaid programs. CMS concurred with this recommendation and has sought legislative authority. The President's FY 2017 Budget includes a proposal to allow the Secretary of HHS to establish a program in Part D that would require high-risk Medicare beneficiaries to utilize only certain prescribers and/or pharmacies to obtain controlled substance prescriptions. We continue to monitor progress, and the recommendation will remain unimplemented until legislation is enacted.

Report: OEI-02-11-00170 – August 2014

Expected Impact: Improved payment efficiency, improved program integrity

TMC: This recommendation relates to HHS's Top Management Challenge: Ensuring Appropriate Use of Prescription Drugs

Summary of Recommendations from Five Reports Related to Ensuring the Integrity of Medicare Part D

Recommendation

CMS should require plan sponsors to report all potential fraud and abuse to CMS and/or the Medicare Drug Integrity Contractor (MEDIC)

Companion Recommendations

- Evaluate the extent to which Medicare payment rates for therapy should be reduced.
- Change the method of paying for therapy.

We synthesized numerous OIG reports in *Ensuring the Integrity of Medicare Part D* (OEI-03-15-00180)—a portfolio that presented an overview of OIG investigations, audits, evaluations, and legal guidance related to Part D. As part of this portfolio, we reviewed five unimplemented recommendations from reports that identified weaknesses in CMS's ability to review the effectiveness of Part D plan sponsors' processes for fraud detection. The objective of the most recent of these five reports was to determine the extent to which Part D plan sponsors voluntarily reported data on potential fraud and abuse to CMS for 2010 through 2012, and the extent to which CMS used these data to monitor or oversee sponsors' activities to control fraud and abuse. We found that more than half of Part D plan sponsors did not report data on potential fraud and abuse between 2010 and 2012. Plan sponsors are private companies that contract with CMS to provide Part D drug coverage to Medicare beneficiaries. Sponsors are required to have a comprehensive program to detect and deter fraud and abuse. Upon identifying potential fraud and abuse, sponsors are required to conduct an inquiry and initiate appropriate corrective action. CMS recommends that sponsors refer potential fraud and abuse incidents to the MEDIC and/or law enforcement agencies.

We found that, of those sponsors that voluntarily reported data, more than one-third did not identify any incidents for at least one of their reporting years. In total, sponsors reported identifying 64,135 incidents of potential fraud and abuse between 2010 and 2012. Sponsors' identification of such incidents varied significantly, from 0 to almost 14,000 incidents a year. CMS requires sponsors to conduct inquiries and implement corrective actions in response to incidents of potential fraud and abuse. However, 28 percent of Part D plan sponsors reported performing none of these actions between 2010 and 2012. Although CMS reported that it conducted basic summary analyses of the data on potential fraud and abuse, it did not perform quality assurance checks on the data or use them to monitor or oversee the Part D program.

Implementation Status

CMS did not concur with the recommendation and stated that it does not intend to pursue regulatory changes to require plan sponsors to refer all potential fraud and abuse incidents that may warrant further investigation. CMS based its decisions on various factors: (1) plan sponsors currently have several options for referring incidents, (2) CMS has conducted outreach and education activities for plan

sponsors to improve organizational performance, and (3) plan sponsors share information on current fraud schemes and best practices for prevention and detection through regular meetings. In subsequent discussions with OIG, CMS indicated that it could consider an appropriate threshold for required reporting of potential fraud and abuse incidents or possible incentives for voluntarily reporting. Because these data are voluntarily reported, there is not a comprehensive set of data that enables CMS to monitor sponsors' fraud, waste, and abuse programs. OIG believes that requiring sponsors to report these data will provide CMS with a more complete and accurate accounting of the identification of potential fraud and abuse incidents, as well as plan sponsors' efforts to reduce fraud and abuse in Medicare. We continue to recommend that CMS amend regulations to require the reporting of these data.

Report: Reports: OEI-03-13-00030, OEI-03-10-00310, OEI-03-07-00380, OEI-03-08-00420, and OEI-02-09-00600

Expected Impact: Improved program integrity

TMC: This recommendation relates to HHS's Top Management Challenge: Ensuring Appropriate Use of Prescription Drugs

Human Services Programs

HHS funds and operates public health and human services programs to promote health and economic and social well-being. Effective management is essential to ensure that these programs achieve their goals and best serve the programs' intended beneficiaries.

The Administration for Children and Families (ACF) operates over 30 programs that promote the economic and social well-being of children, families, and communities. These programs include the Temporary Assistance for Needy Families program; the national child support enforcement system; the Head Start program for preschool children; and assistance for childcare, foster care, and adoption services. ACF provides support to address a number of social areas, including homelessness, human trafficking, and community economic development.

Review of 24 Head Start Grantees' Compliance With Health and Safety Requirements

Recommendation

ACF should amend current policy and regulations to require that any prospective or current employee be disqualified for or terminated from employment with a Head Start grantee if the individual has been convicted of sexual abuse of a child, other forms of child abuse and neglect, or a violent felony.

Our objective was to summarize the results of 24 Head Start health and safety audits that determined whether grantees complied with applicable Federal, State, and local regulations and standards. Of the 24 Head Start grantees we reviewed, none fully complied with Federal Head Start or State requirements to protect children from unsafe materials and equipment, such as toxic chemicals, broken fences and gates, and unsafe playground equipment. In addition, we found that 21 of 24 grantees did not fully comply with Federal Head Start or State requirements to conduct criminal records checks, conduct recurring background checks, document criminal records checks, conduct checks of childcare exclusion lists, or conduct checks of child abuse and neglect registries. Among these grantees' employees, 588 out of 2,409 (24 percent) had not met all Federal or State pre-employment requirements.

The Head Start program is administered by each State's designated oversight entity, and varying sets of requirements nationwide present obstacles to ACF's oversight and grant management. Strengthening Federal regulations and requirements regarding employee background checks and employment qualifications will improve ACF's nationwide oversight of health and safety requirements in Head Start.

Implementation Status

ACF's Notice of Proposed Rule Making was published in the Federal Register on June 19, 2015. On Subpart I—Human Resources Management, § 1302.90(b)(3) and (4), Recruitment and selection procedures for all staff requires a program to review each employment application to assess the relevancy of any issue uncovered by the complete background check, including any arrest, pending criminal charge, or conviction. A program must use State licensing disqualification factors in any employment decisions and conduct a complete background check as described in paragraph (b) of this section for each staff member at least once every 5 years. We await notification from Office of Head Start on the final issuance of the proposed rule to ascertain that the intent of our recommendation has been addressed.

Report: A-01-11-02503 – December 2011

Expected Impact: Improved grants management, improved safety for children

TMC: This recommendation relates to HHS's Top Management Challenge: Administration of Grants, Contracts, and Financial and Administrative Management Systems

Not All Children in Foster Care Who Were Enrolled in Medicaid Received Required Health Screenings

Recommendation

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.

Our objective was to determine the extent to which children in foster care who were enrolled in Medicaid received required health screenings as established in States' health services oversight and coordination plans. We found that nearly one-third of children in foster care who were enrolled in Medicaid did not receive at least one required health screening. Health screenings are essential, because children in foster care often experience chronic medical, developmental, and mental health issues. States' ability to ensure that foster children receive needed health services is critical to these children's well-being. The Social Security Act requires each State to develop a plan for ongoing oversight and coordination of health services for children in foster care, which includes establishing a schedule for initial and periodic screenings. Screenings may include medical, dental, hearing, vision, mental health, and other (e.g., developmental) assessments. Furthermore, ACF is responsible for monitoring States' foster care programs, including States' oversight and coordination of health services for children.

In addition to our finding that nearly one-third of Medicaid children in foster care did not receive at least one required health screening, we found that just over one-quarter of Medicaid children in foster care received at least one required screening late. Moreover, ACF's reviews do not ensure that children in foster care receive the required screenings according to State schedules.

Implementation Status

ACF did not concur or nonconcur with the recommendation but stated that the initial round of Child and Family Service Reviews determined whether children in foster care received health screenings according to the timeframes specified in States' plans. However, ACF reported challenges with making these determinations, such as obtaining documentation needed to support the determination. As a result, ACF chose to focus on whether children's individual health needs were met in subsequent reviews. ACF stated that it is currently implementing its third round of Child and Family Service Reviews, which are expected to be completed in 2018. ACF stated that it would assess whether reviewing receipt of required screenings according to State timeframes can be included in future reviews. OIG continues to encourage ACF to expand future Child and Family Services Reviews to determine whether children in foster care receive required health screenings according to timeframes specified in States' plans. We continue to monitor ACF's progress in implementing our recommendation.

Report: OEI-07-13-00460 – March 2015

Expected Impact: Improved quality, Improved access, improved program management

TMC: This recommendation relates to HHS's Top Management Challenge: Effectively Operating Public Health and Human Services Pro

Food and Drug Safety

HHS funds and operates public health and human services programs to promote health and economic and social well-being. Effective management is essential to ensure that these programs achieve their goals and best serve the programs' intended beneficiaries.

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA plays a role in the Nation's counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats. In addition, FDA regulates the manufacturing, marketing, and distribution of tobacco products.

Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements

Recommendation

FDA should seek statutory authority to review substantiation for structure/function claims to determine whether claims are truthful and not misleading.

Our objective was to analyze the structure/function claims for a purposive sample of dietary supplements marketed for weight loss or immune system support and to determine the extent to which they complied with FDA regulations. Manufacturers have used these claims to promote the health benefits of their products. We found that overall, substantiation documents for the sampled supplements were inconsistent with FDA guidance on competent and reliable scientific evidence. Manufacturers are not required to submit dietary supplements to FDA for safety testing or approval prior to sale, but must have competent and reliable scientific evidence to show that claims are truthful and not misleading. Manufacturers must notify FDA when they use structure/function claims, but they do not have to submit the substantiation to FDA. Finally, a product label must include a disclaimer stating that FDA has not reviewed the claim and that the product is not intended to diagnose, treat, cure, or prevent any disease.

We also found that FDA could not readily determine whether manufacturers had submitted the required notification for their claims. Seven percent of the supplements lacked the required disclaimer, and 20 percent included prohibited disease claims on their labels. These results raise questions about the extent to which structure/function claims are truthful and not misleading.

Implementation Status

FDA is still considering whether to seek explicit statutory authority to review substantiation for structure/function claims beyond its existing authorities. We continue to monitor FDA's progress in implementing our recommendation.

Report: OEI-01-11-00210 – October 2012

Expected Impact: Improved safety, improved program oversight

TMC: This recommendation relates to HHS's Top Management Challenge: Ensuring the Safety of Food, Drugs, and Medical Devices

Medicaid Program

The programs of the Centers for Medicare & Medicaid Services which include Medicare, Medicaid, and CHIP account for over 80 percent of HHS's budget. The programs provide medical coverage for adults and children in certain statutorily defined categories. CMS is also responsible within HHS for the health insurance marketplaces and related programs under the Affordable Care Act.

The Federal Government and States jointly fund Medicaid, which provides medical assistance to certain low-income individuals. The Federal share of a State's expenditures is called the Federal medical assistance percentage (FMAP). States have considerable flexibility in structuring their Medicaid programs within broad Federal guidelines governing eligibility, provider payment levels, and benefits. As a result, Medicaid programs vary widely from State to State.

Enrollment in Medicaid and Children's Health Insurance programs has grown by 14.1 million people since October 2013 to a total of 71 million individuals enrolled at the end of November 2015.⁷ Total Medicaid spending for FY 2014 was \$500 billion.⁸

Protecting these expanding programs from fraud, waste, and abuse takes on a heightened urgency as the programs continue to grow in spending and in the number of people they serve.

⁷ Medicaid & CHIP: November 2015 Monthly Applications, Eligibility Determinations and Enrollment Report, <https://www.medicaid.gov/medicaid-chip-program-information/program-information/downloads/november-2015-enrollment-report.pdf>

⁸ Medicaid and CHIP Payment and Access Commission, <https://www.macpac.gov/macstats/program-enrollment-and-spending/>

Second-Generation Antipsychotic Drug Use Among Medicaid-Enrolled Children: Quality-of-Care Concerns

Recommendation

CMS should work with State Medicaid programs to perform utilization reviews of second-generation antipsychotic drugs (SGA) prescribed to children.

Our objective was to determine the extent to which claims for SGAs prescribed to children enrolled in Medicaid presented quality-of-care concerns and were prescribed for indications other than medically accepted indications and/or in the presence of conditions specified in the FDA boxed warning. In the five States reviewed, we found that quality-of-care concerns were identified in the medical records associated with 67 percent of claims for SGAs prescribed to children, and two or more quality-of-care concerns were identified in the medical records for 49 percent of claims. We also found that 8 percent of SGAs were prescribed for the limited number of medically accepted pediatric indications. There are only five SGAs with medically accepted pediatric indications. SGAs are a class of drugs used to treat psychiatric disorders, such as schizophrenia, bipolar disorder, and psychotic depression. SGAs are widely used to treat children, including those enrolled in Medicaid, who have mental health conditions. However, SGAs can have serious side effects, and little clinical research has been conducted on the safety of treating children with these drugs. Consequently, children's treatment with SGAs needs careful management and monitoring.

Three of the 11 SGAs carry an FDA boxed warning regarding increased chances of suicidal thinking and behavior in pediatric patients. We found that over one-third of SGAs were prescribed in the presence of conditions described in the FDA boxed warning. Physicians are not prohibited from prescribing a drug for a patient who has the condition(s) specified in the FDA boxed warning if the physician judges that the benefits may outweigh the risks. It is not uncommon for doctors to prescribe, or Medicaid to pay for, SGAs for children for indications that are not medically accepted. Medically accepted indications include both uses of drugs approved by the FDA and uses supported by one or more of three drug compendia. It is difficult to conduct the clinical trials needed to obtain FDA approval or compendia support for pediatric uses of drugs.

Implementation Status

CMS concurred with the recommendation and plans to work with States, through its Medicaid Drug Utilization Review Program, to monitor children's use of antipsychotic medication and provide States feedback on any quality-of-care concerns identified. CMS also plans to collaborate with the American Academy of Child and Adolescent Psychiatry and the Medicaid Medical Directors Network to share utilization review guidelines that can help identify when a more intense review of SGAs prescribed to children is necessary. We continue to monitor CMS's progress in implementing our recommendation.

Report: OEI-07-12-00320 – March 2015

Expected Impact: Improved program integrity, improved safety, improved quality

TMC: This recommendation relates to HHS's Top Management Challenge: Ensuring Appropriate Use of Prescription Drugs

State Medicaid Agencies Can Significantly Reduce Medicaid Costs for Durable Medical Equipment and Supplies

Recommendation

CMS should seek legislative authority to limit State Medicaid durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) reimbursement rates to Medicare program rates and encourage further reduction of Medicaid reimbursement rates through competitive bidding or manufacturer rebates.

Action for Implementation: CMS has sought legislative authority to address the unimplemented recommendation

Our objective was to summarize the results of prior audits that identified opportunities for State Medicaid agencies to achieve cost savings for selected DME. We determined that opportunities existed for the States that were audited to lower provider reimbursement rates, resulting in approximately \$30.1 million in potential cost savings for the States and the Federal Government. During recent Medicaid audits, we determined that selected DME, such as oxygen supplies and equipment, were available to CMS at a cost well below what State Medicaid agencies were paying. We also found that Medicaid provider reimbursement rates for selected DME items varied significantly among the States that we reviewed.

In our previous audits of four State Medicaid agencies, we found that the States could have saved approximately \$18.1 million combined on the purchase of selected DME items if they obtained pricing comparable to pricing under Round 1 of Medicare's Competitive Bidding Program. Since issuing the previous audit reports, we identified \$12 million in additional cost savings for the selected DME items that the four States could have obtained by using pricing comparable to Medicare's Round 2 Competitive Bidding and National Mail-Order Programs.

Implementation Status

CMS concurred with our recommendations and has sought legislative authority. CMS stated that "The FY 2016 President's Budget included a proposal entitled 'Limit Medicaid Reimbursement of Durable Medical Equipment Based on Medicare Rates' that meet the terms of this recommendation." If enacted, the expected savings would be \$4.27 billion over a 10-year period. CMS stated that "States have the flexibility to administer their Medicaid programs in accordance with a CMS-approved State plan. CMS communicates frequently with States through the State plan process to inform them of all available options, including manufacturer rebates and competitive bidding procedures, for their DME purchasing programs." We continue to monitor progress and the recommendation will remain unimplemented until legislation is enacted.

Report: A-05-15-00025 – September 2015

Estimated Savings: \$4.27 billion estimated savings over 10 years, improved program management

TMC: This recommendation relates to HHS's Top Management Challenge: Protecting an Expanding Medicaid Program from Fraud, Waste, and Abuse

Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers

Recommendation

CMS should provide States with definitive guidance for calculating the Medicaid upper payment limit (UPL), which should include using facility-specific UPLs that are based on actual cost report data

Companion recommendation:

- Require that the return of Medicaid payments by a county or local government to the State be declared a refund of those payments and thus be used to offset the Federal share generated by the original payment.

Our objectives were to analyze the States' use of intergovernmental transfers to finance enhanced payments to county- or local-government-owned nursing facilities and hospitals as part of their compliance with Medicaid UPL regulations and to evaluate the financial impact of these transfers on the Medicaid program. We found that in FY 2000 28 States made or planned to make at least \$10.3 billion in Medicaid enhanced payments, which included \$5.8 billion in Federal matching funds. Prior to 1999, only 12 States had enhanced payment programs.

The Federal Government and States share the cost of Medicaid. From time to time, States have developed mechanisms to obtain Federal Medicaid funds without committing the States' shares of required matching funds or, by other means, artificially inflating the Federal share. Such practices limit Congress's ability to assess the public benefits of Medicaid dollars. OIG addressed this issue broadly in an audit in 2001, and since then we have continued to identify similar problems in selected States. For example, Medicaid UPL rules, which establish aggregate caps on payments to different classes of facilities, permit States to provide enhanced payments that qualify for Federal reimbursement to one of those classes. However, some States have required such facilities to transfer the funds to the States to be put to other uses, leaving the facilities underfunded.

Implementation Status

OIG has long recommended that Medicaid payments to public providers be based on the costs of providing services. In 2008, CMS issued a final rule that, among other things, would limit Medicaid payments to public providers to their costs of providing care, but the rule was ultimately vacated by a Federal District Court. We continue to recommend that CMS provide guidance for calculating the Medicaid UPL in order to achieve significant monetary changes.

Report: A-03-00-00216 – September 2001

Expected Impact: Estimated Savings - \$3.87 billion over 5 years, Improved payment efficiency

TMC: This recommendation relates to HHS's Top Management Challenge: Protecting an Expanding Medicaid Program from Fraud, Waste, and Abuse

CMS System for Sharing Information about Terminated Providers Needs Improvement and Providers Terminated from One State Medicaid Program Continued Participating in Other States

Recommendation

CMS should require each State Medicaid agency to report all terminated providers.

Our objective was to determine the extent to which the Medicaid and Children’s Health Insurance Program State Information Sharing System (MCSIS) contained records submitted by CMS and State Medicaid agencies. The report also identified records that did not meet CMS criteria for reporting providers terminated “for cause” from Medicare, Medicaid, or CHIP, and assessed whether records had complete identifying information about providers, including National Provider Identifiers (NPIs), provider types, and provider addresses. We found that, as of June 1, 2013, MCSIS contained records on terminated providers submitted by CMS and 33 State Medicaid agencies and did not contain records from the remaining State Medicaid agencies. The Patient Protection and Affordable Care Act (ACA), section 6401(b)(2), requires CMS to establish a process for sharing information about terminated providers, which must include the name of the terminated provider, the provider’s NPI, and other identifying information. To meet this requirement, CMS established a web-based portal, MCSIS. Sharing terminated provider data among States prevents terminated providers in one State from enrolling in another State. CMS and State agencies can submit information about providers that meet CMS’s criteria for having been terminated “for cause” from Medicare, Medicaid, or CHIP. State Medicaid agencies can use these data to identify these providers and subsequently terminate them from their Medicaid programs, as required under another section of the ACA.

Contrary to CMS guidance, about one-third of the 6,439 records in MCSIS did not relate to providers terminated “for cause.” Over half of MCSIS records did not contain NPIs, a critical data element for accurately identifying providers. Additionally, one-third of MCSIS records did not identify the provider types and one-quarter had no provider addresses. A 2015 companion report also found that the lack of a comprehensive centralized data source that identifies terminated providers creates challenges for State agencies seeking to learn about such providers. This report reiterated the recommendation to require reporting of all terminations “for cause.” The report identified continued participation by terminated providers in other States’ Medicaid programs. Specifically, we found 12 percent (295 of 2,539) of providers terminated “for cause” in 2011 continued to participate in other States’ Medicaid programs as late as January 2014.

Implementation Status

CMS concurred with our recommendation and stated that it is committed to improving Medicaid program integrity efforts. CMS indicated that it has taken steps to improve the process of sharing information regarding terminated providers. However, it did not indicate that it planned to require State reporting of terminations “for cause.” Unless CMS requires such reporting, we believe that a centralized data source will not be comprehensive and creates a challenge for State Medicaid agencies to terminate the Medicaid participation of providers who were terminated “for cause” by other State Medicaid programs. We continue to monitor CMS’s progress in implementing our recommendation.

Report: OEI-06-12-00031 – March 2014, OEI-06-12-00030 – August 2015

Expected Impact: Improved program management, improved patient safety

TMC: This recommendation relates to HHS's Top Management Challenge: Protecting an Expanding Medicaid Program from Fraud, Waste, and Abuse

Personal Care Services: Trends, Vulnerabilities, and Recommendations for Improvement

Recommendation

CMS should promulgate regulations to reduce significant variation in States' personal care services (PCS) laws and regulations by creating or expanding Federal requirements and issuing operational guidance for claims documentation, beneficiary assessments, plans of care, and supervision of attendants.

Our objective was to identify trends in payment, compliance, oversight, or fraud vulnerabilities requiring priority attention and action. Available data indicate that States continue to expand the use of PCS to provide long-term-care services to beneficiaries in their homes or in other community-based settings. Although PCS are not medical services, PCS provide support for beneficiaries to maintain their daily life functions and avoid institutional care, including services such as bathing, dressing, light housework, money management, meal preparation, and transportation. In many States, the individuals who provide PCS (often called PCS attendants) work for personal care agencies. These agencies are enrolled in the Medicaid program and bill for services on the attendants' behalf. As more and more State Medicaid programs explore home care options like PCS, it is critical that adequate safeguards exist to ensure beneficiaries' safety and prevent fraud, waste, and abuse in PCS and other important home care benefits.

Based on 10 years of audits, evaluations, and investigations, OIG's extensive body of work examining Medicaid PCS has found significant and persistent compliance, payment, and fraud vulnerabilities that demonstrate the need for CMS to take a more active role with States to address these issues. OIG identified fraud vulnerabilities caused by the lack of available data for PCS to identify questionable billing patterns. Some vulnerabilities are caused by State billing policies that do not require PCS attendants to be identified on claims or that allow agencies to bill for spans of time without having to provide specific dates of service. The inability to identify service dates and PCS attendants on claims presents a significant law enforcement and oversight challenge. Additionally, seven audits of State PCS programs identified over \$582 million in questioned costs based on deficiencies. For example, in one state over a 30-month time period, OIG identified 464 instances where PCS providers billed and were improperly paid during beneficiaries' inpatient hospital stays. Some deficiencies, such as attendants who failed to meet State qualification and/or training requirements, also signal poor compliance with State standards designed to ensure patient safety and high quality of care. As these issues indicate, there is an additional need to provide States with a clear framework of program integrity measures, which are essential to ensuring the safety of beneficiaries and curbing fraud, waste, and abuse in PCS.

Companion Recommendations

- Promulgate regulations to reduce significant variation in State PCS attendant qualification standards and the potential for beneficiary exposure to unqualified PCS attendants by establishing minimum Federal qualification standards applicable to all PCS reimbursed by Medicaid.
- Promulgate regulations to improve CMS's and States' ability to monitor billing and care quality by requiring States to (1) either enroll all PCS attendants as providers or require all PCS attendants to register with the State Medicaid agencies and assign each attendant a unique identifier and (2)

require that PCS claims include the specific date(s) when services were performed and the identities of the rendering PCS attendants.

- Issue guidance to States regarding adequate prepayment controls.
- Consider whether additional controls are needed to ensure that PCS are allowed under program rules and are provided.
- Take action to provide States with data suitable for identifying overpayments for PCS claims during periods when beneficiaries are receiving institutional care paid for by Medicare or Medicaid.

Implementation Status

CMS concurred with the recommendation. In April 2015, CMS indicated that it promulgated final rules for the new Community First Choice benefit, under Section 1915(k) and for home- and community-based services provided under Sections 1915(c) and 1915(i) of the Social Security Act. However, OIG believes that CMS's actions do not implement the recommendation. The final rules addressed beneficiary assessments and plans of care provisions for a limited number of programs that provide PCS. In February 2016, CMS provided training for monitoring fraud, waste, and abuse in home- and community-based settings for PCS. OIG believes that CMS's February 2016 training identified a number of actions States should take that, if adopted through formal guidance from CMS, would be a significant step toward implementing OIG recommendations.

Report: OIG-12-12-01 – November 2012

Expected Impact: Improved program management, Improved program integrity, improved patient safety

TMC: This recommendation relates to HHS's Top Management Challenge: Protecting an Expanding Medicaid Program from Fraud, Waste, and Abuse

Not All States Reported Medicaid Managed Care Encounter Data as Required and Early Outcomes Show Limited Progress for the Transformed Medicaid Statistical Information System

Recommendation

CMS should ensure that Medicaid data are complete, accurate, and timely. This can be achieved through CMS's monitoring of State- submitted managed care encounter data and by implementing the national Transformed Medicaid Statistical Information System (T-MSIS).

Our objectives were to determine the: (1) extent to which States reported encounter data for all managed care entities to the Medicaid Statistical Information System (MSIS) and (2) status of CMS's national implementation of T-MSIS. In the MSIS Encounter Data review, we found that 8 of the 38 States we reviewed did not report encounter data from any managed care entities by the required deadline. An additional 11 States did not report encounter data for all managed care entities. Previous OIG studies raised concerns about the completeness, timeliness, and accuracy of national Medicaid data, not only with encounter data, as identified above. CMS's continued efforts to improve MSIS will result in a new national Medicaid dataset called T-MSIS. T-MSIS is designed to be a detailed national database of Medicaid and CHIP information to cover a broad range of user needs, including program integrity. CMS may withhold Federal matching payments for the use, maintenance, or modification of automated data systems from States that fail to report required data.

A fully functioning Medicaid data system, including encounter data, is essential to help protect the integrity of Medicaid. We found that, as of January 2013, CMS and the 12 volunteer States piloting the implementation of T-MSIS had made some progress in implementing T-MSIS. However, most other States had not started implementing T-MSIS, and they reported varied timeframes for when they planned to begin. We also found that early T-MSIS implementation outcomes raised questions about the completeness and accuracy of T-MSIS data upon national implementation. None of the 12 volunteer States could make all T-MSIS data elements available. CMS and the 12 States expressed concerns about the accuracy of the data they could provide upon implementation.

Implementation Status

CMS concurred with the recommendations from both the MSIS Encounter Data review and the T-MSIS review. For the recommendations related to the MSIS Encounter Data review, CMS is working with States to ensure that capitated managed care programs submit encounter data and that submitted encounter data include all contracted managed care entities and plan identifiers. We will monitor CMS's planned actions to address this recommendation. For the recommendations related to the T-MSIS review, CMS is working to implement T-MSIS with all States. OIG has ongoing work that will assess the extent to which States will be able to submit T-MSIS data and challenges faced by CMS and States during T-MSIS implementation. We will continue to monitor CMS's progress in implementing our recommendation. As CMS works with States to ensure implementation of T-MSIS, actions should be taken to ensure States are collecting managed care encounter data.

Report: OEI-07-13-00120 – July 2015, OEI-05-12-00610 – September 2013

Expected Impact: Improved program efficiency, Improved program integrity

TMC: This recommendation relates to HHS's Top Management Challenge: Meaningful and Secure Exchange and Use of Electronic Information and Health IT

Affordable Care Act: Marketplaces

OIG is focused on reviewing the economy, efficiency, and effectiveness of programs across HHS that were implemented pursuant to the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (ACA). The ACA vested in the Department substantial responsibilities for increasing access to health insurance for those who are eligible for coverage, improving access to and the quality of health care, and lowering health care costs and increasing value for taxpayers and patients. In particular, implementation, operation, and oversight of the marketplaces are among the most significant challenges for the Department.

OIG's ACA oversight strategy focuses on the health insurance marketplaces, reforms in the Medicare and Medicaid programs, and public health programs. Key focus areas for our marketplace oversight include payment accuracy, eligibility, management and administration, and security.

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

Recommendation

CMS should implement computerized systems to maintain confirmed enrollee and payment information so that CMS does not have to rely on qualified health plan (QHP) issuers' attestations in calculating payments.

Companion recommendations:

- CMS should implement a computerized system so State marketplaces can submit enrollee eligibility data.
- CMS should develop interim reconciliation procedures to address potentially inappropriate cost-sharing reduction payments.

Our objective was to determine whether CMS's internal controls were effective in ensuring the accuracy of financial assistance payments to QHP issuers made during the first 4 months that these payments were made. We determined that CMS's internal controls (i.e., processes put in place to prevent or detect any possible substantial errors) for calculating and authorizing financial assistance payments were not effective. Specifically, we found that CMS: (1) relied on issuer attestations that did not ensure that advance cost-sharing reduction payment rates identified as outliers were appropriate, (2) did not have systems in place to ensure that financial assistance payments were made on behalf of confirmed enrollees and in the correct amounts, (3) did not have systems in place for State marketplaces to submit enrollee eligibility data for financial assistance payments, and (4) did not always follow its guidance for calculating advance cost-sharing reduction payments and did not plan to perform a timely reconciliation of these payments.

The internal control deficiencies that we identified limited CMS's ability to make accurate payments to QHP issuers. On the basis of our sample results, we concluded that CMS's system of internal controls could not ensure that CMS made correct financial assistance payments from January through April 2014. Without effective internal controls for ensuring that financial assistance payments are calculated and applied correctly, we determined that approximately \$2.8 billion in Federal funds are at risk of being misspent.

Implementation Status

CMS concurred with our recommendations. In December 2015, CMS issued guidance indicating that most Federally facilitated marketplace QHP issuers would be required to use the automated policy-based system beginning January 2016, and State-based marketplace issuers would continue to use the manual process for 2016 payments. In January 2016, CMS transitioned most issuers to the portion of the Enrollment and Payment System (EPS) that calculates payment amounts and enrollment numbers, replacing the manual calculation method with a more precise, policy-based method. CMS continues to add issuers to the automated system as they meet the agency's criteria for readiness to transition. CMS plans to complete the remaining EPS functions during 2016, hoping to make financial management of the Federal marketplace more efficient and lower cost, and to improve the accuracy of payments and data. In February 2015, CMS issued guidance stating that it will postpone the reconciliation of advance cost-sharing reduction payments made for the 2014 and 2015 benefit years until April 30, 2016. We continue to monitor CMS's progress in implementing these recommendations.

Report: A-02-14-02006 – June 2015

Expected Impact: Improved program integrity, improved payment efficiency

TMC: This recommendation relates to HHS’s Top Management Challenge: Implementing, Operating, and Overseeing the Health Insurance Marketplaces

Not All of the Federally Facilitated Marketplace’s Internal Controls Were Effective in Ensuring that Individuals Were Properly Determined Eligible for Qualified Health Plans and Insurance Affordability Programs

Recommendation

CMS should take action to improve the Federal marketplace’s internal controls related to verifying applicants’ eligibility and resolving and expiring inconsistencies to address the specific deficiencies we identified.

Companion recommendations:

- Re-determine, if necessary, the eligibility of the sample applicants for whom we determined that verifications of eligibility and resolutions and expirations of inconsistencies were not performed according to Federal requirements.
- Improve procedures related to resolving inconsistencies.
- Develop and make public a plan on how and by what date the Federal marketplace will resolve inconsistencies.⁹
- Conduct additional oversight of State marketplaces to ensure that they are resolving inconsistencies according to Federal requirements.¹⁰

Our objective was to determine whether the Federally facilitated marketplace’s internal controls were effective in ensuring that individuals were determined (a) eligible for enrollment in qualified health plans (QHPs), and (b) eligible for insurance affordability programs, according to Federal requirements. We found that not all of the Federal marketplace’s internal controls were effective in doing so. The ACA requires the establishment of a health insurance marketplace exchange in each State and the District of Columbia. A marketplace is designed to serve as a “one-stop shop” at which individuals get information about their health insurance options; are evaluated for eligibility for a QHP and, when applicable, eligibility for insurance affordability programs; and enroll in the QHP of their choice.

On the basis of our sample reviews and performing other audit procedures, we determined that the Federal marketplace had deficiencies related to verifying applicants’ eligibility and resolving and expiring inconsistencies. In addition, we identified several weaknesses in the Federal marketplace’s procedures for resolving inconsistencies. Although these weaknesses did not result in noncompliance with Federal requirements, the procedures could be improved to ensure that applicants meet eligibility requirements for enrollment in QHPs and for insurance affordability programs, and that the amounts of the advance premium tax credit and cost-sharing reductions are determined correctly.

⁹ This recommendation is from the report entitled *Marketplaces Faced Early Challenges Resolving Inconsistencies* (June 2014 – OEI-01-14-00180).

¹⁰ Ibid.

Implementation Status

CMS concurred with our recommendations and provided OIG with actions it had taken or planned to take to address our recommendations. Specifically, CMS stated that it (1) has an extensive resolution process in place to resolve “data matching issues” and is continuously improving and refining the process; (2) had rectified system issues we identified in this report; and (3) had resolved and provided documentation to OIG for five sample applicants regarding annual household income data-matching issues and confirmed that their eligibility was appropriately determined. CMS also stated that it would review the remaining sample applicants to confirm that their eligibility was determined appropriately. We continue to assess and monitor CMS’s progress in implementing our recommendations.

Report: A-09-14-01011 – August 2015

Expected Impact: Improved program integrity, improved payment accuracy

TMC: This recommendation relates to HHS’s Top Management Challenge: Implementing, Operating, and Overseeing the Health Insurance Marketplaces

Federal Marketplace: Inadequacies in Contract Planning and Procurement

Recommendation

HHS should improve acquisition planning and oversight, including completing acquisition strategies, as required by regulation.

Our objective was to examine CMS's acquisition planning and procurement activities for the Federal marketplace. We found that, when awarding the Federal marketplace contracts, CMS did not always meet contracting requirements. The Federal marketplace at HealthCare.gov was designed to enable millions of Americans to select health insurance in a "one-stop shop" environment. CMS awarded 60 contracts across 33 companies to perform this work. The troubled launch of the Federal marketplace at HealthCare.gov in October 2013 raised a number of concerns, including questions about the adequacy of CMS's planning and procurement efforts for this key project under the ACA.

Our report found that CMS did not develop an overarching acquisition strategy for the Federal marketplace or perform all required oversight activities. Moreover, for a project of this size and importance, CMS missed opportunities to leverage all available acquisition planning tools and contracting approaches to identify and mitigate risks. Specifically, CMS did not exercise the option to plan for a lead systems integrator to coordinate all contractors' efforts prior to the launch of the Federal marketplace. The complexity of the Federal marketplace underscored the need for CMS to select the most qualified contractors. However, CMS did not perform thorough reviews of contractor past performance when awarding two key contracts. CMS also made contracting decisions that may have limited the number of acceptable proposals for much of the key Federal marketplace work. In addition, CMS selected contract types that placed the risk of cost increases for this work solely on the Government.

Implementation Status

CMS concurred with this recommendation and stated that HHS has issued its recent policy for acquisition strategies and acquisition plans. CMS provided OIG with HHS's Directive for Acquisition Strategy (dated April 23, 2015) and Directive for Acquisition Planning (dated April 15, 2015), and OIG acknowledged the Department's efforts to establish robust acquisition strategy requirements and guidance. However, OIG found that CMS did not develop an acquisition strategy for the Federal marketplace project despite an HHS Acquisition Requirement and an HHS acquisition strategy template and guidance. The HHS Directive for Acquisition Strategy does not contain any information about how CMS is ensuring that acquisition strategies are initiated and who within CMS has primary responsibility for ensuring that acquisition strategies are completed, as required. We request that CMS provide clarification regarding how it is ensuring the completion of required acquisition strategies for all contracts. We continue to monitor CMS's progress in implementing our recommendation.

Report: OEI-03-14-00230 – January 2015

Expected Impact: Improved contractor management, improved program management

TMC: This recommendation relates to HHS's Top Management Challenge: Implementing, Operating, and Overseeing the Health Insurance Marketplaces

Improper Payments Information

IMPROPER PAYMENTS INFORMATION: The Improper Payments Elimination and Recovery Act of 2010 (IPERA; P.L. No. 111-204) requires OIGs to review and report on agencies' annual improper-payment information included in their Agency Financial Reports (AFR) to determine compliance with the Improper Payments Information Act of 2002 (IPIA; P.L. No. 107-300) as amended by the IPERA as well as the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA; P.L. No. 112-248). These legislative items, together called "IPIA," were created to improve accountability of Federal agencies' administration of funds, and they require agencies, including HHS, to annually report to the President and Congress on the agencies' improper payments. An improper payment is any payment that should not have been made or that was made in an incorrect amount (either overpayments or underpayments), or that was sent to a wrong recipient.

As required by IPERA and the Office of Management and Budget's (OMB) implementing guidance, agencies must report on seven key issues, which are: (1) publishing an AFR and posting it on the agency website, (2) conducting a program-specific risk assessment, (3) developing improper-payment estimates for programs and activities identified as risk-susceptible, (4) publishing corrective action plans, (5) establishing annual reduction targets for those risk-susceptible programs, (6) reporting gross improper-payment rates of less than 10 percent, and (7) reporting on its efforts to recapture improper payments. In addition to assessing compliance with the IPIA, Appendix C to OMB Circular A-123 states that OIG should evaluate the accuracy and completeness of agency reporting as well as its performance in reducing and recapturing improper payments.

HHS Met Many Requirements of the Improper Payments Information Act of 2002 but Did Not Fully Comply for FY 2013 and FY 2014

Recommendation

HHS should: (1) report an improper-payment estimate for Temporary Assistance for Needy Families (TANF), and (2) reduce the Medicare Fee-for-Service (FFS) program's error rates below 10 percent.

Our objectives were to: (1) determine whether HHS complied with the IPIA for FY 2014, in accordance with the related OMB guidance; (2) evaluate HHS's assessment of the level of risk and the quality of the improper-payment estimates and methodology for high-priority programs¹¹; and (3) assess HHS's performance in reducing and recapturing improper-payments. Although HHS met many IPIA requirements and other OMB reporting requirements, it did not fully comply with the IPIA. To improve accountability of Federal agencies' administration of funds, the IPIA requires agencies, including HHS, to annually report to the President and Congress on the agencies' improper-payments.

As noted in our report on HHS's FY 2014 improper-payment information, HHS did not fully comply with the IPIA requirements for FY 2014. Specifically, HHS did not publish an improper-payment rate for the TANF program and did not report an improper-payment estimate of less than 10 percent for the Medicare FFS program.

Implementation Status

HHS reported in its FY 2015 Agency Financial Report a number of corrective actions to address improper-payments for the TANF and Medicare FFS programs. HHS has taken the following actions to assist the States in reducing improper-payments in the TANF program: (1) analyzing Single Audit material noncompliance findings and implementing corrective actions, and (2) performing a detailed risk assessment of the TANF program and working to mitigate these program risks. Also, HHS has several corrective actions for the Medicare FFS program that it believes will have a considerable impact in preventing and reducing improper-payments. The corrective actions cover the following areas:

- Implemented corrective actions to address program payment vulnerabilities related to home health services;
- Proposed an update to the "Two Midnight" rule (CMS-1633-P) regarding when hospital admissions are appropriate for payment under Medicare Part A;
- Expanded the use of prior authorization in the Medicare FFS program, including implementing two demonstrations projects to test whether prior authorization reduces expenditures while maintaining or improving quality of care for certain nonemergent services; and
- Issued a proposed rule to establish: (1) a master list of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items that are frequently subject to unnecessary utilization and potentially could be subject to prior authorization, and (2) a required prior authorization list of certain DMEPOS that would be subject to a prior authorization process.

Reports: A-17-14-52000 – April 2014, A-17-15-52000 – May 2014

Expected Impact: Improved program efficiency, improved program management

TMC: This recommendation relates to HHS's Top Management Challenge: Administration of Grants, Contracts, and Financial and Administrative Management Systems

¹¹ A high-priority program is one that has improper payments of greater than \$750 million (OMB Circular A-123 Appendix C, Figure 1)

Health Information Technology

The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of the administration's health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care. ONC is organizationally within the Office of the Secretary for HHS.

ONC is the principal Federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. The position of National Coordinator was created in 2004, through an Executive Order, and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009.

Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology

Recommendation

ONC and CMS should collaborate to develop a comprehensive plan to address fraud vulnerabilities in electronic health records (EHR).

Our objective was to determine how hospitals that received EHR Medicare incentive payments, which are administered by CMS, had implemented recommended fraud safeguards for EHR technology. We found that nearly all hospitals with EHR technology had RTI International (RTI)-recommended audit functions in place, but they may not be using them to their full extent. We also found that nearly all hospitals were using RTI-recommended data transfer safeguards, and all hospitals employed a variety of RTI-recommended user authorization and access controls. ONC, which coordinates the adoption, implementation, and exchange of EHRs, contracted with RTI to develop recommendations to enhance data protection; increase data validity, accuracy, and integrity; and strengthen fraud protection in EHR technology.

We found that only about one-quarter of hospitals had policies regarding the use of the copy-paste feature in EHR technology, which, if used improperly, could pose a fraud vulnerability.

Implementation Status

CMS and ONC concurred with the recommendation. CMS stated that it continues to work with ONC to develop a comprehensive plan to detect and reduce fraud. CMS also stated that it is conducting prepayment audits as well as prepayment edit checks. Although we acknowledge the usefulness of conducting audits and prepayment checks as a strategy to detect fraud and abuse, these efforts do not address our recommendation to work with ONC on strengthening its collaborative efforts. ONC stated that it is committed to providing technical assistance to Federal agencies that have health care fraud enforcement authority. OIG believes that all divisions of the Department have a shared responsibility for the integrity of departmental programs, regardless of whether they have health care fraud enforcement authority.

Report: OEI-01-11-00570 – December 2013

Expected Impact: Improved program integrity, protecting beneficiaries's personal identifying information

TMC: This recommendation relates to HHS's Top Management Challenge: Meaningful and Secure Exchange and Use of Electronic Information and Health IT

APPENDIX

Appendix of Significant Unimplemented Recommendations

The Appendix is a comprehensive list of OIG’s significant unimplemented recommendations. This list includes the top 25 unimplemented recommendations, which are designated below with an asterisk (*). The recommendations represent opportunities to achieve expected impact through costs savings, improvements in program effectiveness and efficiency, and increasing quality of care and safety of beneficiaries. The recommendations are generally grouped by the HHS program area and operating division.

HHS Area	Recommendation	Impact	Report Title/Link
Medicare Parts A & B*	<p>CMS should:</p> <ul style="list-style-type: none"> Seek legislation that would exempt the reduced expenditures as a result of lower outpatient prospective payment system (OPPS) payment rates from budget neutrality adjustments for ambulatory surgical center (ASC) approved procedures. Reduce OPPS payment rates for ASC-approved procedures on beneficiaries with no-risk or low-risk clinical needs in outpatient departments. Develop and implement a payment strategy in which outpatient departments would continue to receive the standard OPPS payment rate for ASC-approved procedures that must be provided in an outpatient department because of a beneficiary’s individual clinical needs. 	Estimated savings of \$15 billion and improved payment efficiency	Medicare and Beneficiaries Could Save Billions If CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center Approved Procedures to Ambulatory Surgical Center Payment Rates A-05-12-00020 (Apr. 2014)
Medicare Parts A & B*	CMS should change regulations or pursue a legislative change, if necessary, to establish a hospital transfer payment policy for early discharges to hospice care.	Estimated savings of \$602.5 million and improved payment efficiency	Medicare Could Save Millions by Implementing a Hospital Transfer Payment Policy for Early Discharges to Hospice Care A-01-12-00507 (May 2013)
Medicare Parts A & B*	CMS should ensure that all claims with exception codes are processed consistently and pursuant to Federal requirements.	Estimated savings of \$33.6 million and improved payment efficiency	Medicare Improperly Paid Providers Millions of Dollars for Incarcerated Beneficiaries Who Received Services During 2009 Through 2011 A-07-12-01113 (Jan. 2013)

Medicare Parts A & B*	CMS should enhance efforts to identify adverse events to ensure quality of care and safety.	Improved quality and improved safety	Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries OEI-06-11-00370 (Feb. 2014)
Medicare Parts A & B*	CMS should reform payments to reduce the incentive for hospices to target beneficiaries with certain diagnoses and those likely to have long stays.	Improved program integrity and payment efficiency	Medicare Hospices Have Financial Incentives To Provide Care in Assisted Living Facilities OEI-02-14-00070 (Jan. 2015)
Medicare Parts A & B*	CMS should seek legislative authority to modify how coinsurance is calculated for outpatient services received at Critical Access Hospitals (CAHs).	Savings for beneficiaries and improved payment efficiency	Medicare Beneficiaries Paid Nearly Half of the Costs for Outpatient Services at Critical Access Hospitals OEI-05-12-00085 (Oct. 2014)
Medicare Parts A & B*	CMS should consider pursuing rulemaking to expand the price substitution policy.	Estimated savings of \$6 million and improved payment efficiency	Comparing Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2013 OEI-03-14-00520 (Feb. 2015)
Medicare Parts A & B*	CMS should: <ul style="list-style-type: none"> • Reevaluate and reform the way Medicare pays skilled nursing facilities (SNFs) for therapy services. • Evaluate the extent to which Medicare payment rates for therapy should be reduced. • Change the method of paying for therapy. 	Improved quality of care and payment efficiency	The Medicare Payment System for Skilled Nursing Facilities Needs To Be Reevaluated OEI-02-13-00610 (Sept. 2014)
Medicare Parts A & B	CMS should: <ul style="list-style-type: none"> • Ensure that Medicare contractors collect the remaining overpayments identified in our individual reviews. • Continue to educate providers on correct billing of outpatient drugs. • Instruct Medicare contractors to review payments to providers for outpatient drugs billed from July 2012 through June 2014, which could represent overpayments of \$11.5 million. • Continue to implement line item and date-of-service MUEs for additional drugs. 	Improved payment efficiency	Medicare Part B Overpaid Millions for Selected Outpatient Drugs A-09-14-02024 (July 2015)

<p>Medicare Parts A & B</p>	<ul style="list-style-type: none"> • Office of Medicare Hearings and Appeals (OMHA) and CMS should identify and clarify Medicare policies that are unclear and are interpreted differently. • OMHA and CMS should standardize case files and make them electronic. • OMHA should revise regulations to provide more guidance to Administrative Law Judges (ALJs) regarding the acceptance of new evidence. • CMS should improve the handling of appeals from appellants who are also under fraud investigation and seek statutory authority to postpone these appeals when necessary. • OMHA should implement a quality assurance process to review ALJ decisions. • OMHA should develop policies to handle suspicions of fraud appropriately and consistently and train staff accordingly. 	<p>Improved program management</p>	<p>Improvements Are Needed at the Administrative Law Judge Level of Medicare Appeals OEI-02-10-00340 (Nov. 2012)</p>
<p>Medicare Parts A & B</p>	<p>We recommended that CMS:</p> <ul style="list-style-type: none"> • Seek legislative authority to remove Necessary Provider Critical Access Hospitals' (CAHs) permanent exemption from the distance requirement, thus allowing CMS to reassess these CAHs. • Seek legislative authority to revise the CAH Conditions of Participation to include alternative location-related requirements. • Periodically reassess CAHs' compliance with all location-related Conditions of Participation. 	<p>Estimated savings: \$449 million¹²</p>	<p>Most Critical Access Hospitals Would Not Meet the Location Requirements if Required To Re-enroll in Medicare OEI-05-12-00080 (Aug. 2013)</p>
<p>Medicare Parts A & B</p>	<p>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.</p>	<p>Improved payment efficiency</p>	<p>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 (Sept. 2014)</p>

¹² 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

<p>Medicare Parts A & B</p>	<p>CMS should adjust the estimated number of evaluation and management (E&M) services within 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.</p>	<p>Estimated savings: \$97.6 million per year¹³</p>	<p>Nationwide Review of Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005 A-05-07-00077 (Apr. 2009)</p>
<p>Medicare Parts A & B</p>	<p>CMS should adjust the estimated number of 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.</p>	<p>Estimated savings: \$49 million</p>	<p>Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided A-05-09-00053 (May 2012)</p>
<p>Medicare Parts A & B</p>	<p>CMS should seek legislative authority to expand the diagnostic related group (DRG) window to include:</p> <ul style="list-style-type: none"> • Additional days prior to the inpatient admission, and • Other hospital ownership arrangements, such as affiliated hospital groups. 	<p>Estimated savings: \$308 million¹⁴</p>	<p>Medicare and Beneficiaries Could Realize Substantial Savings if the DRG Window Were Expanded OEI-05-12-00480 (Feb. 2014)</p>
<p>Medicare Parts A & B</p>	<p>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.</p>	<p>Estimated savings: \$14.6 million</p>	<p>Cardiovascular Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided A-05-09-00054 (May 2012)</p>

¹³ Estimate based on CY 2005 data.

¹⁴ The estimated \$308 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.

<p>Medicare Parts A & B</p>	<p>CMS should:</p> <ul style="list-style-type: none"> • Reinstate beneficiary deductibles and coinsurance (and notifications of amounts paid on their behalf) as a means of controlling utilization. • Periodically evaluate the national fee schedule to ensure that reimbursement is aligned with the prices that physicians pay for clinical laboratory tests. 	<p>Estimated savings: \$23.8 billion¹⁵</p>	<p>Follow-up Report to “Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests” A-09-93-00056 (Jan. 1996) Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests A-09-89-00031 (Jan. 1990)</p>
<p>Medicare Parts A & B</p>	<p>We recommended that CMS:</p> <ul style="list-style-type: none"> • Direct the Medicare contractors to recover the \$4,574,228 in identified overpayments for incorrectly billed claims that are within the 3-year recovery period. • Work with the Medicare contractors to notify providers of potential overpayments outside of the 3-year recovery period, which we estimate to be much as \$1,767,213 for our audit period. • Review the 58 inpatient claims from October 2013 through April 2015 for stem cell transplants with lengths of stays of 1 to 2 days, which could save as much as \$2,054,306. • Strengthen controls related to MSDRGs for stem cell transplants. • Educate hospitals on the appropriate billing of stem cell transplants. 	<p>Estimated savings: \$3.8 million</p>	<p>Medicare Did Not Pay Selected Inpatient Claims for Bone Marrow and Stem Cell Transplant Procedures in Accordance with Medicare Requirements A-09-14-02037 (Feb. 2016)</p>
<p>Medicare Parts A & B</p>	<p>CMS should complete a process that would allow the claims processing system to interface with State survey agency systems to identify, on a prepayment basis, home health agency claims without accepted Outcome and Assessment Information Set (OASIS) data submissions.</p>	<p>Estimated savings: \$25.1 million</p>	<p>Medicare Often Made Overpayments to New England Home Health Agencies for Claims Without Required Outcome and Assessment Information Set Data for Calendar Year 2010 A-01-12-00508 (Mar. 2014)</p>

¹⁵ The Congressional Budget Office’s December 2008 “Budget Options Volume I – Healthcare” (p. 159) estimated savings of \$23.8 billion over 10 years from reinstating standard deductible and coinsurance requirements, with annual savings of \$2.4 billion by 2014.

Medicare Parts A & B	<p>CMS should:</p> <ul style="list-style-type: none"> • Conduct additional analysis to determine the extent to which financial incentives influence long-term-care hospital (LTCH) readmission decisions. • Take appropriate action regarding LTCHs with a high number of readmissions immediately after the fixed-day period and LTCHs with a high number of readmissions following multiple short stays at intervening facilities. 	Improved payment efficiency	Vulnerabilities in Medicare’s Interrupted-Stay Policy for Long-Term Care Hospitals OEI-04-12-00490 (June 2014)
Medicare Parts A & B	<p>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 these types of improper payments after our audit period but before implementation of policies and procedures and ensure that Medicare contractors recoup the improper payments.</p>	Improved payment efficiency	Medicare Improperly Paid Providers Millions of Dollars for Entitlement-Terminated Beneficiaries Who Received Services During 2010 Through 2012 A-07-13-01127 (Apr. 2014)
Medicare Parts A & B	<p>CMS should modify the payment system for hospice care in nursing facilities, seeking statutory authority, if necessary.</p>	Improved payment efficiency	Medicare Hospices That Focus on Nursing Facility Residents OEI-02-10-00070 (July 2011)
Medicare Parts A & B	<p>CMS should:</p> <ul style="list-style-type: none"> • Increase monitoring of billing for electrodiagnostic tests. • Take appropriate action regarding physicians we identified as having inappropriate or questionable billing. 	Improved payment efficiency	Questionable Billing for Medicare Electrodiagnostic Tests OEI-04-12-00420 (Apr. 2014)
Medicare Parts A & B	<p>CMS should:</p> <ul style="list-style-type: none"> • Instruct Medicare contractors to increase monitoring of outlier payments. • Examine whether diagnosis codes associated with high rates of outlier payments warrant coding changes or other adjustments. 	Improved payment efficiency	Medicare Hospital Outlier Payments Warrant Increased Scrutiny OEI-06-10-00520 (Nov. 2013)
Medicare Parts A & B	<p>CMS should continue to provide specific education to inpatient rehabilitation facilities on the importance of reporting the correct patient assessment instruments transmission dates on their claims.</p>	Improved payment efficiency	Medicare Overpaid Inpatient Rehabilitation Facilities Millions of Dollars for Claims with Late Patient Assessment Instruments for Calendar Years 2009 and 2010 A-01-11-00534 (Sept. 2012)

Medicare Parts A & B	CMS should develop an alternative mechanism, such as having contractors perform additional prepay and post-pay reviews, to ensure that suppliers maintain the required documentation for the specific medical equipment and supply items that currently use the KX modifier.	Estimated savings: \$316.4 million	Claim Modifier Did Not Prevent Medicare from Paying Millions in Unallowable Claims for Selected Durable Medical Equipment A-04-10-04004 (Apr. 2012)
Medicare Parts A & B	CMS should: <ul style="list-style-type: none"> • Monitor compliance with the new therapy assessments. • Change the current method for determining how much therapy is needed to ensure appropriate payments. • Improve the accuracy of data items submitted by SNFs. 	Improved payment efficiency	Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than \$1 Billion in 2009 OEI-02-09-00200 (Nov. 2012)
Medicare Parts A & B	CMS should: <ul style="list-style-type: none"> • Reduce the financial incentive for SNFs to use assessments differently when decreasing therapy than when increasing it. • Strengthen the oversight of SNF billing for changes in therapy. 	Improved payment efficiency	Skilled Nursing Facility Billing for Changes in Therapy: Improvements Are Needed OEI-02-13-00611 (June 2015)
Medicare Parts A & B	CMS should implement the HHA surety bond requirement.	Improved payment efficiency	Surety Bonds Remain an Unused Tool to Protect Medicare from Home Health Overpayments OEI-03-12-00070 (Sept. 2012)
Medicare Parts A & B	We recommended that CMS: <ul style="list-style-type: none"> • Establish a cumulative payment threshold, taking into consideration costs and potential program integrity benefits, above which a clinician's claims would be selected for review. • Implement a procedure for timely identification and review of clinicians' claims that exceed the cumulative payment threshold. 	Improved program integrity	Reviews of Clinicians Associated with High Cumulative Payments could Improve Medicare Program Integrity Efforts A-01-11-00511 (Dec. 2013)
Medicare Parts A & B	CMS should implement additional claims processing edits or improve existing edits to ensure claims are paid appropriately.	Improved payment efficiency and program integrity	Medicare Paid \$22 Million in 2012 for Potentially Inappropriate Ophthalmology Claims OEI-04-12-00281 (Dec. 2014)
Medicare Parts A & B	We recommended that CMS ensure that collections information is consistently recorded in the Audit Tracking and Reporting System, and collect sustained amounts related to OIG recommendations	Improved financial management	Obstacles to Collection of Millions in Medicare Overpayments A-04-10-03059 (May 2012)

	made after our audit period to the extent allowed under the law.		
Medicare Parts A & B	CMS should distinguish payments in the End Stage Renal Disease base rate between independent and hospital-based dialysis facilities.	Improved payment efficiency	Update: Medicare Payments for End-Stage Renal Disease Drugs OEI-03-12-00550 (Mar. 2014)
Medicare Parts A & B	CMS should: <ul style="list-style-type: none"> Review the process for overseeing contractors' error rate reduction. Ensure that contractors submit clear plans for reducing their error rates. Provide additional guidance for contractors and CMS staff who review plans. Provide error rate reduction incentives that are aligned with the contracts' error rates and performance periods. 	Improved payment efficiency	Medicare Claims Administrative Contractors' Error Rate Reduction Plans OEI-09-12-00090 (Jan. 2014)
Medicare Parts A & B	CMS should clarify the workload definitions in the CMS Analysis, Reporting, and Tracking System to ensure that Zone Program Integrity Contractor's (ZPIC) workload statistics are accurate and that ZPICs report their data uniformly.	Improved program management	Zone Program Integrity Contractors' Data Issues Hinder Effective Oversight OEI-03-09-00520 (Nov. 2011)
Medicare Parts A & B	CMS should: <ul style="list-style-type: none"> Provide guidance to claims processors about handling [for program integrity purposes] Medicare Summary Notices that are returned as undeliverable. Ensure that the address information used by claims processors to print addresses on Medicare Summary Notices is complete and properly formatted. 	Improved program management	Over Four Million Medicare Summary Notices Mailed to Beneficiaries Were Not Delivered in 2012 OEI-03-12-00600 (Jan. 2014)
Medicare Parts A & B	CMS should: <ul style="list-style-type: none"> Explore the possibility of requiring providers to identify on the Part B claims the pharmacies that produced the compounded drugs. Explore the possibility of conducting descriptive analyses of Part B claims for compounded drugs. 	Improved program management	Compounded Drugs Under Medicare Part B: Payment and Oversight OEI-03-13-00270 (Apr. 2014)
Medicare Parts A & B	CMS should: <ul style="list-style-type: none"> Define "grievance" for facilities. Provide guidance to facilities on what constitutes a robust process for anonymous grievances. 	Improved program management	The ESRD Beneficiary Grievance Process OEI- 01-11-00550 (Dec. 2013)

	<ul style="list-style-type: none"> • Work with AHRQ to add a question to the Consumer Assessment of Healthcare Providers and Systems to assess beneficiaries' fear of reprisal. • Provide networks with better technical support for the Contact Utility database. 		
Medicare Parts A & B	CMS should promote minimum standards in background check procedures.	Improved program integrity and safety	Home Health Agencies Conducted Background Checks of Varying Types OEI-07-14-00130 (May 2015)
Medicare Parts A & B	CMS should provide interpretive guidelines for State survey agencies to assess hospital compliance to track and monitor adverse events.	Improved quality	Adverse Events in Hospitals: Methods for Identifying Events OEI-06-08-00221 (Mar. 2010)
Medicare Parts A & B	CMS should: <ul style="list-style-type: none"> • Strengthen regulations on care planning and discharge planning. • Provide guidance to SNFs to improve care planning and discharge planning. • Increase surveyor efforts to identify SNFs that do not meet care planning and discharge planning requirements and to hold these SNFs accountable. • Link payments to meeting quality-of-care requirements. 	Improved quality	Skilled Nursing Facilities Often Fail To Meet Care Planning and Discharge Planning Requirements OEI-02-09-00201 (Feb. 2013)
Medicare Parts A & B	CMS should ensure that nursing facilities: <ul style="list-style-type: none"> • Maintain policies related to reporting allegations of abuse or neglect. • Comply with their responsibilities under section 1150B of the Social Security Act. • Report allegations of abuse or neglect and investigation results in a timely manner and to the appropriate individuals, as required 	Improved quality	Nursing Facilities' Compliance With Federal Requirements for Reporting Allegations of Abuse or Neglect OEI-07-13 00010 (Aug. 2014)
Medicare Parts A & B	CMS should determine the relative contribution of each of its quality improvement efforts.	Improved quality	Quality Improvement Organizations Provide Support to More Than Half of Hospital but Overlap with Other Programs OEI-01-12-00650 (Jan. 2015)
Medicare Parts A & B	CMS should coordinate activities to deter Community Mental Health Center fraud in Florida.	Improved program integrity	Vulnerabilities in CMS's and Contractors' Activities to Detect and Deter Fraud in Community Mental Health Centers OEI-04-11-00101 (Jan. 2013)

<p>Medicare Parts C & D*</p>	<p>CMS should:</p> <ul style="list-style-type: none"> • Implement policies and procedures to notify Medicare Advantage (MA) organizations of unlawful- presence information and thereby prevent enrollment in MA organizations, prevent enrollment of unlawfully present beneficiaries in Part D, disenroll beneficiaries already enrolled, automatically reject prescription drug event records, and recoup any improper payments. • Identify and recoup improper payments made to MA organizations for unlawfully present beneficiaries after our audit period and until policies and procedures have been implemented. • Recoup \$26 million in improper payments in accordance with legal requirements. • Prevent enrollment of unlawfully present beneficiaries, disenroll any currently enrolled unlawful beneficiaries, and automatically reject prescription drug event records submitted by sponsors for prescription drugs provided to this population. • Reopen and revise final payment determinations for CYs 2009 through 2011 to remove prescription drug costs for unlawfully present beneficiaries. 	<p>Improved program management and payment efficiency</p>	<p>Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2010 through 2012 A-07-13-01125 (Apr. 2014) Medicare Improperly Paid Millions of Dollars for Prescription Drugs Provided to Unlawfully Present Beneficiaries during 2009 through 2011 A-07-12-06038 (Oct. 2013)</p>
<p>Medicare Parts C & D*</p>	<p>CMS should:</p> <ul style="list-style-type: none"> • Restrict certain beneficiaries to a limited number of pharmacies or prescribers. • Expand sponsors' drug utilization review programs. • Expand sponsors' use of beneficiary-specific controls. • Expand the Overutilization Monitoring System to include additional drugs susceptible to fraud, waste, and abuse. • Limit the ability of certain beneficiaries to switch plans. • Increase monitoring of beneficiaries' utilization patterns. 	<p>Improved program efficiency and program integrity</p>	<p>Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs OEI-02-11-00170 (Aug. 2014)</p>

<p>Medicare Parts C & D</p>	<p>CMS should:</p> <ul style="list-style-type: none"> Require plan sponsors to report all potential fraud and abuse to CMS and/or the Medicare Drug Integrity Contractor (MEDIC). Evaluate the extent to which Medicare payment rates for therapy should be reduced. Change the method of paying for therapy. 	<p>Improved program management and program integrity</p>	<p>Summary of Recommendations from Five Reports Related to Ensuring the Integrity of Medicare Part D OEI-03-13-00030 OEI-03-10-00310 OEI-03-07-00380 OEI-03-08-00420 OEI-02-09-00600</p>
<p>Medicare Parts C & D</p>	<p>CMS should change its practice of paying for drugs that have a date of service within 32 days after the beneficiary's date of death.</p>	<p>Improved payment efficiency</p>	<p>Medicare Paid for HIV Drugs for Deceased Beneficiaries OEI-02-11-00172 (Oct. 2014)</p>
<p>Medicare Parts C & D</p>	<p>We recommended that CMS implement an edit to reject PDE records for Schedule II drugs when the prescriber ID field contains an invalid prescriber ID number and issue specific guidance requiring sponsors to include a valid DEA number on both standard and nonstandard format PDE records involving Schedule II drugs.</p>	<p>Improved program integrity</p>	<p>Schedule II Drugs: Oversight of the Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs A-14-09-00302 (Feb. 2011)</p>
<p>Medicare Parts C & D</p>	<p>We recommended that CMS:</p> <ul style="list-style-type: none"> Exclude Schedule II refills when calculating payments to sponsors. Follow up on sponsors and pharmacies with high numbers of refills. 	<p>Improved payment efficiency</p>	<p>Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills OEI-02-09-00605 (Sept. 2012)</p>
<p>Medicare Parts C & D</p>	<p>We recommended that CMS:</p> <ul style="list-style-type: none"> Provide the MEDIC with centralized Part C data to enable it to more comprehensively and proactively identify and investigate Part C fraud and abuse. 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 involving inappropriate services for further action. Amend regulations to require Part C and Part D plan sponsors to refer potential fraud and abuse incidents to the MEDIC. Enhance monthly workload-reporting requirements to improve CMS's oversight of the MEDIC's benefit integrity activities. 	<p>Improved program integrity</p>	<p>MEDIC Benefit Integrity Activities in Medicare Parts C and D OEI-03-11-00310 (Jan. 2013)</p>

Medicare Parts C & D	CMS should cooperate with industry stakeholder efforts to identify a solution to prevent coupons from being used to purchase drugs paid for by Part D.	Improved program management	Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs OEI-05-12-00540 (Sept. 2014)
Medicare Parts C & D	CMS should: <ul style="list-style-type: none"> • Define Pharmacy Benefit Managers (PBM) 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 pharmacy and therapeutics (P&T) committee. • Oversee compliance with P&T committee conflict-of-interest requirements and guidance. 	Improved program management	Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions OEI-05-10-00450 (Mar. 2013)
Medicare Parts C & D	CMS should: <ul style="list-style-type: none"> • Determine whether outlier data values submitted by MA organizations reflect inaccurate reporting or atypical performance. • Use appropriate Part C reporting requirements data as part of its reviews of MA organizations' performance. 	Improved program integrity	CMS Regularly Reviews Part C Reporting Requirements Data, But Its Followup and Use of the Data Are Limited OEI-03-11-00720 (Mar. 2014)
Administration for Children and Families*	ACF should amend current policy and regulations to require that any prospective or current employee be disqualified for or terminated from employment with a Head Start grantee if the individual has been convicted of sexual abuse of a child, other forms of child abuse and neglect, or a violent felony.	Improved safety for children and program management	Review of 24 Head Start Grantees' Compliance With Health and Safety Requirements A-01-11-02503 (Dec. 2011)
Administration for Children and Families*	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.	Improved access, quality, and program management	Not All Children in Foster Care Who Were Enrolled in Medicaid Received Required Health Screenings OEI-07-13-00460 (Mar. 2015)

Administration for Children and Families	ACF should: <ul style="list-style-type: none"> • Conduct periodic reviews of States' compliance with their own requirements related to minimum health and safety standards [applicable to licensed child care providers]. • Ensure that State plans comply with health and safety requirements and take action when States do not comply. 	Improved safety	Child Care and Development Fund. Monitoring of Licensed Child Care Providers OEI-07-10-00230 (Nov. 2013)
Food and Drug Administration*	FDA should seek statutory authority to review substantiation for structure/function claims to determine whether claims are truthful and not misleading.	Improved safety and program oversight	Dietary Supplements: Structure/Function Claims Fail To Meet Federal Requirements OEI-01-11-00210 (Oct. 2012)
Food and Drug Administration	FDA should: <ul style="list-style-type: none"> • Improve the accuracy of the information in its Food Facility Registry. • Seek statutory authority to impose civil monetary penalties on companies that do not comply with registration requirements. • Educate the dietary supplement industry about registration and labeling requirements. 	Improved safety	Dietary Supplements: Companies May Be Difficult to Locate in an Emergency OEI-01-11-00211 (Oct. 2012)
Food and Drug Administration	FDA should: <ul style="list-style-type: none"> • Ensure that violations are corrected for all facilities that receive official action indicated (OAI) classifications, particularly those that have histories of violations. • Consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements. 	Improved safety	FDA Inspections of Domestic Food Facilities OEI-02-08-00080 (Apr. 2010)
Food and Drug Administration	FDA should: <ul style="list-style-type: none"> • Develop and implement a plan to identify, develop, validate, and assess Risk Evaluation and Mitigation Strategies (REMS) components. • Identify REMS that are not meeting their goals and take appropriate actions to protect the public health. • Identify incomplete sponsor assessments and work with sponsors to obtain missing information. 	Improved safety	FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety OEI-04-11-00510 (Feb. 2013)

	<ul style="list-style-type: none"> • Clarify expectations for sponsors' assessments in FDA assessment plans. • Seek legislative authority to enforce FDA assessment plans. • Ensure that assessment reviews are timely. 		
Food and Drug Administration	<p>FDA should:</p> <ul style="list-style-type: none"> • Use its authority to request records in lieu of or in advance of an inspection. • Conduct outstanding preapproval inspections of manufacturers of generic drugs, where appropriate. 	Improved safety	FDA Has Made Progress on Oversight and Inspections of Manufacturers of Generic Drugs OEI-01-13-00600 (May 2015)
National Institutes of Health	<p>NIH should:</p> <ul style="list-style-type: none"> • Develop and disseminate guidance on methods to verify researchers' financial interests. • Ensure that grantee institutions are providing adequate oversight of subgrantee compliance with Federal financial conflicts of interest regulations. • Ensure that grantee institutions are maintaining proper documentation as outlined in the Federal financial conflict-of-interest regulations. • Ensure that grantee institutions take appropriate actions against researchers who do not follow grantee institutions' financial conflict-of-interest policies and procedures. • Develop regulations that address institutional financial conflicts of interest. 	Improved program management	How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health OEI-03-07-00700 (Nov. 2009)
National Institutes of Health	NIH should promulgate regulations that address institutional financial conflicts of interest.	Improved program management	Institutional Conflicts of Interest at NIH Grantees OEI-03-09-00480 (Jan. 2011)
National Institutes of Health	<p>NIH should:</p> <ul style="list-style-type: none"> • Confirm that grants management staff ensure timely submission of required awardee reports. • Revise the NIH Policy Manual and Award Worksheet Report to require a brief narrative documenting awardee progress and stating whether any change in research goals influences continued funding. 	Improved program management	NIH Postaward Grant Administration and Oversight Could be Improved OEI-07-11-00190 (Aug. 2015)

Medicaid*	CMS should work with State Medicaid programs to perform utilization reviews of second-generation antipsychotic drugs (SGA) prescribed to children.	Improved safety, quality, and program integrity	Second-Generation Antipsychotic Drug Use Among Medicaid-Enrolled Children: Quality-of-Care Concerns OEI-07-12-00320 (Mar. 2015)
Medicaid*	CMS should seek legislative authority to limit State Medicaid durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) reimbursement rates to Medicare program rates and encourage further reduction of Medicaid reimbursement rates through competitive bidding or manufacturer rebates.	Improved program management and estimated savings of \$4.27 billion over 10 years	State Medicaid Agencies Can Significantly Reduce Medicaid Costs for Durable Medical Equipment and Supplies A-05-15-00025 (Sept. 2014)
Medicaid*	CMS should: <ul style="list-style-type: none"> • Provide States with definitive guidance for calculating the Medicaid upper payment limit (UPL), which should include using facility-specific UPLs that are based on actual cost report data. • Require that the return of Medicaid payments by a county or local government to the State be declared a refund of those payments and thus be used to offset the Federal share generated by the original payment. 	Estimated savings of \$3.87 billion over 5 years and improved program management	Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers A-03-00-00216 (Sept. 2001)
Medicaid*	CMS should require each State Medicaid agency to report all terminated providers.	Improved program management and patient safety	CMS System for Sharing Information about Terminated Providers Needs Improvement OEI-06-12-00031 (Mar. 2014) Providers Terminated from One State Medicaid Program Continued Participating in Other States OEI-06-12-00030 (Aug. 2015)
Medicaid*	CMS should promulgate regulations to reduce significant variation in States' personal care services (PCS) laws and regulations by creating or expanding Federal requirements and issuing operational guidance for claims documentation, beneficiary assessments, plans of care, and supervision of attendants. <ul style="list-style-type: none"> • Promulgate regulations to reduce significant variation in State PCS attendant qualification standards and the potential for beneficiary exposure to unqualified PCS attendants by establishing minimum Federal qualification standards applicable to all PCS reimbursed by Medicaid. 	Improved program management, patient safety, and program integrity	Personal Care Services: Trends, Vulnerabilities, and Recommendations for Improvement OIG-12-12-01 (Nov. 2012)

	<ul style="list-style-type: none"> • Promulgate regulations to improve CMS's and States' ability to monitor billing and care quality by requiring States to (1) either enroll all PCS attendants as providers or require all PCS attendants to register with the State Medicaid agencies and assign each attendant a unique identifier and (2) require that PCS claims include the specific date(s) when services were performed and the identities of the rendering PCS attendants. • Issue guidance to States regarding adequate prepayment controls. • Consider whether additional controls are needed to ensure that PCS are allowed under program rules and are provided. • Take action to provide States with data suitable for identifying overpayments for PCS claims during periods when beneficiaries are receiving institutional care paid for by Medicare or Medicaid. 		
Medicaid*	CMS should ensure that Medicaid data are complete, accurate, and timely. This can be achieved through CMS's monitoring of State-submitted managed care encounter data and by implementing the national Transformed Medicaid Statistical Information System (T-MSIS).	Improved program efficiency and program integrity	Not All States Reported Medicaid Managed Care Encounter Data as Required OEI-07-13-00120 (July 2015) Early Outcomes Show Limited Progress for the Transformed Medicaid Statistical Information System OEI-05-12-00610 (Sept. 2013)
Medicaid	CMS should provide the results of this review to States for their use when they consider changes to their pharmacy reimbursement methodologies, including those for single-source drugs, brand-name multiple-source drugs, and generic multiple-source drugs.	Improved payment efficiency	Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices A-06-11-00002 (Oct. 2011)
Medicaid	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.	Improved payment efficiency	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 (Aug. 2015)
Medicaid	Indiana Family & Social Services Administration should take appropriate action on the dental providers identified as having questionable billing.	Improved payment efficiency	Questionable Billing for Medicaid Pediatric Dental Services in Indiana OEI-02-14-00250 (Nov. 2014)

Medicaid	<p>CMS should:</p> <ul style="list-style-type: none"> Review and address delays in resolving OIG audit recommendations and promptly pursue corrective actions. Maintain adequate documentation to support the collection of overpayments in accordance with OMB Circular A-50 and CMS Standard Operating Procedures. Educate the States about their responsibility to report overpayments on the correct line of the CMS-64 to improve oversight of the reporting process. Collect the remaining \$225.6 million we identified as due the Federal Government. 	Improved program efficiency and estimated savings: \$225.6 million	Medicaid Overpayments—The Centers for Medicare & Medicaid Services Collected the Majority of Medicaid Overpayments but Millions Remain Uncollected A-05-11-00071 (Feb. 2013)
Medicaid	<p>CMS should:</p> <ul style="list-style-type: none"> Ensure that all States appropriately report offset rebate amounts. Consider further whether to encourage all States to establish supplemental rebate programs. Encourage States to explore alternate methods for calculating supplemental rebates. 	Improved program management	States’ Collection of Offset and Supplemental Medicaid Rebates OEI-03-12-00520 (Dec. 2014)
Medicaid	CMS should issue guidance to States on monitoring managed care entities’ compliance with the Federal provider nondiscrimination contract provision.	Improved program management	State and CMS Oversight of the Medicaid Managed Care Credentialing Process OEI-09-10-00270 (Nov. 2013)
Medicaid	CMS should issue guidance to States on the requirement for participating in the Medicaid Interstate Match.	Improved program management and integrity	Public Assistance Reporting Information System: State Participation in the Medicaid Interstate Match Is Limited OEI-09-11-00780 (July 2014)
Medicaid	<p>CMS should:</p> <ul style="list-style-type: none"> Require States to report vision and hearing screenings. Collaborate with States and providers to develop effective strategies to encourage beneficiary participation in screenings. Collaborate with States and providers to develop education and incentives for providers to encourage complete medical screenings. Identify and disseminate promising State practices for increasing children’s participation in screenings and providers’ delivery of complete medical screenings. 	Improved quality	Most Medicaid Children in Nine States are Not Receiving All Required Preventive Screening Services OEI-05-08-00520 (May 2010)

<p>Medicaid</p>	<p>CMS should work with States to:</p> <ul style="list-style-type: none"> • Ensure that plans are complying with existing State standards and assess whether additional standards are needed. • Ensure that plans' networks are adequate and meet the needs of their Medicaid managed care enrollees. • Assess the number of providers offering appointments and improve the accuracy of plan information. 	<p>Improved quality and access</p>	<p>Access to Care: Provide Availability in Medicaid Managed Care OEI-02-13-00670 (Dec. 2014)</p>
<p>Medicaid</p>	<p>CMS should:</p> <ul style="list-style-type: none"> • 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. • Improve States' efforts to identify and address violations of access standards. • Provide technical assistance and share effective practices. 	<p>Improved quality and access</p>	<p>State Standards for Access to Care in Medicaid Managed Care OEI-02-11-00320 (Sept. 2014)</p>
<p>Medicaid</p>	<p>CMS should:</p> <ul style="list-style-type: none"> • Work with States to develop uniform terminology to clearly denote terminations for cause. • Furnish guidance to State Medicaid agencies that termination is not contingent on the provider's active licensure status. • Require that State Medicaid programs enroll all providers participating in Medicaid managed care. 	<p>Improved program integrity</p>	<p>Providers Terminated from One State Medicaid Program Continued Participating in Other States OEI-06-12-00030 (Aug. 2015)</p>
<p>Medicaid</p>	<p>CMS should:</p> <ul style="list-style-type: none"> • Require that State contracts with managed care entities include methods to verify with beneficiaries whether services billed by providers were received. • Update guidance to reflect concerns expressed by MCEs and States. 	<p>Improved program integrity</p>	<p>Medicaid Managed Care: Fraud and Abuse Concerns Remain Despite Safeguards OEI-01-09-00550 (Dec. 2011)</p>

Medicaid	<p>CMS should:</p> <ul style="list-style-type: none"> • Work with States to improve the quality of claims data submitted by providers and pharmacies. • Help States obtain better data on ineligible drugs. 	Improved program management	Medicaid Drug Rebate Dispute Resolution Could Be Improved OEI-05-11-00580 (Aug. 2014)
Centers for Medicare and Medicaid Services	<p>CMS should:</p> <ul style="list-style-type: none"> • Revise Federal regulations by identifying and including in its regulations requirements for specific elements of emergency plans and training. • Update the <i>State Operations Manual</i> to provide detailed guidance for surveyors assessing compliance with Federal regulations for nursing home emergency planning and training. 	Improved safety	Gaps Continue to Exist in Nursing Home Emergency Preparedness and Response During Disasters: 2007-2010 OEI-06-09-00270 (Apr. 2012)
Affordable Care Act: Marketplaces*	<p>CMS should:</p> <ul style="list-style-type: none"> • Implement computerized systems to maintain confirmed enrollee and payment information so that CMS does not have to rely on qualified health plan (QHP) issuers' attestations in calculating payments. • Implement a computerized system so State marketplaces can submit enrollee eligibility data. • Develop interim reconciliation procedures to address potentially inappropriate cost-sharing-reduction payments. 	Improved payment efficiency and program integrity	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)
Affordable Care Act: Marketplaces*	<p>CMS should:</p> <ul style="list-style-type: none"> • Take action to improve the Federal marketplace's internal controls related to verifying applicants' eligibility and resolving and expiring inconsistencies to address the specific deficiencies we identified. • Re-determine, if necessary, the eligibility of the sample applicants for whom we determined that verifications of eligibility and resolutions and expirations of inconsistencies were not performed according to Federal requirements. • Improve procedures related to resolving inconsistencies. • Improve internal controls related to determining applicants' eligibility for 	Improved payment accuracy and program integrity	Not All of the Federally Facilitated Marketplace's Internal Controls were Effective in Ensuring that Individuals were Properly Determined Eligible for Qualified Health Plans and Insurance Affordability Programs A-09-14-01011 (Aug. 2015)

	<p>enrollment in QHPs and eligibility for insurance affordability programs.¹⁶</p> <ul style="list-style-type: none"> • Develop and make public a plan on how and by what date the Federal marketplace will resolve inconsistencies.¹⁷ • Conduct additional oversight of State marketplaces to ensure that they are resolving inconsistencies according to Federal requirements.¹⁸ 		
Affordable Care Act: Marketplaces	HHS should improve acquisition planning and oversight, including completing acquisition strategies, as required by regulation.	Improved program management and program efficiency	Federal Marketplace: Inadequacies in Contract Planning and Procurement OEI-03-14-00230 (Jan. 2015)
Affordable Care Act Marketplaces	<p>The Maryland Department of Health and Mental Hygiene should:</p> <ul style="list-style-type: none"> • Refund \$15.9 million to CMS that was misallocated to the establishment grants because it did not prospectively use updated actual enrollment data. • Refund \$12.5 million to CMS that was misallocated to the establishment grants using a methodology that included a material defect. • Immediately amend the Cost Allocation Plan and the Advance Planning Document for the period July 1 through December 31, 2014, so that allocated costs correspond to the relative benefits received. • Develop a written policy that explains how to calculate cost allocations and that emphasizes the necessity to use updated and actual data. • Oversee operations to ensure (1) the identification and correction of enrollment projection errors, (2) the use of better or updated enrollment data, and (3) the application of these data to allocate costs. 	Improved program management and estimated savings: \$28.4 million	Maryland Misallocated Millions to Establishment Grants for a Health Insurance Marketplace A-01-14-02503 (Mar. 2015)
Affordable Care Act Marketplaces	CMS should:	Improved program management	Actual Enrollment and Profitability Was Lower Than Projections Made by the Consumer Operated and Oriented Plans

¹⁶ This recommendation is from the report entitled *Not All Internal Controls Implemented by the Federal, California, and Connecticut Marketplaces Were Effective in Ensuring That Individuals Were Enrolled in Qualified Health Plans According to Federal Requirements* (June 2014 – [A-09-14-01000](#)).

¹⁷ This recommendation is from the report entitled *Marketplaces Faced Early Challenges Resolving Inconsistencies* (June 2014 – OEI-01-14-00180).

¹⁸ Ibid

	<ul style="list-style-type: none"> • Continue to place underperforming CO-OPs on enhanced oversight or corrective action plans, in accordance with Federal requirements. • Work with State insurance regulators to identify and correct underperforming CO-OPs. • Provide guidance or establish criteria to determine when a CO-OP is no longer viable or sustainable. • Pursue available remedies for recovery of funds from terminated CO-OPs, in accordance with the loan agreements. 		<p>and May Affect Their Ability to Repay Loans Provided Under the Affordable Care Act A-05-14-00055 (July 2015)</p>
Affordable Care Act: Marketplaces	<p>CMS should:</p> <ul style="list-style-type: none"> • Include all relevant contract costs when it identifies total obligations and expenditures related to the design, development, and operation of the Federal marketplace. • Review all charges submitted by CGI Federal for the Federally facilitated marketplace contract and make a final determination on the appropriate amount to withhold for correcting defects by validating the \$267,420 withheld for the fixed fee. 	Improved program integrity and payment accuracy	<p>CMS Did Not Identify All Federal Marketplace Contract Costs and Did Not Properly Validate the Amount to Withhold for Defect Resolution on the Principal Federal Marketplace Contract A-03-14-03002 (Sept. 2015)</p>
Affordable Care Act: Marketplaces	<p>CMS, Covered California, and Access Health CT should:</p> <ul style="list-style-type: none"> • Improve internal controls related to determining applicants' eligibility for enrollment in qualified health plans and eligibility for insurance affordability programs. • Improve internal controls related to verifying identity of applicants and entering applicant information. • Improve internal controls related to maintaining and updating eligibility and enrollment data. • Redetermine, if necessary, the eligibility of the sample applicants for whom we determined that verifications were not performed according to Federal requirements. 	Improved program integrity and payment accuracy	<p>Not All Internal Controls Implemented by the Federal, California, and Connecticut Marketplaces Were Effective in Ensuring that Individuals Were Enrolled in Qualified Health Plans According to Federal Requirements A-09-14-01000 (June 2014)</p>

Improper Payments Information*	<p>HHS should:</p> <ul style="list-style-type: none"> • Report an improper-payment estimate for Temporary Assistance for Needy Families (TANF), and • Reduce the Medicare Fee-for-Service (FFS) program’s error rates below 10 percent. 	Improved program management and program efficiency	<p>HHS Met Many Requirements of the Improper Payments Information Act of 2002 but Did Not Fully Comply for FY 2013 and FY 2014</p> <p>A-17-14-52000 (Apr. 2014) A-17-15-52000 (May 2015)</p>
Improper Payments Information	HHS should conduct risk assessments of payments to employees and charge card payments as part of its risk assessment process.	Improved financial management	<p>HHS Met Many Requirements of the Improper Payments Information Act of 2002 but Did Not Fully Comply for FY 2014</p> <p>A-17-15-52000 (May 2015)</p>
Improper Payments Information	HHS should assess the need for additional actions to meet improper-payment rate reduction targets.	Improved financial management	<p>U.S. Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 But Was Not Fully Compliant</p> <p>A-17-13-52000 (Mar. 2013)</p>
Health Information Technology*	ONC and CMS should collaborate to develop a comprehensive plan to address fraud vulnerabilities in electronic health records (EHR).	Improved program integrity and protecting beneficiaries’ personal identifying information	<p>Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology</p> <p>OEI-01-11-00570 (Dec. 2013)</p>
Office of the Assistant Secretary for Financial Resources	<p>ASFR should:</p> <ul style="list-style-type: none"> • Improve procedures to check for duplicative awards. • Create a central office to oversee the Small Business Innovation Research (SBIR) program. 	Improved program management	<p>Vulnerabilities in the HHS Small Business Innovation Research Program</p> <p>OEI-04-11-00530 (Apr. 2014)</p>
Office of the Assistant Secretary for Financial Resources	ASFR should establish a departmentwide source of adverse information from audits of grantees.	Improved program management	<p>HHS Oversight of Grantees could be Improved through Better Information-Sharing</p> <p>OEI-07-12-00110 (Sept. 2015)</p>
Office of the Assistant Secretary for Preparedness and Response	<ul style="list-style-type: none"> • ASPR should continue to promote Federal, State, and community collaboration in major disasters. • CMS should examine existing policies and provide guidance regarding flexibility for reimbursement under disaster conditions. 	Improved safety	<p>Hospital Emergency Preparedness and Response During Superstorm Sandy</p> <p>OEI-06-13-00260 (Sept. 2014)</p>

<p>HHS Financial Reports</p>	<p>HHS should:</p> <ul style="list-style-type: none"> • Continue to develop and refine its financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity. • Continue to focus on remediating the remaining financial management system deficiencies and improve its financial management and review processes. 	<p>Improved financial management</p>	<p>Department of Health and Human Services Fiscal Year 2015 Agency Financial Report. Section II. Daniel R. Levinson, Inspector General, <i>OIG Report on the Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2015</i> (pp. 55, 56, 57, 58, 65, 68, 69, 70, 75, 76, and 77) A-17-15-00001 (Nov. 2015)</p>
<p>HHS Financial Reports</p>	<p>To improve CMS’s financial reporting and related processes, CMS should:</p> <ul style="list-style-type: none"> • Continuously monitor the State Medicaid draws and improve grant oversight activities and report timely, accurately, and consistently on the funds drawn. • Establish a process to perform a claims-level detailed lookback analysis of Medicaid entitlement benefits due and payable to determine the reasonableness of the methodology used to estimate the accrual. • Continue to improve the efficiency of the various error rate processes to allow more time to analyze the findings and the development of remediation plans. • Continue to implement an integrated financial management system to promote consistency and reliability in accounting and financial reporting. • Continue to enhance its process related to the development, documentation, and validation of critical accounting matters and to delegate the responsibility of the centers or offices to provide robust analyses on a routine and recurring basis. • Strengthen oversight and support that will serve to prevent an inordinate backlog of uncertified claims and continue to adhere to established policies and procedures to ensure that the statement of social insurance model methodology, related calculations, and estimates are consistently documented. <p>To improve Medicare information systems controls, CMS should:</p>	<p>Improved financial management</p>	<p>CMS Financial Report, Fiscal Year 2015. Audit Opinion Section. Daniel R. Levinson, Inspector General, <i>Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2015</i> (pp. 118 through 125) A-17-15-02015 (Nov. 2015)</p>

	<ul style="list-style-type: none">• Continually assess the governance and oversight across its organization units charged with responsibility for configuration management and information security of its Medicare FFS systems and data for both the Central Office and the CMS FFS contractors.• Ensure that all application changes and interfaces to CMS systems, including Medicare FFS shared systems, are documented and tested timely, adequately, and completely.• Ensure that appropriate segregation of duties is established for all systems that support CMS's programs, including Medicare FFS claims and related financial processing at claims processing contractors and enterprise data centers to prevent excessive or inappropriate access.		
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