

in the news

Health Care



November 2015

Ignorance is Not Bliss: Get to Know the OIG FY 2016 Work Plan





In this Issue:

Mhat's Now in EV 2016

What s new in FY 2010	_
What's Still a Priority	4
For More Information	5
About Polsinelli's False Claims Act Defense Practice	6

he Department of Health and Human Services Office of Inspector General (HHS-OIG) recently released its FY 2016 Work Plan, in which it identified key areas of focus for the upcoming year. Consistent with its mandate to detect fraud, waste, and abuse, and to hold accountable those who do not meet program requirements or who violate Federal health care laws, the OIG's Work Plan outlines several enforcement initiatives. As a result of the its enforcement initiatives in FY 2015, the OIG excluded over 4,000 individuals and entities from Federal health care program participation and expects to recover over \$3 billion in Federal health care program payments. The 2016 Work Plan runs the gamut of the healthcare industry and offers providers a valuable tool for staying ahead of OIG's enforcement and recovery initiatives.

What Providers Should Know

OIG's FY 2016 Work Plan makes clear that OIG remains committed to ensuring that Federal health care program funds are appropriately used and are recouped where necessary. The OIG conducts audits, evaluations, and investigations to uncover instances of health care fraud and abuse and can impose civil monetary penalties (CMP) where appropriate. Given that CMPs under both the FCA and the Civil Monetary Penalties Law are set to increase by virtue of the newly enacted Bipartisan Budget Act of 2015, it is more important than ever for providers to ensure that they are in compliance with the multitudinous rules and regulations governing the provision of health care services. Health care providers should use the Work Plan as a tool to guide their compliance efforts both now and in the future. For help understanding the initiatives outlined in the Work Plan and how they might impact your entity, please contact Polsinelli.



What's New in FY 2016

For the upcoming fiscal year, the OIG added many new or revised areas of focus. The corresponding FY 2016 audits, evaluations, and investigations will inevitably affect a wide range of providers, though to varying degrees. The following is a sampling of the OIG's new or revised concerns and plans, identified by provider or service type:

Hospitals

- Medicare payments during the MS-DRG payment window. Hospitals should not separately bill Medicare Part B for items, supplies, or services given to hospital inpatients that are covered under Part A. The OIG has identified this as a risk area and will review Medicare hospital payments to determine whether Part B claims for services provided during inpatient stays were allowable.
- Validation of quality reporting data. Because the Centers for Medicare & Medicaid Services (CMS) uses hospital inpatient quality reporting data for the valuebased purchasing program and hospital acquired condition reduction program, the OIG will determine the extent to which CMS validated this data.
- Oversight of provider-based status. The OIG will continue to determine the extent to which provider-based facilities meet federal regulations and CMS guidance. As a new area of focus, the OIG plans to determine the number of provider-based facilities that hospitals own, the extent to which CMS has methods to oversee provider-based billing, and any challenges associated with the provider-based attestation review process.
- Networked medical devices. Because computerized
 medical devices that are integrated with electronic
 medical records and other networks pose a growing
 threat to the security and privacy of patient information,
 OIG plans to assess whether the Food and Drug
 Administration's oversight of networked medical devices
 effectively protects patient information.

Nursing homes

Oversight of corrective action plans. Federal
regulations require nursing homes to submit correction
plans to State survey agencies or CMS when
deficiencies are identified during recertification surveys.
The OIG will determine whether State survey agencies
have, as required by CMS, verified the correction of
identified deficiencies by conducting onsite reviews or
obtaining other evidence of correction.

Therapy billing

• SNF Prospective Payment Requirements. In light of prior reviews finding that Medicare payments for therapy provided at skilled nursing facilities (SNF) greatly exceeded SNF's costs, and that SNFs have increasingly billed for the highest level of therapy, OIG will determine whether SNF Medicare claims were paid at proper levels and in accordance with Federal laws and regulations. This review includes determining whether SNFs complied with documentation requirements to ensure that the care was both reasonable and necessary.¹

Hospice

 Inpatient Care. OIG will expand its audit of Medicare claims for hospice general inpatient care by reviewing patient records to determine the medical necessity of inpatient care and plans of care to determine whether they meet key Medicare requirements.





Physicians

- Provider Eligibility and Enrollment. In an effort to prevent fraud, waste, and abuse resulting from vulnerabilities in the Medicare enrollment process, CMS will determine the extent to which and the way in which CMS and its contractors have implemented enhanced screening procedures for Medicare providers, and will implement site visits, fingerprinting, and background checks. OIG will also review certain Medicare-reimbursed services, supplies and durable medical equipment (DME) to determine whether they were referred/ordered by Medicare-enrolled physicians or non-physician practitioners who are legally eligible to refer/order such services, supplies, or DME.
- **Evaluation and Management Services.** OIG will determine whether evaluation and management home visits, in lieu of an office or outpatient visit, were reasonable and necessary and whether prolonged evaluation and management services, considered to be rare and unusual, were billed in accordance with the Medicare Claims Process manual, given that such services are rarely needed.

Accountable Care Organizations (ACOs)

Medicare Shared Savings Program. OIG will review the performance of ACOs that participate in the Medicare Shared Savings Program for their performance on the program's quality measures and cost savings. OIG will describe the characteristics of those ACOs that performed well, and will identify ACOs' strategies for, and challenges to, achieving quality and cost savings.

Pharmacies

Part D Eligibility Verification transactions. The OIG will review the validity of data submitted by pharmacies with E1 transactions. These are Medicare Eligibility Verification transactions that determine a beneficiary's Part D eligibility and Part D insurance coverage information to the True Out-of-Pocket facilitator, which provides

- pharmacies with information needed to submit a prescription drug event.
- Part D pharmacy enrollment. The OIG reiterated its past concerns about the oversight of Part B and pharmacy-related fraud and will determine the extent to which pharmacies that bill for Part D drugs are enrolled in Medicare.
- Prices of brand-name drugs under Part D. In response to substantial raises in prices, the OIG plans to evaluate the extent to which Part D pharmacy reimbursement for brand-name drugs changed in comparison to the rate of inflation from 2010 to 2014.

Medical Equipment & Supplies

- Medicare payments for orthotic braces. The OIG will compare current Medicare fee schedule amounts for orthotic braces to those of other payors to determine the reasonableness of current rates and to identify potentially wasteful spending. Further, the OIG plans to review Part B payments for orthotic braces to see whether Durable Medical Equipment Prosthetics/ Orthotics, and Supplies (DMEPOS) supplier claims were medically necessary and supported by proper documentation.
- Increased billing for ventilators. In response to increased billing for ventilators in recent years, the OIG will identify billing trends and review factors associated with the increase. The OIG believes suppliers may be inappropriately billing for ventilators for Medicare beneficiaries who do not have life-threatening conditions.





Prescription Drugs

340B Program. The OIG is concerned that Medicare payments for 340B-purchased drugs substantially exceed providers' costs and since 2014 has focused on Part B payments for drugs purchased under the 340B Program. The OIG reiterates in the Work Plan the need to explore different shared savings arrangements, this time specifying that it will determine the financial impact of three shared savings arrangements that would enable both Medicare and its beneficiaries to share in cost savings from the 340B Program.

All Providers

IDC-10 implementation. With the ICD-10 code implementation in its early stages, the OIG indicates that it may assess how the transition is affecting claims processing, including claims resubmissions, appeals, and medical reviews. The OIG may also determine how ICD-10 codes are being applied to certain CMS payment rules and safeguards. Fortunately for providers, the OIG reiterates that CMS will be somewhat flexible during the first 12 months of implementation and that claims may not be denied solely on the specificity of the ICD-10 diagnosis if the physician/ practitioner used the correct family of codes.

Oversight of the security of electronic PHI. The Health Information Technology for Economic and Clinical Health (HITECH) Act requires the Office for Civil Rights (OCR) to periodically audit covered entities and business associates to ensure compliance with the HITECH Act and the Health Insurance Portability and Accountability Act (HIPAA). The OIG is concerned that OCR is not assessing the risks, establishing priorities, or implementing controls for this audit requirement. As a result, the OIG plans to determine the adequacy of OCR's oversight over the security of electronic PHI.

What's Still a Priority

Many areas of focus in years past remain a priority for OIG in FY 2016. Overall, OIG continues to focus on identifying improper and/or fraudulent claims for services that were not

medically necessary. In FY 2016, the OIG plans specifically to continue its enforcement efforts on the following:

- Hospitals. OIG will continue its review of (i) Medicare outlier payments; (ii) how Medicare payments for outpatient and inpatient stays changed under the twomidnight rule; (iii) Medicare payment for compliance with select billing requirements for those hospitals with claims that may be at risk for overpayments; (iv) the extent to which hospitals comply with the contingency planning requirements under the HIPAA Security Rule; and (v) whether hospitals inappropriately received Medicaid payments for care associated with heath care acquired conditions and provider-preventable conditions.
- Home health. OIG will continue to focus on the high incidence of fraud and abuse in the provision and billing of home health services and plans to review home health claims paid by Medicare, including the documentation required to support such claims. The OIG also plans to review Medicaid payments for adult day care services to determine whether providers complied with federal and state requirements.
- **DMEPOS Suppliers.** OIG will continue to focus on compliance with payment requirements for power mobility devices, nebulizer machines, and diabetes testing supplies.
- End Stage Renal Disease (ESRD) Facilities. OIG will continue to review Medicare payments for and utilization of renal dialysis services and related drugs pursuant to the bundled ESRD prospective payment system. Specifically, OIG will review whether the annual updates appropriately reflect changes in price of goods and services.





- Laboratories. OIG remains focused on independent clinical laboratories' compliance with Medicare billing requirements and plans to review payments to identify those labs that routinely submit improper claims and recommend overpayment recovery.
- Nursing homes. Because a high occurrence of emergency transfers often indicates poor quality of care, OIG will continue to review the rate of and reasons for the transfer of nursing home residents to the emergency department.
- Medicaid Program Integrity at the State Level. Because of the significant oversight role the OIG plays over state Medicaid programs, the activities of the OIG are always a pain point for states. When attempting to negotiate resolution to Medicaid audits and investigations, it is always important to have an answer to the question in the state's mind, "what will OIG say when they come to audit us?" The 2016 Work Plan focuses on three Medicaid program integrity issues: (1) oversight of provider ownership information, (2) enhanced provider

screening, and (3) provider payment suspensions following a credible allegation of fraud. Issues (1) and (2) counsel careful attention to Medicaid enrollment revalidations that are ongoing through 2016 in many states. For providers who furnish only limited services to out-state Medicaid beneficiaries, there is a risk that the revalidation and potential screening will not be handled with care for the programs that are billed infrequently. Providers should use caution to avoid automated termination from any state Medicaid program as a result of careless responses to revalidation requirements.

Payment suspensions following a credible allegation of fraud are <u>required</u> by state Medicaid programs unless the program affirmatively determines that a payment suspension could have an adverse effect on an investigation or on Medicaid beneficiaries. Not all states have robustly implemented this rule, but are likely to do so following publication of the 2016 Work Plan. Providers should educate AR staff on the possibility of payment suspensions so they can respond quickly and effectively.



For More Information

For more information regarding this alert, please contact one of the authors, a member of the Polsinelli's False Claims Act practice, or your Polsinelli attorney.

- Brian D. Bewley | 816.360.4372 (KC) 202.626.8326 (DC) | bbewley@polsinelli.com
- Brian F. McEvoy | 404.253.6021 | bmcevoy@polsinelli.com
- Jennifer L. Evans | 3303.583.8211 | jevans@polsinelli.com
- Dayna C. LaPlante | 312.463.6348 | dlaplante@polsinelli.com
- Kevin M. Coffey | 312.873.2986 | kcoffey@polsinelli.com

To contact a member of our Health Care team, click here or visit our website at www.polsinelli.com > Services > Health Care Services > Related Professionals.

To learn more about our Health Care practice, click here or visit our website at www.polsinelli.com > Services > Health Care Services.





About Polsinelli's Health Care Practice

The Polsinelli Health Care practice comprises one of the largest concentrations of health care attorneys and professionals in the nation. From the strength of its national platform, the firm offers clients a depth of resources that cannot be matched in their dedication to and understanding of the full range of hospital-physician lifecycle and business issues confronting health care providers across the United States.

Recognized as the "Law Firm of the Year" in Health Care for 2015 by *U.S. News & World Report*, Polsinelli is ranked no. 1 by *Modern Healthcare* and no. 2 by The American Health Lawyers Association.* Polsinelli's highly trained attorneys work as a fully integrated practice to seamlessly partner with clients on the full gamut of issues. The firm's diverse mix of seasoned attorneys well known in the health care industry, along with its bright and talented young lawyers, enables our team to provide counsel that aligns legal strategies with our clients' unique business objectives.

*Modern Healthcare and AHLA Connections (June 2015).

About Polsinelli

real challenges. real answers. SM

Polsinelli is an Am Law 100 firm with more than 750 attorneys in 18 offices, serving corporations, institutions, entrepreneurs and individuals nationally. Ranked in the top five percent of law firms for client service and top five percent of firms for innovating new and valuable services*, the firm has risen more than 100 spots in Am Law's annual firm ranking over the past six years. Polsinelli attorneys provide practical legal counsel infused with business insight, and focus on health care, financial services, real estate, life sciences and technology, and business litigation. Polsinelli attorneys have depth of experience in 100 service areas and 70 industries. The firm can be found online at www.polsinelli.com. Polsinelli PC. In California, Polsinelli LLP.

* BTI Client Service A-Team 2015 and BTI Brand Elite 2015

About this Publication

Polsinelli provides this material for informational purposes only. The material provided herein is general and is not intended to be legal advice. The choice of a lawyer is an important decision and should not be based solely upon advertisements.

Polsinelli PC. In California, Polsinelli LLP.

