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Department of Health and Human Services OIG Releases 2015 Work Plan

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The United States Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") released its Fiscal Year 2015 Work Plan ("2015 Plan") on October 31, 2014. OIG releases a work plan annually to identify the new and ongoing investigative, enforcement and compliance activities that it will undertake during that fiscal year ("FY").

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Takeaways From OIG's Work Plan

When analyzed and applied effectively, the 2015 Work Plan can be a valuable resource for health care organizations. New initiatives indicate OIG's new priorities. However, continuing initiatives emphasize OIG's continued – and potentially heightened – interest in areas of focus.

Organizations should consider developing internal audit and compliance plans based on OIG's initiatives, including an analysis as to how new and continued initiatives may highlight trends or important areas of focus for the organization. OIG's Work Plan should not be the only compliance guidelines an organization uses for its internal initiatives, but OIG's focus on specific initiatives (including the degree of specificity of OIG's focus) can help an organization shape its compliance program for the coming year.

The remainder of this Update will provide a summary of some of OIG's initiatives as outlined in the 2015 Plan.

Review of 2015 Plan

OIG's annual work plan provides an indication of OIG enforcement priorities during the year. In FY 2014, OIG reported expected recoveries of over $4.9 billion, including nearly $834.7 million in audit receivables and approximately $4.1 billion in investigative receivables. OIG also reported FY 2014 exclusions of 4,017 individuals and entities from participation in federal health care programs; 971 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 533 civil actions, including false claims and unjust enrichment lawsuits, civil monetary penalty settlements and administrative recoveries related to provider self-disclosure matters.

The 2015 Plan includes many initiatives continued from previous years. It also includes new initiatives for FY 2015, including efforts aimed at hospitals, physicians, institutional providers and others, as well as reviews for Medicare Part D, Medicaid, and the Affordable Care Act ("ACA"). This Update summarizes new initiatives as well as highlights of the 2015 Plan.

Medicare Parts A and B

Hospitals and Institutional Providers

OIG reports that its work planning for FY 2015 and beyond will include assessment of: (1) quality of care, including identified gaps in program safeguards and access to care; (2) appropriate payments, including inefficient payment policies or practices, deficiencies in services or medical devices and noncompliance or other vulnerabilities in care settings with high payment error rates; and (3) oversight of payment and delivery reform, including examining the transition from volume- to value-based payments, care coordination and administration of

new payment models.

The 2015 Plan contains two new initiatives for hospitals and institutional providers and continuing initiatives based on OIG's three work planning considerations:

- New Inpatient Admission Criteria. OIG will continue to study the impact of new inpatient admission criteria on billing and payment and how billing varied among hospitals. OIG cited its previous work finding overpayments due to outpatient stays billed as inpatient stays.
- Medicare Costs for Defective Medical Devices. The 2015 Plan notes that OIG will also continue to study the impact of defective medical devices on Medicare costs. OIG cited a concern by the Centers for Medicare and Medicaid Services ("CMS") about the cost of replacement devices.
- Oversight of Provider-Based Status. OIG will study whether provider-based facilities comply with the requirements for provided-based status.
- Swing-Bed Payment Policy. OIG will also study payments for swing-bed services as compared with traditional skilled nursing facility payments. OIG may suggest an alternative payment methodology for swing-bed services.
- Indirect Medical Education ("IME") Payments. In FY 2015, OIG will continue to study payments for indirect medical education, whether providers receive duplicate or excessive IME payments, and whether payments are made in accordance with regulations and guidelines.
- Incorrect Evaluation and Management Coding. OIG will continue to study Medicare payments to hospitals for evaluation and management of "new" patients when patients may not be "new" under Medicare rules.
- Hospital Privileging. OIG will also review hospital processes for privileging medical staff, including verification of credentials and queries of the National Practitioner Databank.
- Hospital Controls Over Wage Data Used to Calculate Medicare Wage Indices. Prior OIG studies of hospital wage data identified substantial incorrectly reported wage data. As a result, CMS changed hospital reporting of deferred compensation cost. While the 2015 Plan does not provide any additional information on what areas of the wage index OIG may investigate, the 2015 Plan notes that OIG intends to review hospital controls over reporting wage data as a new initiative for FY 2015.
- Adverse Events Occurring in Long-Term-Care Hospitals ("LTCHs"). Also new for FY 2015, OIG will estimate the incidence of harm to patients receiving care in LTCHs and will determine factors that contribute to patient harm. OIG notes that LTCHs account for almost 11 percent of post-acute Medicare costs, behind skilled nursing facilities and independent rehabilitation facilities.

Medical Equipment and Supplies

Although the 2015 Plan contains no new medical equipment and supplies initiatives, OIG will continue to study competitive bidding and payments and compliance for specific items, including power mobility devices, lower limb prosthetics, nebulizers, and diabetes testing supplies.

Other Providers and Suppliers

The 2015 Plan outlines enforcement priorities for various other types of providers and suppliers that bill Medicare, including:

- Selected Independent Clinical Laboratory Billing Requirements. New for FY 2015, OIG will review billing practices by independent clinical laboratories to identify such laboratories that routinely use improper billing practices in order to seek recovery of overpayments.
- Inappropriate Billing. OIG plans to examine claims for ambulance, chiropractic and ophthalmology services to determine the extent of questionable and inappropriate billing.
- Medical Necessity and Billing Compliance. OIG will review payments for higher-cost diagnostic radiology tests to determine the medical necessity of such tests and whether the use of such tests has increased. In FY 2015, OIG will also review outpatient services provided by independent physical therapists to determine whether such services were medically necessary and otherwise billed in accordance with Medicare regulations.
- End-Stage Renal Disease Facilities. OIG will review payments and utilization of renal dialysis services and

related drugs under the new bundled end-stage renal disease prospective payment system.

- Anesthesia Services. The 2015 Plan includes OIG's review of payments under Medicare Part B to determine whether anesthesia services were personally performed or medically directed.
- Portable X-ray Equipment. OIG will assess qualifications of technologists that performed portable x-ray services and review documentation used to seek Medicare reimbursement.
- Sleep Disorder Clinics. In FY 2015, OIG plans to analyze whether provision of high-use sleep-testing procedures is appropriate and consistent with applicable regulations.
- Imaging Services. The 2015 Plan includes a determination as to whether payments for imaging services reflect expenses incurred and whether utilization rates are appropriate for industry standards.
- Place-of-Service Codes. OIG will continue to examine physician place-of-service codes to determine whether appropriate codes are used when services are performed in an outpatient setting versus an inpatient setting.

Prescription Drugs

While the 2015 Plan contains no new prescription drug initiatives, OIG will continue a number of initiatives, including the following:

- 340B Program Savings. OIG will study whether Part B payments for drugs could be reduced if Medicare shares in 340B savings.
- Payments for Outpatient Drugs and Administration of Drugs. OIG will analyze Medicare outpatient payments for certain drugs to determine whether Medicare overpaid for the drugs due to incorrect billing.
- Clinical Uses of Part B Drugs. OIG will review the actions of CMS and its contractors to determine if these organizations are ensuring that their Part B drug payments meet coverage criteria, and, as a result, are considered to be safe and effective.

Information Technology Security, Protected Health Information and Data Accuracy

The 2015 Plan notes that the security of electronic data and the use and exchange of health information technology are key considerations for OIG's FY 2015 initiatives, including:

- Medicare Contractor Information Systems Security Programs—Annual Report to Congress. In 2015, OIG intends to review independent evaluations of information systems security programs of Medicare Fiscal Intermediaries, carriers, and Medicare Administrative Contractors and report to Congress on the scope and sufficiency of the independent evaluations.
- Controls Over Networked Medical Devices at Hospitals. OIG will also examine whether CMS oversight of hospital security controls over networked medical devices (e.g., dialysis machines, radiology systems, and medication dispensing systems integrated with electronic medical records) is sufficient to effectively protect electronic health information under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and ensure Medicare beneficiary safety.

In addition to these initiatives, OIG will also examine the extent to which CMS (and its contractors) have implemented enhanced screening procedures (e.g., site visits, fingerprinting, background checks, and automated provider screening processes) for Medicare providers pursuant to ACA requirements. New for FY 2015, OIG will also conduct a risk assessment of internal controls over administration of the Pioneer Accountable Care Organization model.

Medicare Part C and Part D

The 2015 Plan contains one new initiative (oversight of conflicts of interest, as described below) for FY 2015. However, OIG plans to continue its audits and reviews of Part C Medicare Advantage ("MA") and Part D compliance, including the following initiatives:

- Data Integrity of Encounter and Risk Adjustment Data. OIG will review the extent to which MA encounter data are complete and consistent and verified for accuracy by CMS. This review stems from prior audits indicating vulnerabilities in accuracy of risk adjustment data. In FY 2015, OIG will also review medical record documentation to ensure it supports diagnoses submitted by MA organizations and complies with federal requirements. This review also stems from prior reviews indicating lack of support for diagnoses submitted

to CMS.

- Sponsor Compliance with Part D Requirements. OIG will assess sponsors' compliance with Part D requirements, including: (1) the sufficiency of Part D sponsors' documentation supporting administrative costs in annual bid proposals; (2) compliance with requirements for reporting direct and indirect remuneration; (3) adequacy of sponsor compliance and sponsor-submitted data with CMS requirements for reopening final determinations; and (4) the extent to which drug formularies developed by Part D sponsors include drugs commonly used by dual-eligible beneficiaries.

- Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions. New for FY 2015, OIG will determine what steps CMS has taken to improve oversight of Part D sponsors' Pharmacy and Therapeutics committee conflict-of-interest procedures. This new initiative is in response to an OIG report that found that CMS does not adequately oversee compliance with such conflict-of-interest requirements.

In addition to these initiatives, in FY 2015, OIG will assess Part D billing and payment compliance, including documentation of pharmacies' prescription drug event data, payments for HIV drugs for deceased beneficiaries, and quality of sponsor data used to calculate coverage-gap discounts.

Medicaid

OIG's focus on the Medicaid program for FY 2015 expands OIG's interest on fraud, waste, and abuse and continues OIG's previous initiatives addressing prescription drugs, billing and payment, quality and safety, community-based care, information system controls and security, and Medicaid managed care.

- Medicaid Prescription Drug Reviews. OIG will continue to monitor manufacturer compliance with average manufacturer price reporting and state rebate collection and reporting, including a new initiative that studies state collections of prescription drug rebates from Medicaid managed care organizations.

- Billing and Payment, State Claims for Federal Reimbursement and Quality of Care and Safety of Beneficiaries. In FY 2015, OIG will review payments for adult day care services to assess compliance with state and federal requirements, including the requirement for services to be furnished in accordance with a plan of care. OIG will also assess whether states claimed federal reimbursement for unallowable room and board costs under the Home and Community Based Services waiver program. Further, OIG will review health-screening records of home health agency health care works to determine compliance with federal and state requirements for screenings.

- Billing and Payment. OIG will continue to determine whether Medicaid payments for medical equipment and supplies could be lowered through mechanisms such as rebates and competitive bidding. OIG will also continue to study Medicaid payments and compliance issues for certain services, including transportation, health-care-acquired conditions, dental services for children, and family planning services.

- State Claims for Federal Reimbursement. OIG has two new initiatives for state claims for federal funding. One will study the Community First Choice State plan option, a new program under ACA that permits states to provide attendant services and other support to individuals who qualify for institutional care. The other study will review state claims under the Balancing Incentive Program, another new program under ACA that provides states enhanced funding for Medicaid long-term services and support.

- Quality of Care and Safety of Beneficiaries. OIG will continue two quality and safety studies for Medicaid beneficiaries. It will continue to review access to pediatric dental care and use of preventive screening services for children. OIG will also start a new review of Medicaid beneficiary transfers between group homes or nursing facilities to hospital emergency departments. According to OIG, these transfers raise quality of care concerns and are of "congressional interest."

- Medicaid Eligibility Determinations. In FY 2015, OIG will determine the extent to which states made inaccurate eligibility determinations, including states that expanded their Medicaid programs under ACA as well as states that did not expand their Medicaid programs. OIG will calculate the Medicaid eligibility error rate and determine the amount of payments associated with beneficiaries who received incorrect eligibility determinations.

- Program Integrity Actions and Oversight of Fraud Control Units. The 2015 Plan notes that OIG will: review state actions to address vulnerabilities identified during CMS reviews, assess providers' patient accounts to determine whether there are Medicaid overpayments in accounts with credit balances, review payments to providers during pending investigations of credible fraud allegations and conduct in-depth onsite reviews of state Medicaid Fraud Control Units and identify areas for improvement.

- Medicaid Information System Controls and Security. OIG's focus on information system controls and security will also include Medicaid-related reviews in FY 2015, including: assessment of the adequacy of CMS oversight of state security controls for information system networks, databases, web-facing applications, logical access and wireless access as well as disaster recovery plan and physical security.

- Medicaid Managed Care. New for FY 2015, OIG will identify trends in Medicaid managed care claims with dates of service after beneficiaries' dates of death and assess Medicaid managed care payments made on behalf of beneficiaries not eligible for Medicaid. OIG will also examine the completeness and accuracy of managed care encounter data in the Medicaid Statistical Management System, assess whether Medicaid managed care organizations identified and addressed potential fraud and abuse incidents, and review beneficiary protections (e.g., provider networks and access to services, grievances and appeals processes, and marketing practices).

CMS-Related Legal and Investigative Activities

The 2015 Plan notes that OIG will continue to leverage its authority under the False Claims Act, Civil Monetary Penalties statute, Anti-Kickback and Stark rules, among other statutes and regulations, to combat fraud against federal healthcare programs.

Public Health Reviews

OIG reports that it will continue to work with public health agencies within HHS, such as the Centers for Disease Control and Prevention, in FY 2015 to ensure such agencies are effectively managed and receiving proper resources to address key risk areas, including preparedness to respond to public health emergencies.

Affordable Care Act Reviews

OIG's planned reviews for FY 2015 will assess implementation and operation of ACA programs as well as progress toward achieving program goals. OIG reports that it will prioritize three main areas in FY 2015: (1) the health insurance marketplaces; (2) Medicare and Medicaid reforms; and (3) grant expenditures for public health programs. OIG FY 2015 initiatives include:

- Marketplaces, Financial Assistance Payments, and Market Stabilization Payments. OIG will focus on proper expenditure of taxpayer funds and the efficient and effective operation of the marketplaces in FY 2015. This review includes assessment of: (1) accuracy of aggregate payments to quality health plan issuers for advanced premium tax credits and cost sharing reductions; (2) accuracy of advance premium tax credits and cost sharing reduction payments for individual enrollees; and (3) CMS internal controls for generating, reviewing, and approving advance premium tax credit payments. The 2015 Plan also includes a number of additional related initiatives for FY 2015.

- Eligibility. OIG will assess effectiveness and efficiency of marketplace eligibility and enrollment, including enrollment safeguards, eligibility verifications for premium tax credits, and inconsistencies in the federally facilitated marketplace data.

- Security. OIG will also review information system security of HealthCare.gov, which may include conducting vulnerability scans and review of reports related to prior vulnerability assessments and timeliness of remediation. OIG will also review whether information security controls for state-based marketplaces have been implemented in accordance with federal requirements and recognized industry best practices. These state-based reviews will also include vulnerability scans of web-based systems.

In addition to the initiatives outlined above, the 2015 Plan notes that OIG is committed in FY 2015 to initiating at least five to ten additional reviews addressing ACA programs, which would focus on emerging marketplace issues, Medicaid expansion, new Medicare payment and delivery models or new grant programs.

Recovery Act Reviews

Under the American Recovery and Reinvestment Act of 2009 ("Recovery Act"), OIG received funding for discretionary oversight of certain HHS programs and operations. The 2015 Plan includes OIG's continuing initiatives to monitor oversight of HHS agencies' use of Recovery Act funds, including:

- Adoption of Electronic Health Records. OIG will review Medicare incentive payments to eligible health care professionals and hospitals adopting electronic health records ("EHRs") to identify providers that should not have received incentive payments (i.e., providers that did not meet meaningful use criteria). OIG will also review Medicaid incentive payments to Medicaid providers and hospitals for adopting EHRs and CMS

safeguards to prevent erroneous incentive payments. OIG will review whether such incentive payments were claimed in accordance with Medicaid requirements and assess CMS actions to recover erroneous incentive payments.

- Systems and Information Security. In FY 2015, OIG will perform audits of various covered entities receiving EHR incentive payments as well as their business associates to determine whether they adequately protect electronic health information created or maintained by certified EHR technology.
- Fraud and Whistleblower Reprisals. The 2015 Plan notes that OIG will also continue to evaluate credible allegations of improper expenditures of Recovery Act funds and credible allegations of reprisals against whistleblowers to identify cases in which criminal investigations should be opened and enforcement actions pursued.

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