Summary of HHS OIG's 2012 Work Plan

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The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) recently issued its Work Plan for fiscal year (FY) 2012. The plan identifies OIG's primary focus areas of reviews for the coming year, some of which are new. The summary below identifies the most significant reviews identified in the Work Plan.

Part I: Medicare Part A

Home Health Services

In the upcoming year, HHS will take a more proactive step in regulating the submission of and payment for Medicare Part A benefits. Regarding claim sufficiency, OIG intends on reviewing Outcome and Assessment Information Set (OASIS) data submitted by Medicare-certified home health agencies (HHAs), including the Centers for Medicare & Medicaid Services' (CMS') process for ensuring that HHAs submit accurate and complete OASIS data. This data, among other things, specifically reflects HHAs'

performance in helping patients to regain or maintain their ability to function and perform activities of daily living. In addition, OIG will review HHAs' OASIS data (which is submitted electronically to CMS) to identify payments for episodes for which OASIS data were not submitted or for which the billing code on the claim is inconsistent with OASIS data.

Also, OIG will take an active role in the oversight of Medicare Administrative Contractors (MAC) whose purpose is to reduce payment errors by preventing initial payment of claims that are not compliant with Medicare's coverage, coding, payment, and billing policies. OIG will begin to review the reduction of payment errors by MACs.

In addition to the oversight of MACs, OIG also will be reviewing home health claims to identify HHAs that exhibited questionable billing (claims that exhibit certain characteristics that may indicate potential fraud) in 2010. Moreover, a more in-depth review of claims submitted by HHAs will determine the extent to which the claims meet Medicare coverage requirements, specifically assessing the accuracy of resource group codes from 2008 to identify characteristics of miscoding. Prospectively, Medicare will reimburse for home health episodes using a system that categorizes beneficiaries into groups based on care and resource needs called Home Health Resource Groups (HHRG).

HHAs operate under the Prospective Payment System (PPS). OIG will review compliance with various aspects of the home health PPS including documentation in support of claims. The cost report data also will be reviewed to determine whether the payment methodology should be adjusted since HHA expenditures have increased significantly since PPS was implemented.

Hospitals

Ongoing reviews of hospital policy and procedure were noted. Specifically, OIG will review: the type of information hospitals' incident-reporting systems capture about adverse events to determine the extent to which hospital systems captured adverse events and reported the information to external patient-safety oversight entities;

hospitals' controls for ensuring the accuracy and validity of data related to quality of care that they submit to CMS for Medicare reimbursement; provider data from CMS' Intern and Resident Information System (IRIS) to determine duplicate or excessive graduate medical education payments; and whether hospitals reported occupational-mix data used to calculate inpatient wage indexes in compliance with Medicare regulations.

To determine proper services and billing, OIG will review claims to determine which types of facilities are most frequently transferring patients with certain diagnoses that were coded as being present on admission (POA) and particularly review the accuracy of the POA indicators on inpatient claims submitted in 2008. Additionally, OIG will continue to review Medicare claims to determine trends in the number of same-day hospital readmission cases and begin to review claims for inpatient stays for which the beneficiary was transferred to hospice care to examine the relationship between the acute-care hospital and the hospice provider, as well as the appropriateness of admissions to Inpatient Rehabilitation Facilities (IRFs).

To protect the Medicare Trust Fund, OIG will pay particular attention to Medicare payments to hospitals to determine compliance with selected billing requirements, the results of which will recommend recovery of overpayments and identify providers that routinely submit improper claims. Also, a review of inpatient outlier payments, to determine trends of outlier payments nationally, will be conducted that will help determine whether CMS performed the necessary reconciliations in a timely manner. Claims with high payments will be reviewed for appropriateness as well as payments for non-physician outpatient services that were provided to beneficiaries shortly before or during Medicare Part A covered stays at acute care hospitals or non-inpatient prospective payment system hospitals and observation services provided by hospital outpatient departments

Payments for brachytherapy will continue to be reviewed to ensure compliance with Medicare requirements. Lastly, OIG will review payments for the insertion of replacement medical devices for compliance and begin to review reimbursement for dental services that are generally excluded.

Nursing Homes

OIG will continue reviewing how SNFs have addressed certain federal requirements related to quality of care. They also will begin reviewing the quality of care and safety of Medicare beneficiaries transferred from acute-care hospitals to post-acute care, in particular the transfer process and rates of adverse events and preventable hospital readmissions. Similarly, CMS' and states' use of enforcement measures to determine their impact on improving the quality of care that beneficiaries received in poorly performing nursing homes will be reviewed.

Generally, Medicare- and Medicaid-certified nursing homes' implementation of compliance plans as part of their day-to-day operations and whether the plans contain elements identified in OIG's compliance program guide will be assessed. Likewise, OIG will assess deficiencies of nursing homes' emergency plans and emergency preparedness cited by state surveyors for sufficiency.

Also, OIG will review: the extent to which payments to SNFs meet Medicare coverage requirements and the extent to which Medicare beneficiaries residing in nursing homes have been hospitalized and rehospitalized. OIG also will identify questionable billing patterns associated with nursing homes and Medicare providers for Part B services provided to nursing home residents whose stays are not paid for under Medicare's Part A SNF benefit.

Hospices

Hospices' marketing materials and practices and their financial relationship with nursing facilities will be reviewed since OIG found in a recent report that 82% of hospice claims for beneficiaries in nursing facilities did not meet Medicare coverage requirements. Also, the appropriateness of hospices' general inpatient care claims and hospice beneficiaries' drug claims billed under Part D will be reviewed using data from hospice general inpatient care from 2005 to 2010.

Medicare Part A and Part B Contractor Operations

The only new review relating to Medicare contractors is the Contractor Error Rate Reduction Plans (CERT). OIG will focus particularly on the extent to which Medicare contractors have error rate reduction plans in place and the extent to which the plans have resulted in lower error rates for contractors. These plans should describe the corrective actions that contractors plan to take to lower the CERT paid-claims error rate and provider-compliance error rate in their jurisdictions.

Part I: Medicare Part B

Common to All Part B Claims

OIG will review Medicare claims submitted with G Modifiers (indicating that the supplier expected Medicare to deny payment), and the extent to which Medicare paid such claims. OIG also will look for suppliers with atypically high billing related to the G modifiers. Another review will seek to determine the nature and extent of Medicare payments for services ordered or referred by excluded providers. In another ongoing review, OIG will review Part A and Part B claims submitted by "error-prone" providers, project the results to the populations of claims (i.e., extrapolate), and recommend that CMS request refunds on projected overpayments.

Laboratories

No new reviews were proposed for clinical laboratories, but ongoing projects were noted, all of which are expected to be completed during FY 2012. These include a review of trends in laboratory utilization, including the types of tests and the numbers of tests ordered. This analysis also will include OIG scrutiny as to what factors may influence physician ordering of laboratory tests. Another ongoing review will examine how the methods of establishing Medicare laboratory test payment rates vary from those of state Medicaid and Federal Employee Health Benefits programs. The

methodology for this review will compare Medicare payment rates for 20 lab tests (those identified as most frequently ordered and most costly in terms of total dollars paid) against the payment rates of those other programs. Finally, OIG will continue to work on its review of Part B payments for glycated hemoglobin A1C tests, with a focus on the Medicare contractors' procedures for screening for appropriate frequency of testing.

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Ongoing Reviews

DMEPOS suppliers continue to attract significant attention from OIG. One ongoing review is focusing on the Medicare contractors' processes for enrolling and monitoring suppliers, including use of enrollment screening mechanisms to identify applicants that pose fraud risks, and the extent to which applicants omitted ownership information on their applications. OIG will continue its scrutiny of the credentials of orthotists and prothetists, including whether CMS provided adequate guidance to state licensing boards and industry on how to define a "qualified practitioner." Another ongoing OIG review will compare supplier acquisition costs to Medicare reimbursement for back orthoses, noting that internet pricing is significantly lower than what Medicare pays. OIG also plans to continue to review the appropriateness of Medicare durable medical equipment (DME) payments by scrutinizing DME suppliers in selected geographic areas with high-volume claims including power mobility devices, hospital beds and accessories, oxygen concentrators, and enteral/parenteral nutrition.

The frequency of replacement of supplies for DME also will continue to be reviewed, with the Work Plan specifically noting preliminary OIG work that identified the shipment of supplies without a physician order for refills in contradiction to Medicare's rules. OIG also will review DMEPOS claims to determine if modifiers are being used that correctly indicate that appropriate documentation is available to support the suppliers' claims. In another review, Medicare's fee schedule for parenteral nutrition will be compared to other sources of reimbursement. Claims for home glucose testing supplies also will be reviewed for appropriateness, compliance with the physician order documentation

requirements, and appropriate use of modifiers on the claims to denote insulin treatment.

Two ongoing reviews will address competitive bidding. The first will examine the process used by CMS to implement competitive bidding (this review is required by law). The second will interview physicians to determine whether those suppliers participating in competitive bidding are soliciting physicians to prescribe certain products that are more profitable for the suppliers. OIG also will review billing patterns to identify changes resulting from competitive bidding.

New Reviews: The Work Plan indicates that all the new DMEPOS reviews are expected to be completed during FY 2012. These include one review that focuses on the effectiveness of CMS contractor system edits to prevent payments to multiple suppliers for the same beneficiary's home blood glucose testing supplies. Another review will look at claims for diabetic testing supplies to identify "questionable billing," and identify characteristics that may be indicative of fraud, waste, and abuse (one example given: diabetic testing supplies provided at irregular intervals). OIG also will scrutinize supplier acquisition costs for support surfaces as compared to Medicare payment rates. In addition, OIG will review CMS' use of surety bonds to recover overpayments made to DMEPOS suppliers.

Organ Procurement Organizations

In a study new for FY 2012, OIG will review Medicare payments to Organ Procurement Organizations to determine if those payments were correct and supported by documentation, including whether the organizations correctly reported organ statistics for purposes of proper allocation of costs in their cost reports.

Ambulances

One new review will compare reimbursements by other payors to those of the Medicare fee schedule for similar services. Another new review will examine Medicare claims data to identify questionable billing, such as transports that were potentially not medically reasonable and necessary, and potentially unnecessary billing for Advanced Life Support Services and specialty care transport. OIG also plans to examine relationships between ambulance companies and other providers.

Physicians

Ongoing Reviews: OIG will continue the review of physicians' compliance with the assignment rules to determine to what extent beneficiaries are being inappropriately billed in excess of the Medicare allowable amounts. OIG also will continue its study of Place-of-Service (POS) claims errors when physician services are provided in a location that receives facility fees (resulting in excess payments to the physician if the POS is identified as a non-facility setting).

OIG will continue its review of Evaluation and Management (E/M) services, seeking to identify trends in the coding of E/M services from 2000-2009. It also will continue its study to determine if implementation of a global surgery fee has affected the number of E/M services provided by physicians. (In a new study, OIG also will look at the use of modifiers for services provided during the global surgery period.) OIG will continue to assess the extent to which CMS made potentially inappropriate payments for E/M services and the consistency of E/M medical review determinations.

New Reviews

OIG will examine payment systems controls that identify high cumulative payments to physicians and suppliers, a factor that OIG's prior work has indicated is often a clue to incorrect billing or fraud and abuse. OIG also will review the extent to which physician-owned distributors (PODs) provide spinal implants purchased by hospitals, and whether

those PODs are associated with high use of spinal implants. “Incident to” services will be reviewed to determine whether they reflect a higher rate of error than that of non-incident-to services; OIG noted its concerns with the potential for unqualified non-physicians performing incident-to services, and its suspicions that such services may be prone to overutilization. OIG plans to review the impact of the “opt out” [of Medicare participation] option, to determine whether physicians continue to submit claims despite opting out, as well as whether the option is exercised more prevalently in certain geographic areas and whether beneficiaries are potentially affected by this option. Finally, chiropractic billing will be reviewed to determine if Medicare payments are in accordance with the limited coverage allowed by Medicare requirements.

Ambulatory Surgical Centers (ASCs)

OIG will review the appropriateness of Medicare’s methodology for setting ASC payment rates. In a review new for FY 2012, OIG will examine the safety and quality of care for Medicare beneficiaries receiving services in ASC and Hospital Outpatient Departments, apparently looking to compare the results for the two settings.

Part B Imaging Services

OIG will continue its review of Medicare payments to determine whether they reflect the expenses incurred and whether utilization rates reflect industry practice.

Clinical Social Workers

OIG will continue its review as to whether clinical social worker services were inappropriately billed to Part B during a beneficiary’s Part A hospital or SNF stay.

Partial Hospitalization

In a new study, OIG will identify “questionable billing” characteristics associated with partial hospitalization (PHP) claims submitted by community mental health centers, and examine fraud prevention and detection activities by relevant CMS contractors. OIG also will continue its ongoing review of PHP services in other settings, including whether payments met Medicare requirements for documentation of plan of care and physician supervision and certification requirements.

Independent Therapists

OIG will continue its review of outpatient physical therapy services, focusing on independent therapists who have a high utilization rate.

Sleep Disorder Clinics

For this ongoing review, OIG will examine the appropriateness of Medicare payments to physicians and independent diagnostic testing facilities for sleep test procedures, including appropriate use of modifiers that impact payment. Polysomnography payments also will be examined.

Diagnostic Radiology

For this ongoing review, OIG will look at Medicare payments for high-cost diagnostic radiology tests to determine if they were medically necessary and whether the same diagnostic tests are repeated for the same beneficiary when ordered by different physicians treating the patient.

Comprehensive Outpatient Rehabilitation Facilities (CORFs)

In this ongoing study, OIG will review utilization patterns, identify CORFs in high-utilization areas, and determine whether they met basic Medicare requirements.

End-Stage Renal Disease (ESRD)

In one ongoing review, OIG will look at payments for ESRD benefits for individuals who may no longer meet eligibility criteria (for example, those receiving benefits more than 36 months after a kidney transplant). In one new study, OIG will look at Medicare's oversight of dialysis facilities, including the accountability of state survey and certification agencies. In another new review, OIG will look at Medicare pricing and utilization under the new ESRD-PPS "bundled" payment. OIG will also be reviewing ESRD drug payments.

Part B Payments for Prescription Drugs

Ongoing Reviews

OIG will continue several ongoing reviews, including a comparison of average sales prices to average manufacturer prices; and a comparison of average sales prices to widely available market prices. It also will continue its review as to whether immunosuppressive drugs were billed according to their Food and Drug Administration (FDA)-approved labels. OIG will continue to examine payments for off-label anticancer pharmaceuticals and biologicals, and whether alternative drugs might have continued to be used instead. OIG also will look at acquisition costs and payments, and usage patterns and payments, for Lucentis and Avastin related to treating wet age-related macular degeneration.

New Reviews

OIG has identified five new reviews for FY 2012. It will review payments for ESRD drugs under the new bundled system (ESRD-PPS). Another review will focus on payments for commonly used physician administered drugs and biologicals to determine if significant savings could be achieved by a change in Part B reimbursement methodologies. Another new review will focus on off-label and off-compendia use of drugs, and identify CMS oversight mechanisms. OIG also will be scrutinizing payments associated with the

drug Herceptin, and whether wastage allowances were billed appropriately. OIG also will look to see if outpatient drug claims (e.g., chemotherapy) were paid inappropriately because of incorrect coding or overbilling of units.

Part II: Medicare Parts C and D

Part C (Medicare Advantage (MA))

OIG will review the appropriateness of reimbursement for beneficiaries classified as institutionalized, ESRD, or Medicaid eligible to determine the inaccurate or invalid classification of beneficiaries on Medicare payments to MA plans. On a related note, a review of the extent to which certain drugs for institutionalized beneficiaries were paid by Part D in 2008, which should have been covered by Part C, will be conducted. Similarly, OIG will look at supporting data for beneficiary diagnosis codes submitted by MA organizations that offer prescription drug plans (MA-PD) to determine the accuracy of the data and the validity of the diagnosis codes.

To ensure the quality of care, quality of claims, and validity of payments under an MA plan, OIG will continue to: determine whether the diagnoses that MA organizations submitted to CMS for use in CMS' risk-score calculations complied with federal requirements; determine whether CMS properly adjusted payments to MA plans based on the results of its calendar year (CY) 2007 data validation reviews; assess work performed by CMS' Office of the Actuary and its contracted actuary reviewers to ensure that its reviewers of Part C bids are in accordance with Medicare policies and procedures and that issues identified during reviews are sufficiently addressed before bid approval; review MA organizations' oversight of contractors that provide enrollees benefits, such as prescription drugs and mental health services; review MA plans' oversight of contractors that provide DME and services to enrollees; review the extent to which potential fraud and abuse incidents were identified and addressed by MA organizations in 2009; and review MA organizations' compliance with CMS' reporting requirements for plan year 2009.

Significantly, OIG will begin reviews to: determine the amounts of quality-based bonus payments made to unrated MA plans in 2011 and 2012 (and the extent to which CMS collects data for MA plans that are unrated); and determine the extent to which MA plans vary in their compensation of filed marketing organizations.

MA enforcement also will seek to identify duplicate Medicare capitation and fee-for-service (FFS) payments to selected cost-based Health Maintenance Organization (HMO) plans. Also, OIG will review expenditures claimed on cost reports by selected Health Care Prepayment Plans (HCPP) to determine whether selected HCPPs' expenditures were reasonable and allowable for reimbursement.

Part D (Prescription Drug Program)

Part D Drug Pricing and Payment-Related Reviews

OIG will being reviewing annual change in prices for brand-name prescription drugs used by Medicare Part D beneficiaries and determine whether Part D prices (including rebates) are rising faster than inflation. The price increases also will help determine how brand-name drugs affect Medicare Part D payment amounts. Prescription Drug Event (PDE) records for Schedule II drugs now will be reviewed to determine whether Part D sponsors are in compliance with federal regulations prohibiting refills of prescriptions for Schedule II drugs. PDE data also will be used to determine the extent to which sponsors submitted data for prescription drugs for incarcerated individuals under Part D and with Part D payment data and CMS-approved Part D formularies to determine the extent to which selected Part D sponsors submitted data for drugs that were not included on their approved Part D formularies and whether costs submitted by sponsors were for drugs that were not included in their approved formularies.

Claims also will be reviewed for a number of reasons: to determine whether they were duplicated in Part A or Part B, and the extent to which payments for the sampled Part D claims were correct and supported; to determine the appropriateness of drug claims for individuals who are receiving hospice benefits under Medicare Part A and drug coverage under Medicare Part D; to identify aberrant claims and determine how they

relate to pharmacies, physicians, and/or beneficiaries; to determine whether Part D claims were paid at the discounted prices available at certain retail pharmacies, and whether the Plan Finder Website is accurately reporting these prices to beneficiaries; and to identify the extent to which Part D plan sponsors are applying utilization management (UM) controls for drugs on their formularies that are not approved by CMS.

Generally, Part D drugs billed in 2009 will be reviewed to identify characteristics of associated pharmacies, prescribers, and beneficiaries. Also, drug costs for specific Part D-covered drugs on PDE records will be reviewed to determine whether contracted prices between pharmacies and Part D sponsors were accurately reflected. Also, the following will be reviewed relating to Part D sponsors: pharmaceutical manufacturer rebates collected by Part D sponsors and pharmacy benefit managers; risk-sharing between the government and Part D sponsors for plan years 2006 to 2010 and the financial impact of risk corridors on the Part D program; accuracy of Part D sponsors' tracking of beneficiaries' true out-of-pocket costs; and data submitted by Part D sponsors used in calculating the coverage gap discount, for at least ensuring that beneficiary payments were correct.

Regarding particular drugs, OIG will specifically review the extent to which CMS' payments to Part D sponsors subsidized the prescribing of Revatio for erectile dysfunction since January 1, 2007 and identify questionable billing for human immunodeficiency virus (HIV) drugs under Medicare Part D. Lastly, CMS' processes for reopening final payment determinations and the coverage determination and appeals processes Part D sponsors established pursuant to federal regulations will be reviewed.

Part D Administration and Program Integrity

The only new administration and program integrity-related review evaluates the operations of the Medicare Prescription Drug Integrity Contractors (MEDIC) to provide an update on previously identified issues, a functional realignment, and MEDICs' fulfillment of additional responsibilities for the Medicare Part C and D programs.

Part III: Medicaid

In FY 2012, OIG will continue or begin new reviews in six areas of the Medicaid program. OIG identified the following areas for review: prescription drugs; long term and community care; other services; program integrity and accountability; administration; information systems; and managed care. The main focus, as could be expected, will be on fraud detection.

Prescription Drugs

The prescription drug review by OIG will focus on pricing practices of manufacturers and the claim submission process. With regard to pricing, OIG intends to primarily review calculation of average manufacturer prices and federal upper limit amounts. These pricing reviews will be made to assess whether manufacturers are complying with all reporting obligations and whether prices charged to the Medicaid program are appropriate. On the claim submission side, OIG will examine whether states accurately submit claim forms and resolution of rebate disputes. New reviews include states' collection of rebates for drugs paid by managed care organization, federal share of rebates, and rebates on new formulations.

Long Term and Community Care

The review of home, community, and personal care services will focus upon qualifying for such services and the quality of such services. OIG wants to ensure that only eligible Medicaid beneficiaries receive services to avoid overbilling. A new review will be conducted of homebound requirements, which must be met to qualify for home health services. On the quality side, OIG will examine programs to ensure that appropriate standards of care are satisfied.

Other Medicaid Services and Payments

The Other Medicaid Services and Payments review focuses mostly upon ensuring claims for services are accurate or otherwise compliant with regulations. OIG indicated that previous reviews found inconsistencies in bills that did not support claims actually paid out. This review corresponds to similar review and enforcement activities under Medicare. A new review will focus on payments for healthcare-acquired conditions, which are no longer covered as of July 1, 2011.

Medicaid Integrity and Accountability

The Medicaid Integrity and Accountability reviews focus upon fraud detection efforts and state efforts. On the fraud detection front, OIG will assess the performance of various contractors, including Medicaid Integrity Contractors and Medicaid Fraud Control Units, to determine whether such contractors are sufficiently identifying weaknesses in the program. A new push will be made to review compliance with new exclusion provisions that result in exclusion from all programs if a provider or supplier is excluded anywhere. OIG will review information included in Form CMS-64, which will provide information on, among other matters, claim reporting and overpayment recovery. Lastly, OIG will review implementation of the Payment Error Rate Measurement Program.

Program Administration, Information Systems, and Data Integrity

The Program Administration, Information Systems, and Data Integrity reviews seek to ensure that states properly manage their Medicaid programs and do not allow ineligible individuals to receive benefits or provide uncovered services. A new initiative will review implementation of the National Correct Coding Initiative, which all states had to comply with as of April 1, 2011. Reviews of data security also will occur, with a focus on business associate agreements and controls over web-based applications.

Medicaid Managed Care

The Medicaid Managed Care reviews fall in line with the other more general review subjects. OIG wants to ensure that encounter data is complete and accurate, which oversight is the domain of CMS. OIG also will look at marketing practices, state oversight of provider credentialing by managed care entities, employment of excluded individuals, and generalized fraud and abuse safeguards. These reviews will examine compliance with federal law and regulation with regard to program integrity and prevention of waste. Lastly, OIG will review managed care plans' medical loss ratio since prior reviews showed that both loss ratios were not met and refunds were not made to state agencies.

Part IV: Legal and Investigative Activities Related to Medicare and Medicaid

Legal Activities

OIG will continue its full panoply of traditional legal activities, including litigation of program exclusions and civil monetary penalties and assessments, monitoring Corporate Integrity Agreements, and issuing fraud alerts, advisory opinions, and other industry guidance. A significant new activity that OIG will initiate during FY 2012 will include:

Reviews of Entities That Do Not Enter into Corporate Integrity Agreements

OIG will review providers, suppliers, and other entities that settled fraud cases with the government but "declined" to enter into a Corporate Integrity Agreement. OIG says its reviews may be "similar to or more extensive" than those reviews that would be performed by an Independent Review Organization under a Corporate Integrity Agreement.

Investigative Activities

In FY 2012, OIG will continue to devote significant resources to investigating Medicare and Medicaid fraud. It will continue to work collaboratively with the Department of

Justice, CMS, and other federal agencies to quickly identify and prosecute fraud. OIG and CMS will continue to impose payment suspensions on providers and suppliers who have been targeted as engaging in potentially fraudulent activity.

Part V: Public Health Reviews

OIG reviews the activities of many public health agencies within HHS, including the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control (CDC), the FDA, the Health Resources and Services Administration (HRSA), and the National Institutes of Health (NIH). Significant new reviews that OIG will initiate during FY 2012 include:

Early Implementation of Patient Safety Organizations (AHRQ)

OIG will review the policies and activities of Patient Safety Organizations (PSOs), which are non-governmental entities certified by HHS to evaluate adverse events from hospitals and other healthcare settings. OIG's review will include determining the extent of participation among hospitals, PSO practices for evaluating adverse event reports, and the extent to which PSOs provide information to providers and the Network of Patient Safety Databases maintained by AHRQ.

Funding Recipients' Use of Funds and Accounting Procedures (CDC)

OIG will initiate a number of reviews to determine whether CDC's grantees of Affordable Care Act and Prevention and Public Health Funds have the capability to manage and account for those funds, are able to fulfill program requirements, and are using funds for authorized purposes.

Financial Controls (CDC)

OIG will review the CDC's controls over payments for goods and services, including purchases made with Affordable Care Act funds, compliance with federal requirements in the use of service contracts to assist its Procurement and Grants Office (PGO), and CDC processes for designating and monitoring high-risk grantees.

Complaint Investigation Process (FDA)

OIG will begin reviewing the adequacy of FDA's complaint investigation processes, including FDA's processes for using complaints to identify potentially significant trends or patterns in reported illnesses or injuries.

Oversight of Investigational New Drug Applications (FDA)

OIG will review the FDA's process for evaluating investigational new drug (IND) applications, including identifying timing issues and challenges in the IND review process.

Implementation of the Risk Evaluation and Mitigation Strategies Program (FDA)

OIG will examine how the FDA ensures drug manufacturer compliance with the requirements of the Risk Evaluation and Mitigation Strategies (REMS) program, including reviewing manufacturer evaluation of the REMS program's ability to minimize consumer risk.

Community Health Centers (HRSA)

OIG will review community health centers that received Affordable Care Act funds to determine whether they are complying with federal requirements, including the centers' ability to manage and account for federal funds.

Informed Consent and Privacy Protection Procedures for NIH Grantees Conducting Genetic Research (NIH)

OIG will review whether NIH grantees that conduct genetic research are complying with federal informed consent requirements for human subjects, and what procedures and protections grantees use to determine that human subjects' private information stored in biobanks is protected in future research.

University Recipients of Research Grants (NIH)

OIG will look at whether university faculty members working on NIH grants inappropriately drew salaries from multiple universities. OIG also will determine whether universities are complying with accounting requirements for federal grants, specifically with respect to cost-sharing requirements.

Part VI: Human Services Reviews

OIG's Human Services reviews focus on the activities and programs of the Administration on Aging (AoA) and the Administration for Children and Families (ACF). With respect to federal healthcare programs, a significant new activity that OIG will initiate during FY 2012 will include:

Reviews of Performance Data for Senior Medicare Patrol Projects

These projects, administered by the AoA, recruit retired professionals to educate and counsel Medicare beneficiaries on how to detect and report fraud, waste, and abuse in the Medicare and Medicaid programs.

Part VII: Other HHS-Related Reviews

OIG annually undertakes a number of reviews addressing department-wide issues, such as financial statement audits; financial accounting; information systems management; and other departmental issues. OIG plans to continue these activities in FY 2012. With respect to federal healthcare programs, a significant new activity that OIG will initiate during FY 2012 will include:

Fraud Vulnerabilities Presented by Electronic Health Records

OIG will investigate fraud and abuse vulnerabilities in electronic health records (EHRs) systems and seek to determine how certified EHR systems address these vulnerabilities.

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