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New OIG Work Plan Offers Healthcare Providers a Road Map of Upcoming Investigations

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The fiscal year (FY) 2016 U.S. Department of Health and Human Services Office of Inspector General (OIG) work plan lists 84 projects applicable to healthcare providers, 19 of which are new for 2016. Much of the FY 2016 work plan is a continuation of prior-year projects and five new projects announced during the midyear update in May 2015. The continuing areas of focus from the FY 2015 work plan include assessment of documentation deficiencies related to inpatient determinations, the appropriateness of claims billed by provider-based entities, patient safety and quality initiatives and reporting, and increasing IT security vulnerabilities.

The midyear update included projects focused on the following:

- Accuracy and appropriateness of intensity-modulated radiation therapy payments
- Accuracy and appropriateness of inpatient rehabilitation facility (IRF) payments under the prospective payment system (PPS)
- Accuracy and appropriateness of claims for payment of home- and community-based attendant services and support provided under the Community First Choice (CFC) plan
- Hospital preparedness and response to high-risk infectious diseases
- Coordination of Accountable Care Organizations (ACOs) and their use of electronic health records (EHR) in managing population health and costs

Management should take these actions:

- Review the OIG work plan focus areas.
- Assess to what extent the organization's culture and compliance program are conducive to and capable of mitigating risks identified in the work plan.

New Projects

These projects are new to the FY 2016 OIG work plan:

New Project	Focus	Description	Significance
Medical device credits for replaced medical devices	All hospitals and ambulatory surgical centers (ASCs)	The OIG will determine whether Medicare payments for replaced medical devices were made in accordance with Medicare requirements.	Medical devices may require replacement because of defects, recalls, mechanical complication, etc. Federal regulations require reductions in Medicare payments for the replacement of implanted devices. This area was included on the 2014 plan but removed from the 2015 plan.
Medicare payments during Medicare Severity diagnosis-related group payment window	Acute care hospitals	The OIG will review Medicare payments to acute care hospitals to determine whether certain outpatient claims billed to Medicare Part B for services provided during inpatient stays were allowable and in accordance with the inpatient prospective payment system.	Certain items, supplies, and services furnished to inpatients are covered under Part A and should not be billed separately to Part B. This area was included on the 2013 plan but removed from the 2014 and 2015 plans.
Centers for Medicare & Medicaid Services (CMS) validation of hospital-submitted quality reporting data	All hospitals	The OIG will determine the extent to which CMS validated hospital inpatient quality reporting data.	Validation of quality data will affect reporting methodologies by hospitals and may result in repayment of quality incentives.
Skilled nursing facility (SNF) prospective payment system requirements	SNFs	The OIG will review compliance with various aspects of the SNF prospective payment system, including the documentation requirement in support of the claims paid by Medicare.	Prior OIG reviews have found that Medicare payments for therapy greatly exceeded SNFs' cost for therapy and SNFs were billing for the highest level of therapy even though key patient characteristics remained largely the same.
Osteogenesis stimulators – lump-sum purchase versus rental	Durable medical equipment (DME) suppliers	The OIG will determine whether potential savings can be achieved by Medicare and its patients if osteogenesis stimulators are rented over a 13-month period rather than acquired through a lump-sum purchase.	Purchase option processes should be reviewed to assess whether appropriate documentation is being obtained for osteogenesis stimulators and coverage requirements are being followed.
Orthotic braces – supplier compliance with payment requirements	DME suppliers	The OIG will review Medicare Part B payments for orthotic braces to determine whether durable medical equipment, prosthetics, orthotics, supplies, and suppliers' claims were medically necessary and were supported in accordance with Medicare requirements.	Prior reviews identified patients receiving multiple braces when the referring physician did not see the patient and the supplier failed to obtain or verify documentation to support coverage of the braces.

New Project	Focus	Description	Significance
Increased billing for ventilators	DME suppliers	The OIG will review inappropriate billing for ventilators (E0464) for patients with non-life-threatening conditions, which would not meet the medical necessity criteria for ventilators and might instead be more appropriately billed to codes for respiratory-assist devices (RADs) or continuous positive airway pressure (CPAP) devices.	Billing processes should be reviewed to ensure accurate coding of RADs and CPAP devices.
Ambulatory surgical centers – quality oversight	ASCs	The OIG will review Medicare's quality oversight of ASCs.	Previous OIG work found problems with Medicare's oversight system, including finding spans of five or more years between certification surveys for some ASCs and poor CMS oversight of state survey agencies and ASC accreditors.
Physicians – referring/ ordering Medicare services and supplies	DME suppliers	The OIG will review select Medicare services, supplies, and DME referred or ordered by physicians and nonphysician practitioners to determine whether the payments were made in accordance with Medicare requirements.	CMS requires that physicians and nonphysician practitioners who order certain services, supplies, and DME must be Medicare-enrolled physicians or nonphysician practitioners and legally eligible to refer or order services, supplies, and DME. If the referring/ ordering physician or nonphysician practitioner is not eligible to order or refer, then Medicare claims are invalid.
Anesthesia services – noncovered services	All hospitals and ASCs	The OIG will review Medicare Part B claims for anesthesia services to determine whether the patient had a Medicare service related to the anesthesia service.	Charge capture should be assessed to ensure that all surgical charges are accurately captured and anesthesia was billed only when appropriate.
Physician home visits – reasonableness of services	Physician practices	The OIG will determine whether Medicare payments to physicians for evaluation and management home visits were reasonable and made in accordance with Medicare requirements.	Physicians are required to document the medical necessity of a home visit in lieu of an office or outpatient visit
Prolonged services–reasonableness of services	Physician practices	The OIG will determine whether Medicare payments to physicians for prolonged evaluation and management services were reasonable and made in accordance with Medicare requirements.	Prolonged services are for additional care provided to a patient after an evaluation and management service has been performed. Physicians submit claims for prolonged services when they spend additional time beyond the time spent with a patient for a usual companion evaluation and management service.

New Project	Focus	Description	Significance
Histocompatibility laboratories – supplier compliance with payment requirements	Laboratories	The OIG will determine whether payments to histocompatibility laboratories were made in accordance with Medicare requirements.	Histocompatibility laboratories are reimbursed on the basis of reasonable costs. Costs claimed in the cost report must be related to the care of patients and be reasonable, necessary, and proper.
Medicare Part D patients' exposure to inappropriate drug pairs	Pharmacies	The OIG will determine whether Medicare Part D patients were being prescribed drugs that should not be prescribed in combination with other drugs. These would include drugs that have a severe interaction when used in combination with other drugs and drugs that should not be coprescribed with component drugs.	Pharmacy systems should be reviewed to ensure accuracy of contraindications in the formulary. Processes should be reviewed to verify that contraindications are verified by pharmacists prior to dispensing.
Payments for incarcerated patients	All organizations	The OIG will review Medicare payments for incarcerated patients to determine whether the payments were made for patients who did not meet the criteria for exception identified in Medicare regulations.	Medicare exceptions for payment of services provided to incarcerated patients include: 1. State or local law requires those individuals or groups of individuals to repay the cost of medical services they receive while in custody. 2. The state or local government entity enforces the requirement to pay by billing and seeking collection from all such individuals or groups of individuals in custody with the same legal status (for example, not guilty by reason of insanity), whether insured or uninsured. The state or local government also must pursue collection of the amounts owed in the same manner and with the same vigor that it pursues the collection of other debts. This includes the collection of any Medicare deductible and coinsurance amounts and the costs of items and services that are not covered by Medicare.
Medicare payments for patients unlawfully present in the United States	All organizations	The OIG will review the procedures established by CMS to prevent and recoup Medicare payments for items and services furnished to patients unlawfully present in the United States.	"Medicare Claims Processing Manual," Ch. 1, §10.1.4.8 states that Medicare payment may not be made for items and services furnished to alien patients who are not lawfully present in the United States.

New Project	Focus	Description	Significance
CMS management of the International Classification of Diseases, 10th revision (ICD-10) implementation	All hospitals	The OIG will review aspects of CMS' early management of the implementation of ICD-10 codes in Medicare Parts A and B.	CMS has advised providers that it will allow for some flexibility during the first 12 months of implementation. As a result, Medicare review contractors will not deny claims billed under the Part B physician fee schedule based solely on the specificity of the ICD-10 diagnosis code as long as a code from the correct "family" of codes was used.
State agency verification of deficiency corrections	Nursing facilities	The OIG will determine whether state survey agencies verified correction plans for deficiencies identified during nursing home recertification surveys.	Federal regulations require nursing homes to submit correction plans to the state survey agency or CMS for deficiencies identified during surveys. Failure of a facility to correct deficiencies is not negated by failure of accreditation agencies to conduct follow-up.
Controls over networked medical devices at hospitals	All hospitals	The OIG will examine whether the Food and Drug Administration (FDA) oversight of hospitals' networked medical devices is sufficient to effectively protect associated electronic protected health information and ensure patient safety.	Computerized medical devices, such as dialysis machines, radiology systems, and medication-dispensing systems that are integrated with electronic medical records and the larger health network, pose a growing threat to the security and privacy of personal health information. Note that the 2016 plan lists this area as new under FDA areas. This area was listed on the 2015 plan under IT areas.

Continuing Projects of Interest

The following projects carried forward from the 2015 OIG work plan include slight changes in scope or focus or continue to be areas where control deficiencies frequently are identified.

Project	Focus	Description	Significance
Medicare oversight of provider-based status	Hospitals	The OIG will determine the number of provider-based facilities that hospitals own and the extent to which CMS has methods to oversee provider-based billing. The OIG also will determine the extent to which provider-based facilities met the requirements for provider-based status and whether there were any challenges associated with the provider-based attestation review.	Universal requirements, management contract terms, and joint venture rules will be assessed. Additionally, billing regulations related to the three-day window rule, correct listing of the place of service on claims, and the billing of incident-to and professional fees when provided in a shared or split visit are under scrutiny.

Project	Focus	Description	Significance
Hospitals' use of outpatient and inpatient stays under Medicare's two-midnight rule	Hospitals	The OIG will determine how hospitals' use of outpatient and inpatient stays changed under Medicare's two-midnight rule as well as how Medicare and patient payments for these stays changed. The OIG also will determine the extent to which the use of outpatient and inpatient stays varied among hospitals.	Hospitals should continue to monitor for compliance with the two-midnight rule, including complete documentation to support patient status and accurate billing of inpatient and observation patients. Additionally, compliance with rules requiring the inpatient order be signed before discharge, even if the case does not require a certification, should be assessed. Certification is required for admissions exceeding 20 days.
Hospice general inpatient care	Hospices	The OIG will review the use of hospice general inpatient care and will assess the appropriateness of hospices' general inpatient care claims and the content of election statements for hospice patients who received general inpatient care. It also will review hospices' medical records to address concerns that this level of hospice care was not medically necessary.	Reviews will focus on patients' plans of care and determinations of whether they met key requirements and whether Medicare payments for hospice services were made in accordance with Medicare requirements.
Covered uses for Medicare Part B drugs	Part B drugs	The OIG will review the oversight actions CMS and its claims processing contractors took to ensure that payments for Part B drugs met the appropriate coverage criteria.	Medicare Part B generally covers drugs when they are used to treat conditions approved by the FDA, referred to as "on-label" uses. Part B also may cover drugs when an "off-label" use of the drug is supported in major drug compendia or by clinical evidence in authoritative medical literature.
Review of financial interests reported under the Open Payments program	Compliance	The OIG will determine the number and nature of financial interests that were reported to CMS under the Open Payments program.	The Affordable Care Act requires that manufacturers disclose to CMS payments made to physicians and teaching hospitals. Manufacturers and group purchasing organizations also must report ownership and investment interests held by physicians.
National Correct Coding Initiative (NCCI) edits and CMS oversight	Patient financial services/billing	The OIG will review selected states' implementation of NCCI edits for Medicaid claims and describe CMS' oversight of NCCI edits. States were permitted to deactivate some or all NCCI edits because of conflicts with state laws, regulations, administrative rules, payment policies, and/or the states' levels of operational readiness.	After April 1, 2011, the only basis for deactivation is conflicts with state laws, regulations, administrative rules, and/or payment policies. Levels of operational readiness no longer are exceptions to the requirement. Billing departments should ensure that accurate edit software is in place and routinely assessed for updates.

Total Projects

The following summarizes the total projects by OIG focus area:

OIG Focus Area	New Projects for 2016	Total Projects	Percentage of New Projects
Hospitals	3	23	13%
Nursing homes	1	2	50%
Hospices	0	1	0%
Home health	0	1	0%
Medical equipment and supplies	3	7	43%
Other providers and suppliers	6	18	33%
Prescription drugs	0	2	0%
Medicare Advantage (Part C)	0	1	0%
Medicare Part D	1	3	33%
Other management issues	3	9	38%
Appendix B *Recovery Act* reviews	0	3	0%
Medicaid prescription drugs	0	2	0%
Medicaid home health	0	1	0%
Other Medicaid services, supplies, and equipment	1	7	14%
Medicaid IS controls and security	0	2	0%
Medicaid managed care	0	2	0%
Food and Drug Administration	1	1	100%
Totals	**19**	**84**	**23%**

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