New Items in the OIG’s Work Plan Updates - June 2020

The Office of Inspector General (OIG) has published the latest additions to its Work Plan. The following is PYA’s insight on foreign influence on federally funded research, Medicare’s acute and post-acute transfer policies, Medicare’s Part B payments for co-surgery procedures, patient protection policies, Schedule II-controlled substance dispensation, and psychotropic drug use in nursing homes. Readers should evaluate this and the additional OIG updates and determine how those additions can be incorporated into their organization’s compliance program to help inform their risk assessment, compliance, and/or internal audit work plan.

Grantee Institutions’ Actions to Strengthen Policies in Response to Concerns Regarding Potential Foreign Influence on NIH-Funded Research - NIH

According to the March OIG Work Plan Update:

The National Institutes of Health (NIH) requires grantee institutions to report their researchers’ financial interests and affiliations with foreign entities. NIH and Congress have raised concerns that the failure by some NIH-funded researchers to disclose to grantee institutions substantial contributions of resources from other organizations, including foreign governments, threatens to distort decisions about the appropriate use of NIH funds. In response to these concerns, NIH has taken steps to improve the accurate reporting of all sources of research support, financial interests, and affiliations. In July 2019, NIH released a notice to its extramural research community clarifying its policy regarding other support, including foreign affiliations.

Given NIH’s efforts to increase awareness among its grantee institutions regarding financial interests and foreign influence, this [NIH] evaluation will focus on grantee institutions’ policies and procedures related to: (1) ensuring that researchers report all foreign affiliations, including foreign positions and scientific appointments, financial interests in foreign entities, research support from foreign entities, and any other foreign affiliations, and (2) reviewing the foreign affiliations that researchers report. This evaluation will also determine to what extent grantee institutions have updated or revised these policies and procedures to address recent concerns and NIH guidance.

What You Need to Know:
Collaboration between research institutions and scientific communities around the world contributes to significant advancements in the biological, physical, and social sciences. As these collaborations develop, conflicts can result, ranging from simple and obvious, to complex and problematic agreements that can expose organizations to financial and regulatory risk. A Financial Conflict of Interest (FCOI) exists when the design, conduct, or reporting of funded research could be directly affected and potentially compromised. In order to evaluate potential and actual conflicts of interest, organizations are required to retain an investigator and report financial relationships that could pose conflicts by means of the FCOI. Disclosing conflicts exposes the nature of financial tie between researchers and the industry. Organizations can then evaluate and balance the conflict against the merits of the research and develop a management plan to ensure integrity of the teaching, research, clinical care, and services. The responsibilities of research institutions regarding FCOI rules, and the management and reporting thereof, can be found in 42 CFR §50.604-605. The regulations establish a set of standards that promote objectivity and a reasonable expectation that proceeds from grants and agreements are used in a manner free from foreign influence.

What You Need to Do:

The U.S. government is strengthening its oversight of federally funded research programs. Particular concerns are the recruitment of foreign scholars, the risk of undue influence on research results, the misappropriation of funds, and the stealing of intellectual property, all of which threaten the research institutions’ funding.

According to the NIH Grant Policy Statement, “When submitting a grant application, the signature of the [Authorized Organization Representative] AOR certifies the applicant institution’s compliance with the requirements of 42 CFR § 50, Subpart F,” which includes:

1. Up-to-date, written, and enforced administrative processes for the identification and management of FCOI with respect to all research projects for which NIH funding is sought or received.
2. Promotion and enforcement of Investigator compliance with the requirements of the regulation, including those pertaining to disclosure of Significant Financial Interests.
3. Identification and management of FCOIs and the application provisions of initial and ongoing reports to the NIH, as consistent with the requirements of this subpart.
4. Prompt response to any information requests received from the U.S. Department of Health & Human Services (HHS)/NIH related to any Investigator disclosure of financial interests and the institution’s review of and response to such disclosure, whether or not the disclosure resulted in the institution’s determination of an FCOI.
5. Full compliance with the requirements of the regulation by the institution.

Additionally, according to the HHS/NIH Grants & Funding central resource page, “Each institution shall maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with the regulation and make the policy available via a publicly accessible [website].”

The tone at the top of an organization plays a significant role in projecting and enforcing the seriousness of a conflict of interest (COI), and in the way a disclosure is sought out and dealt with appropriately. A strong COI policy and procedure, combined with a Foreign Affiliations program, should be included in your compliance work plan. Conduct periodic reviews to ensure commitment to the accuracy and completeness of a disclosure, demonstrate a pathway to resolve conflicts, deliver ongoing
education regarding foreign relationships, and ensure the institution is following research funding regulations. PYA’s Thought Leadership Insight and Report on Medicare Compliance articles offer additional information on foreign research compliance and can help guide compliance officers through strategic foreign research decisions.

**Medicare Hospital Payments for Claims Involving the Acute and Post-Acute Care Transfer Policies - CMS**

**According to the March OIG Work Plan Update:**

Medicare’s acute and post-acute care transfer policies designate some discharges as transfers when beneficiaries receive care from certain post-acute care facilities. The diagnosis-related group (DRG) payment provides payment in full to hospitals for all inpatient services associated with a particular diagnosis. Because of its transfer payment policies, Medicare pays hospitals a per diem rate for early discharges when beneficiaries are transferred to another prospective payment system hospital or to post-acute care settings, including skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, long-term care hospitals, psychiatric hospitals, and hospice care. This is based on the presumption that hospitals should not receive full payments for beneficiaries discharged early and then admitted for additional care in other clinical settings. Previous OIG reviews identified Medicare overpayments to hospitals that did not comply with Medicare’s post-acute care transfer policy.

We will review Medicare hospital discharges that were paid a full DRG payment when the patient was transferred to a facility covered by the acute and post-acute transfer policies where Medicaid paid for the service. Under the acute and post-acute transfer policies, these hospital inpatient stays should have been paid a reduced amount. Additionally, we will assess the transfer policies to determine if they are adequately preventing cost-shifting across healthcare settings.

**What You Need to Know:**

“Acute and post-acute transfer” refers to a patient who is discharged from an inpatient hospital stay, classified under a DRG payment, for continued care and treatment with another prospective payment setting, such as a skilled nursing facility, an inpatient rehabilitation facility, a home health agency, a long-term care hospital, a psychiatric hospital, or hospice.

CMS Transmittals SE1411 and SE0801 offer providers guidance regarding the assignment of the correct discharge disposition or status code to correctly capture the type of service/continued treatment and transfer location. It is important to accurately assign the correct discharge status code to reflect the discharge/transfer status of the Medicare patient, and to be consistent with state and federal laws, including, but not limited to, the Emergency Medical Treatment and Labor Act (EMTALA).

When a patient is discharged home, the transferring hospital receives full payment. When the patient is discharged and transferred to one of the previously listed facilities for continued care and treatment, the hospital is paid a CMS-defined per diem reduced payment rate. When the transferring hospital indicates the patient was discharged home, but the patient was indeed transferred to another facility, an overpayment may exist.
According to the OIG report for an audit period from January 1, 2016, to December 31, 2018, “Medicare improperly paid acute-care hospitals $54.4 million for 18,647 claims subject to the transfer policy. These hospitals improperly billed the claims by using the incorrect patient discharge status codes.”

**What You Need to Do:**

Hospitals and providers should ensure that their policies and procedures provide guidance for any challenges that may impact the discharge planning process, such as the patient’s anticipated health needs, procedures for a safe transition, and compliance with federal civil rights laws related to “patient dumping.” Hospitals and providers should ensure that all discharge and transfer information and data is complete and captured correctly for acute and post-acute transfers. Excellent discharge planning: 1) supports the plan of care (POC) to improve the patient’s health, 2) accurately contributes to your organization’s patient outcome metrics, and 3) minimizes financial risk related to potential readmissions.

The 42 CFR §§ 412.4 (c)(d) and (f) regulations establish CMS’ transfer policy to avoid the transfer of a beneficiary to a post-acute care setting too early (i.e., before the beneficiary’s condition is stabilized), which would minimize the transferring hospital’s costs while the hospital would also receive the full MS-DRG payment. Accordingly, the transferring hospital is required to follow the post-acute care transfer policy and to accurately report the patient discharge status code on the inpatient claim.

Decisions to discharge or transfer a patient from the hospital should be based on the clinical condition of the patient. When a patient is discharged to a post-acute service provider, all necessary medical information must be communicated to the receiving service provider and to any transport personnel prior to the discharge/transfer. Take care not to minimize the importance of patient discharge education and clear communication with involved caregivers about discharge and transfer procedures.

**Medicare Part B Payments to Physicians for Co-Surgery Procedures – CMS**

**According to the March OIG Work Plan Update:**

Under Medicare Part B, when the individual skills of two surgeons are necessary to perform a specific surgical procedure or distinct parts of a surgical procedure (or procedures) simultaneously on the same patient during the same operative session (co-surgery), each surgeon should report the specific procedure(s) by billing the same procedure code(s) with a modifier “62.” By appending modifier 62 to the procedure code(s), the fee schedule amount applicable to the payment for each co-surgeon is 62.5 percent of the global surgery fee schedule amount. We plan to audit a sample of claim line items—specifically where different physicians billed for the same co-surgery procedure code, for the same beneficiary, on the same date of service. Our objective is to determine whether Medicare Part B payments to physicians for co-surgery procedures were properly made.

**What You Need to Know:**

Due to the complex nature of a patient’s condition or procedure, the individual skills of two surgeons may be required to perform surgery on the same patient during the same operative procedure. Claims can be denied when the medical record documentation and CPT procedure codes listed on the claim do
not support the two surgeon/co-surgeon concept, and/or are inappropriately applied. A clear understanding of the procedure being performed, and accurate documentation of the surgical services is required. Medicare’s MLN Matters SE1322 provides billing instructions for surgical procedures that require modifier 62.

- A **co-surgeon** is a surgeon of a different specialty who performs distinct components of a specific procedure. Each surgeon documents a distinct and separate operative report with the same procedure code. Modifier 62 should be appended.
- An **assistant surgeon** is a surgeon who may be of the same or different specialty or subspecialty and who is simultaneously performing parts of the same procedure. Modifier 62 should not be appended.
- A **team surgeon** is one of multiple (three or more) physicians of different specialties who performs highly complex components of a single specific CPT procedure during the same operative session. Modifier 62 should not be appended.

**What You Need to Do:**

Modifiers describe unique circumstances and expand the definition of specific procedures. Reimbursement for procedures reported with modifiers is calculated and paid differently, so it is important that modifiers are accurately reported on the claim. When billing surgical procedures with modifier 62, providers need to ensure the following:

1. Documentation supports and establishes medical necessity for two surgeons for the procedure. Specifically, each surgeon documents separate operative notes (documentation cannot be shared) detailing the portion of the procedure he or she performed, the work that was involved, and the duration of time the procedure took.
2. One surgeon is identified as the co-surgeon in the documentation.
3. The same diagnoses are linked with the common procedure.
4. Payment rules are used correctly for the two surgeon/co-surgeon concept.

To accurately determine if a specific code is eligible for Medicare reimbursement with modifier 62, reference the **Physician Fee Schedule**, which provides the current version of Relative Value Files regarding billing and payment information for use of the modifier.

Modifier policies differ from payer to payer. Before applying any modifier, and to ensure appropriate reimbursement, confirm that the payer accepted the modifier, that the documentation supports the application of a modifier, and that you are adhering to all applicable published rules for its use.

**Implementation of Indian Health Service Patient Protection Policies in Healthcare Facilities - IHS**

**According to the May OIG Work Plan Update:**

Details surrounding the recent convictions of a former Indian Health Service (IHS) physician for patient abuse raised concerns about IHS policies and procedures to prevent and address patient abuse. IHS partners with 573 federally recognized Tribes to provide healthcare services to its 2.6 million American Indian and Alaska Native beneficiaries, and IHS directly operates 24 hospitals,
51 health centers, 24 health stations, and 2 school health centers. In February 2019, IHS issued new policies to protect children from sexual abuse by healthcare providers. This study is conducted in 2 phases. Phase 1 inventoried and examined IHS nationwide policies and procedures for preventing, reporting, and addressing patient abuse and identified progress and potential challenges to their effective implementation. Phase 2 will evaluate the sufficiency and implementation of these policies at the facility level. We will administer a survey to leadership at all IHS-operated healthcare facilities, conduct interviews with leadership and staff at selected facilities, and review relevant supporting documentation.

**What You Need to Know:**

All healthcare organizations must have in place patient protection policies focused on preventing; responding to; and reporting suspected and detected patient abuse, neglect, and/or harassment. The purpose of a policy is to provide understanding, comprehension, and clear guidance for the affected workforce members. Effective policies must have meaningful metrics to demonstrate progress toward the organizational goal of improving patient protection methods.

**What You Need to Do:**

Patient protection policies and procedures must address how patients are informed of their rights and how patients can report concerns at any time while receiving care. The policies and procedures must require all potential employed caregivers be properly screened prior to hire for any historical records of abuse, neglect, or harassment violations. The organization’s Compliance Officer is responsible for ensuring that all suspected infractions or violations are investigated in a timely and objective manner. The investigation documentation must include status and progress of the investigation and remediation implemented to address the situation. Best practice is to measure the effectiveness of patient protection education and training by evaluating metrics, including staff and physician awareness, and key performance improvement practices, such as reported violations and patient concerns.

**Review of Institutions of Higher Education Grantees Receiving National Institutes of Health Awards - NIH**

**According to the May OIG Work Plan Update:**

More than 80 percent of National Institutes of Health (NIH) funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions located in every state and around the world. OIG has identified areas of potential risk at institutions of higher education receiving NIH awards such as inappropriate or unsupported charges to federal awards, lack of financial conflict-of-interest policies, and deficiencies in internal control related to the financial management system. In addition, Congress, NIH, and federal intelligence agencies have raised concerns about foreign threats to the integrity of U.S. medical research and intellectual property at institutions of higher education. Our objective will be to determine whether institutions of higher education: (1) managed NIH awards to ensure allowability of costs in accordance with federal and award requirements, and (2) met federal conflict-of-interest requirements.

**What You Need to Know:**
Research and healthcare institutions that receive federal awards are required to manage the awards responsibly. Adopting and enforcing policies that minimize the opportunity for improper charges and payments, as well as limiting the potential for non-compliance through inappropriate financial gain and/or tainting of research results, is required. The NIH addresses policy requirements, objectives, and appropriation mandates for awards that apply to the use and provision of monies, and the conduct of the awardees, to ensure compliance with ethical, health, and safety standards, and the proper expenditures of public funds.

What You Need to Do:

Institutions should evaluate their federal grant funding policies and procedures to identify areas of risk related to the following:

1. Charges and cost controls should be indicative of actual, allowable costs incurred by the research project. Costs should be reasonable and necessary; allocated to a specific grant, function, department, or cost objective; assigned with consistency to a particular project or program; and conform with the limits and exclusions contained in the terms and conditions of the award.
2. Conflict-of-interest policies should ensure the institution has a process to identify, manage, and eliminate conflicts of interest. These policies should be coupled with compliance activities that promote and provide compliance education regarding regulatory requirements.
3. Institutions and grant recipients should:
   - Obtain preapproval from the NIH for any research activities with foreign involvement.
   - Validate affiliations.
   - Have explicit disclosure questions regarding foreign involvement.
   - Comply with all reporting requirements when an investigation reveals a violation.

Medicare Part D Payments for Transmucosal Immediate-Release Fentanyl Drugs - CMS

According to the May OIG Work Plan Update:

Transmucosal Immediate-Release Fentanyl (TIRF) drugs are a Schedule II controlled substance. Medicare Part D covers TIRF drugs only for managing breakthrough pain in adult cancer patients who are already receiving and are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. We will determine whether TIRF drugs were appropriately dispensed in Medicare Part D in accordance with Medicare requirements.

What You Need to Know:

TIRF is a prescription opioid (narcotic) pain reliever used to manage breakthrough pain in cancer patients 18 years and older who experience sudden pain not alleviated by the patient’s normal pain management plan. TIRF comes with inherent risks related to misuse, abuse, addiction, overdose, and serious complications due to respiratory depression and medication errors.

What You Need to Do
Providers who prescribe TIRF must have strong utilization review management safeguards in place to prevent adverse events due to TIRF dispensation, such as somnolence, dizziness, and cognitive impairment. Pharmaceutical distributors can only supply TIRF to specially certified pharmacies and providers. Patients must sign a patient-prescriber agreement acknowledging their understanding of the risks, safe use, safe storage, and safe disposal of their TIRF medication. Patients must also receive and review a consumer-friendly, product-specific medication guide on the risks and safe use of TIRF. Complete and current prior authorizations must be in place to ensure continued Medicare coverage benefits and no disruption in prescribing patterns occur. Prescription providers must have compliance strategies in place to track, monitor, and audit quantity limits and claims data to identify egregious patterns of inappropriate drug use, including point-of-sale safety controls to capture early refills, dispensation duplicates, and the patient’s age and diagnosis.

**Monitoring Psychotropic Drug Use in Nursing Homes - CMS**

**According to the May OIG Work Plan Update:**

Previous OIG work found that elderly nursing home residents who were prescribed antipsychotics, a type of psychotropic drug, were at risk for harm. In response, the Centers for Medicare & Medicaid Services (CMS) took steps to address the risk of harm to nursing home residents. One such step was introducing a quality measure to track the rates of antipsychotic drug use in residents without an appropriate diagnosis. Recently, CMS and researchers expressed concerns that some nursing homes underreport antipsychotic drug use and may inaccurately report certain patient diagnoses in order to avoid CMS monitoring. Additionally, research on antipsychotic drug use has highlighted the need to closely monitor all psychotropic drug use to accurately oversee drug use in nursing homes. We will determine the extent to which there are inconsistencies, if any, between: (1) Medicare claims data for residents prescribed psychotropic drugs compared to nursing home self-reported data on residents who received psychotropic drugs, and (2) Medicare claims data as it relates to the diagnoses that exclude residents from monitoring in the antipsychotic quality measure compared to nursing home self-reported data on resident diagnoses.

**What You Need to Know:**

Misuse of antipsychotic drugs with no proper diagnosis to warrant their use can have serious medical complications and can place nursing home residents at an increased risk of injury, harm, and death. CMS has quality measures that capture many of these risks, including two that are specific to the dispensation of antipsychotic drugs to nursing home residents. One gauges the incidence of short-stay residents who receive an antipsychotic medication for the first time, and the second is for long-term residents receiving antipsychotic medication.

Even though the nation has shown dramatic improvement rates in the prevalence of antipsychotic use in long-term nursing residents since launching the [National Partnership to Improve Dementia Care in Nursing Homes](https://www.nationalpartnership.org/) in 2011, many advocates have zero tolerance for antipsychotics use and suspect that other medications, such as antidepressants and benzodiazepines, are being used to make residents more docile. In an article published by [Policy & Medicine](https://wwwpolicyandmedicine.com/), Dr. Jerry Gurwitz, Chief of Geriatric Medicine at the University of Massachusetts Medical School, suggests that some nursing homes might be finding other medications that sedate their patients into passivity without drawing the same level of scrutiny as antipsychotics.
What You Need to Do:

According to a document published by CMS, “Nursing home facilities should work with their pharmacy vendor and consultant pharmacist to use facility level data to identify and track residents on antipsychotic medications. Each resident should be examined by the interdisciplinary team, including the attending physician and pharmacist to determine whether a patient dose of medication can be gradually reduced or discontinued.”

As best practice, nursing homes should attempt to obtain an informed consent from a resident, family, or surrogate prior to administering antipsychotic drugs. If prescribing an antipsychotic drug is in a resident’s best interest and is based on his or her safety, the facility must have clear policies and decision-making tools to make its nursing home ombudsman program a priority. The Administration for Community Living (ACL) administers the ombudsman program for states and advocates on behalf of residents of nursing homes, board and care homes, and assisted living facilities. A long-term care ombudsman can assist residents and guarantors with complaints, education, residents’ rights, facility quality information, and policy and legislative issues. Nursing home facilities that promote compliance with an ombudsman program exhibit their commitment to go above and beyond the state and federal requirements to provide quality care.

How PYA Can Help

PYA compliance consultants combine regulatory expertise with practical experience in healthcare organizations. Our compliance subject matter experts will provide a customized approach to assist you and your organization with today’s ever-changing compliance landscape.

If you would like more information about any matter involving compliance, valuation, strategy and integration, or have regulatory compliance-related questions, contact one of our PYA executives below at (800) 270-9629.