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Navigating healthcare compliance in a new world: A snapshot of the OIG 2021 Work Plan

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While 2020 will undoubtedly always be referred to as the 21st century's annus horribilis, the world experienced a similarly devastating pandemic more than a century ago. The pandemic of 1918 infected more than 500 million people, killing at least 50 million people worldwide.[1] While the pandemic of 1918 was fought and defeated with far fewer resources, healthcare providers were not tasked with navigating that pandemic with today's overwhelming guidelines and laws set in place to defend against potential fraud, waste, and abuse. Today, the healthcare provider entities and systems combatting COVID-19 are burdened with federal and state regulations and a plethora of compliance standards, all while adapting to a new way to provide care and, in turn, ensuring adequate testing and treatment are received.

The Centers for Medicare & Medicaid Services (CMS) has provided emergency waivers and flexibilities, essentially providing a safety mask for healthcare entities and systems navigating the compliance world amid the COVID-19 pandemic. As we see vaccines distributed at a higher and more effective rate, the thought of normalcy has resurfaced, triggering the necessary discussions regarding what will happen once the public health emergency expires. Moreover, what would the healthcare compliance world's layout look like once the "masks" come off?

With more than 30 million cases and more than half a million deaths related to COVID-19 in the United States,[2] it is no surprise that many of the recent works plans of the U.S. Department of Health & Human Services Office of Inspector General (OIG) cover a significant number of pandemic-related items.

As known to any practitioner in the healthcare fraud and abuse sector, the OIG publishes work plans with monthly updates that set forth various projects, including OIG audits and evaluations that are underway or planned for the fiscal year and beyond by OIG's Office of Audit Services and Office of Evaluation and Inspections.[3] It is imperative to monitor potential risk areas outlined by the Work Plan to guarantee compliance for a healthcare provider entity and system.

This article explores several general fraud and abuse topics and highlights issues relevant to the ongoing COVID-19 pandemic, including various telehealth services the OIG is monitoring with a magnifying glass. These items

range from home health to behavioral health services; the Coronavirus Aid, Relief, and Economic Security (CARES) Act resources; and other laboratory testing and billing concerns.

The current ticket items addressed in the OIG Work Plan

Besides items related to the ongoing pandemic, the OIG Work Plan sets forth various projects, including OIG audits and assessments underway or planned to be addressed during the fiscal year. These projects include topics such as risks and concerns regarding fraud, waste, and abuse; extended inpatient hospital overnight stays; home health services, laboratory services, and billing; psychotherapy services; and opioid and compound drug–related issues.

Fraud, waste, and abuse

Medicare requirements for the billing of orthotic braces have been an item heavily scrutinized by the OIG in the past, resulting in findings of improper payments for orthotic braces that were not medically necessary and not documented properly pursuant to Medicare requirements. Therefore, it is no surprise to hear that the saga continues as the OIG now plans to compile prior OIG audits, evaluations, and investigations of orthotic braces paid for by Medicare to identify trends in payment compliance and fraud vulnerabilities in this orthotic brace space.[4] The OIG previously focused on the lack of proper documentation to ensure medical necessity, among other key items. Those OIG reports outlined several documents that are necessary to avoid future compliance issues. Some of those documents included, but were not limited to, a written order detailing the need for orthotic braces from a treating physician and supporting documents indicating the orthotic brace's delivery to the intended beneficiary. It can be assumed that the OIG plans to follow a similar road map as it did with past reviews; therefore, it would be advantageous to familiarize oneself with past OIG reports related to orthotic braces.

Another ticket item worth mentioning in the fraud and abuse area is the OIG's intent to perform on-site reviews of a select sample of Medicaid Fraud Control Units (MFCUs).[5] This review will ensure MFCUs' adherence to federal regulations, policy, and performance standards and collect and analyze performance data to provide continued guidance on better practices for MFCUs.

The two-midnight rule

Contrary to the OIG's previous position on discontinuing short-stays audits, it has announced its intent to begin auditing short-stay claims again and, when appropriate, recommend overpayment collections.[6] Although this announcement conflicts with the OIG's previous statements on short-stay audits, this revival of audits comes as no surprise, particularly since prior OIG audits identified millions of dollars in overpayments for inpatient claims with short lengths of stay. Instead of billing the stays as inpatient claims, the OIG determined several stays should have been billed as outpatient claims, resulting in a lower payment.

OIG plans to commence audits of hospital inpatient claims concerning the two-midnight rule in order to reduce inpatient admission errors. The audit will examine whether inpatient claims with short lengths of stay were billed incorrectly as an inpatient or whether the claims should have been billed as outpatient or outpatient with observation. While doing so, the OIG also plans to review policies and procedures for enforcing the two-midnight rule at the administrative and contractor level.

Home health compliance

Recent OIG reports disclosed high error rates at individual home health agencies (HHAs).[7] These reports

identified improper payments of home health claims of beneficiaries who were not homebound or did not require skilled services. To ensure home health claims are paid in accordance with federal requirements, the OIG plans to continue its review of various aspects of the home health prospective payment systems, including a medical review of the documentation required in support of the claims paid by Medicare. In past reviews, the OIG selected a stratified random sample of 100 home health claims and submitted these claims for medical review to determine medical necessity and whether proper coding requirements were present. To avoid an overpayment situation, an HHA must develop a robust compliance practice to ensure best practices.

Medicare Part B

OIG plans to focus on claims made under Medicare Part B for laboratory and psychotherapy services. Both have been equally affected by the COVID-19 pandemic and were previously audited by the OIG. During the audits of both service lines, the OIG discovered significant risks of noncompliance with Medicare billing requirements and evidence of insufficient documentation, which led to improper billing for services not medically necessary or covered. As a result of the alarming discoveries uncovered during the past audits, the OIG plans to continue its investigation of Medicare Part B payments for laboratory and psychotherapy services to identify providers at risk for overpayment and correct poor documentation practices, among other areas of concern.

Medicare Part B payments for laboratory services

The laboratory billing process is notoriously complex and has also been inherently challenging. OIG previously conducted audits, investigations, and inspections that identified billing areas for clinical laboratory services at risk for noncompliance with Medicare billing requirements. In a continuance of an investigation to ensure compliance with billing requirements, among other essential compliance items, the OIG plans to review Medicare payments for clinical laboratory services to determine compliance.[8] OIG will focus its efforts on claims for clinical laboratory services that may be at risk for overpayments by reviewing claim line modifiers for a code pair, genetic testing, and urine drug testing services for evidence of improper use. These issues continue to also be a basis for claims brought by whistleblowers under the False Claims Act.

Medicare Part B payments for psychotherapy services

In addition to laboratory services, including testing, Medicare Part B also covers certain psychotherapy services, and recently it has been doing so on an expanded basis. In 2016, Medicare Part B allowed approximately $1.2 billion for a wide range of psychotherapy services, including individual and group therapy. OIG discovered that $185 million was inappropriately permitted for outpatient mental health services, which included psychotherapy services.[9] OIG further uncovered signs of insufficient documentation and evidence of services Medicare paid for that were either not covered or medically necessary. As a result of the OIG's previous findings, it plans to review Part B payments for psychotherapy services to determine whether they were allowable according to Medicare documentation requirements.

Medicare Part D

The current OIG Work Plan continues to include several items that focus on opioid and compound drugs–related issues, including oversight of opioid prescribing in selected states and the rapid growth and spending surrounding compound drugs.

As spending for compound drugs, particularly topical drugs, continues to grow, and the OIG continues to encounter an increasing number of potential fraud issues related to compounded drugs, which warrant

investigations, the OIG plans to conduct a risk assessment of CMS' oversight of pharmacies compounding drugs for a beneficiary.[10] This review is to aid the OIG in determining whether systemic vulnerabilities affect the integrity of Medicare Part D and, as a result, place pharmacies at risk of not meeting federal and state requirements.

In addition to the growing concerns with compound drugs, the OIG focuses its efforts on the opioid crisis, which remains prevalent during any public health emergency, including the COVID-19 pandemic.

In February 2021, the OIG published a report concerning opioid use in Medicare Part D during the onset of the COVID-19 pandemic.[11] However, this report was limited to the first eight months of 2020, finding that about 5,000 Medicare beneficiaries per month suffered an opioid overdose as the pandemic advanced, the number of beneficiaries receiving naloxone fluctuated, the number of beneficiaries receiving short-term opioid prescriptions declined, and the number of beneficiaries receiving drugs for medication-assisted treatment of opioid use increased. Approximately 220,000 beneficiaries received high amounts of opioids in the first eight months of the COVID-19 pandemic.

With such an alarming first look at the opioid use and treatment during the COVID-19 pandemic, the OIG plans to continue the analysis until year-end.[12] OIG's continuum of this analysis will provide information on opioid use among beneficiaries enrolled in Medicare Part D in 2020. Additionally, it would provide 2020 data on Part D spending for opioids and the numbers of beneficiaries who received extreme amounts of opioids through Part D and those who appeared to be doctor shopping. The objective is to identify prescribers who ordered opioids for large numbers of these beneficiaries in hopes of identifying patients who are at risk for overdose or abuse.