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The latest in government audit: Five takeaways from 2023

by Evan Schrode, Rebecca Hsu, and Ross Burris

Government contractors continue to revamp their audit activities following a relative slowdown during 2020 and 2021 at the height of the COVID-19 pandemic. 2023 brought a lot of changes for providers in the audits and reimbursement disputes realm, and these changes have established patterns that can be expected to endure beyond this year. This article focuses on five notable audit trends from 2023 of which providers should be aware to prepare for 2024 and beyond.

The end of the Medicare appeals backlog

For the better part of the past decade, the Office of Medicare Hearings and Appeals (OMHA)—which oversees administrative law judge (ALJ) hearings relating to Medicare audit and overpayment appeals—encountered significant delays over the past in administering and adjudicating ALJ hearings. These delays were so substantial that the American Hospital Association—with three other regional hospitals and healthcare systems—sued the U.S. Department of Health and Human Services (HHS) secretary in May 2014, seeking to compel HHS to comply with the statutory deadlines the Medicare Act imposes on the appeals process.[1]

In 2018, the U.S. District Court for the District of Columbia issued a mandamus order directing HHS to clear the Medicare backlog by the end of financial year (FY) 2022.[2] However, at the end of the first quarter of 2022, OMHA had 52,641 appeals remain pending, which was down from 60,062 appeals at the end of the fourth quarter of 2021. Due to the significant backlog of Medicare appeals, the average wait time for those provider appeals to be heard in 2021 was 1,259 days or almost four years.

Notwithstanding, the U.S. District Court acknowledged in an October 26, 2022, order that HHS had achieved admirable results; the court modified its original mandamus order such that HHS was required reduce the prior pending backlog by 98% by the end of the second quarter of FY 2023 and ordered the parties to submit a new status report on April 7, 2023, setting forth the backlog-reduction percentage as of March 30, 2023, and a summary of their positions on how the court should proceed with the backlog.[3]

In a Joint Status Report filed on April 7, 2023, the parties stated that as of March 31, 2023, only 663 backlogged cases were remaining, which the parties asserted surpassed the court's 98% reduction target set in its October

26, 2022, order.[4] As a result of HHS's progress, the Court terminated its original mandamus order compelling HHS to reduce the backlog and withdrew its supervision over the backlog reduction on April 10, 2023.[5]

After almost 10 years since the litigation began, HHS has essentially eliminated the backlog of Medicare appeals. Providers should continue to expect quick turnaround times between when a provider files a request for an ALJ hearing and the ALJ hearing.

OTC COVID-19 test demonstration

From April 4, 2022, until the conclusion of the COVID-19 public health emergency on May 11, 2023, the Centers for Medicare & Medicaid Services (CMS) conducted a demonstration under which Medicare provided coverage and payment for over-the-counter (OTC) COVID-19 tests at no cost to beneficiaries with Medicare Part B.[6] This demonstration also covered those enrolled in original Medicare and Medicare Advantage plans. Under the demonstration, eligible providers and entities were authorized to distribute up to eight U.S. Food and Drug Administration (FDA)-approved or authorized OTC COVID-19 tests per calendar month to each beneficiary; CMS set a fixed national payment rate of $12 per OTC COVID-19 test.[7] If, however, a provider's charge for a test was less than this rate, Medicare would pay the lower amount. Notably, beneficiaries could obtain these tests without a physician's order or supervision, simplifying access to testing. This initiative represented a shift in Medicare policy, addressing the urgent need for accessible COVID-19 testing during the pandemic.

Under the demonstration, participating providers and entities were advised to keep records demonstrating a beneficiary's request for the tests, as failure to provide documentation could lead to CMS recouping payments or taking other administrative actions.

The demonstration was successful, and CMS disbursed approximately $1.1 billion for about 101 million OTC COVID-19 tests to nearly eight million Medicare beneficiaries. However, this period also saw a rise in healthcare fraud activities. The U.S. Department of Justice (DOJ) on April 20, 2023, announced criminal charges against 18 defendants across nine U.S. federal districts for their involvement in various fraud schemes related to healthcare services during the pandemic, including the distribution of unsolicited OTC COVID-19 tests.[8] Concurrently, CMS reported taking adverse administrative actions against 28 medical providers for their alleged roles in COVID-19-related schemes.[9] In August 2023, HHS Office of Inspector General (OIG) announced a work plan to evaluate whether Medicare payments to eligible providers for OTC tests complied with the demonstration's guidelines.[10]

OIG is slated to publish its findings from the work plan in 2024, and providers should expect a noticeable increase in audits and overpayment demands associated with the provision of OTC COVID-19 test kits. Providers who participated in the demonstration should diligently maintain documentation of a patient's request for COVID-19 tests in anticipation of potential audit inquiries. This vigilant approach to recordkeeping is essential for providers to demonstrate compliance and avoid potential recoupments or other actions by CMS.

FEP, OPM, and overpayments

Most, if not all, providers have had the frustrating and unfortunate experience of being subjected to overpayment demands issued by various commercial payers. However, in 2023, commercial payer overpayment demands have added a new wrinkle.

Specifically, providers contracted with a commercial payer may have—unbeknownst to them—providing services to members under the commercial payer's Federal Employee Program (FEP), such as Blue Cross and Blue Shield's FEP. While this may seem unremarkable, these FEPs are part of the Federal Employee Health

Benefit (FEHB) program, administered by the United States Office of Personnel Management (OPM). The OPM contracts with certain fee-for-service carriers like Blue Cross and Blue Shield to provide services to eligible federal employees.

So, why does this matter?

Well, in 2023, many providers received overpayment demands from a commercial carrier about services provided to FEP members under that carrier's FEP. However, though these overpayment demands appear to come directly from the commercial carrier, they are actually issued at the direction of the OPM and subject to federal law governing overpayments and recoupments under the FEHB program. Unfortunately, these laws grant the OPM broad authority to seek repayment for overpayments, including offsetting a provider's future payments from the commercial carrier—even if the provider's provider or facility agreement does not allow or speak to such offsetting activity. The OPM's ability to seek recoupment of any alleged overpayments is valid even if the overpayment resulted through no fault of the provider, and such overpayments are not limited to determinations of medical necessity for paid claims.

Some of these audits and later overpayment demands issued at the direction of the OPM have reached a national scale and have resulted in commercial carriers engaging large law firms to assist with overpayment collections across the country. The silver lining for providers subjected to such audits and overpayment demands is that—notwithstanding the government's broad authority to instruct the carriers to conduct these audits and collect any resulting overpayments—the scale of these activities and inherent unfairness associated with the overpayment demands (depending upon the basis for such demand) may cause a pathway to negotiation of a settlement.

Still, the successful resolution of these overpayment demands may depend largely on effective communication with the appropriate parties, and affected providers should contact their legal counsel for assistance should they find themselves receiving such an overpayment demand.

Analytics-based audits and investigations

The past year has seen a notable escalation in the efforts of DOJ and CMS's Unified Program Integrity Contractors (UPICs) to conduct informal audits and investigations of healthcare providers driven by using data analytics. Data analytics involves collecting and examining a provider's data to identify anomalies that may suggest improper payments, healthcare fraud, or other types of suspicious activities.

CMS has long employed data analysis in determining whether patterns in claims submissions and payments point to potential issues.[11] This process identifies statistical outliers in billing patterns that might indicate improper payment. Data analysis is conducted as part of general surveillance and review of submitted claims or in response to specific problem indicators, such as complaints, input from providers or beneficiaries, fraud alerts, reports from CMS, other Medicare administrative contractors (MACs), or information from independent governmental and nongovernmental agencies. CMS provides DOJ's Health Care Fraud Unit direct access to its data portal. DOJ analysts and UPIC auditors use this data to scrutinize billing and other healthcare data to identify suspicious activities.

Recently, there has been an increase in hospice-related investigations initiated through independent data analysis by UPIC auditors or DOJ rather than traditional methods like provider, beneficiary, or qui tam relator input. This trend is expected to continue, especially after CMS's announcement on August 22, 2023, regarding its intent to correct benefit integrity issues related to hospice care. In 2023, CMS executed over 7,000 hospice site visits with the goal of mitigating fraudulent activities.[12] Following these site visits, approximately 400 hospices are under consideration for potential administrative action as of mid-August. Additionally, we have seen

multiple cases where DOJ has initiated informal investigations into hospice clients, spurred by these site visits and data analyses that identified outliers.

In light of these developments, we advise hospice clients to exercise increased diligence in maintaining their documentation, particularly in aspects related to determining terminal illness and the basis for recertification. This heightened scrutiny underscores the need for healthcare providers—especially in the hospice sector—to be vigilant and proactive in ensuring compliance and accuracy in their billing and documentation practices.

Amniotic fluid allograft injections coming under scrutiny

One area where many providers—especially orthopedic and podiatry practices and practitioners, as well as other providers specializing in the treatment of musculoskeletal conditions—have found themselves in CMS's crosshairs is a particular pain management service that utilizes amniotic fluid allograft products typically delivered through an injection. While amniotic fluid allograft products are not novel in the medical space, their use for the treatment of pain—particularly for orthopedic and podiatric conditions and ailments—is a relatively recent trend that the CMS has, unfortunately, targeted.

While Medicare approves many for wound care treatment with an assigned Healthcare Common Procedure Coding System code classified as a Skin Substitute and Biological, FDA has not cleared these products as safe and effective for alternative uses, including pain management. Therefore, CMS, through UPICs, has been aggressively auditing providers who utilized this code at a relatively high rate and issuing overpayment demands for these services, which can amount to hundreds of thousands of dollars depending upon the volume of usage for these products—leaving providers bewildered and searching for answers.

Despite FDA's lack of clearance for the use of amniotic fluid allograft products for pain management, and though Medicare has taken the stance that it will not cover payment for these services, myriad clinical studies and medical literature are discussing the benefits and effectiveness of amniotic fluid allograft injections for pain management in orthopedic and podiatric conditions. Nevertheless, CMS (through its MACs, CGS Administrators LLC) recently published a new local coverage determination, effective December 10, 2023, concluding that amniotic and placental-derived products injected or applied for treatment of musculoskeletal conditions or pain would be noncovered under Medicare.[13] Thus, providers subjected to audits for these services should expect to face an uphill battle and seek legal counsel to help navigate these complex—and potentially expensive—audits.

Concluding thoughts

The government audit trends that appeared in 2023 do not seem likely to disappear soon. Therefore, providers should begin proactively preparing for potential audits in these areas by working with their internal compliance teams and legal counsel to help identify potential risks and develop strategies to navigate through audits and overpayment demands relating to the same. Fortunately, affected providers can expect their appeal timelines to be drastically reduced compared to recent years following the end of the Medicare appeals backlog.

Takeaways

- The end of the Medicare appeals backlog means providers should expect quicker resolutions for Medicare overpayment appeals.
- Documentation demonstrating a patient's request for tests will be critical in combating government audits inspecting the provision of over-the-counter COVID-19 test kits.
- Government overpayment demands disguised as commercial carrier overpayment demands are increasing

and may present unique hurdles for providers to challenge.

- Providers should expect a rise in informal U.S. Department of Justice investigations and the U.S. Department of Health and Human Services Office of Inspector General audits initiated based on data analytics.
- The Centers for Medicare & Medicaid Services (CMS) is increasingly cracking down on and auditing providers who performed amniotic allograft fluid injections, which CMS does not consider medically reasonable and necessary.

1 American Hospital Association v. Sebelius, No. 1:14-cv-00851-JEB (Dist. Ct. D.C. 2014).
2 American Hospital Association v. Sebelius, Order, No. 1:14-cv-00851-JEB (Dist. Ct. D.C, Nov. 1, 2018).
3 American Hospital Association v. Sebelius, Order, 1–2, No. 1:14-cv-00851-JEB (Dist. Ct. D.C. Oct. 26, 2022).
4 "Joint Status Report," American Hospital Association v. Xavier Becerra, No. 1:14-cv-00851-JEB, April 7, 2023, 1–2, https://www.aha.org/system/files/media/file/2023/04/alj-delay-april-2023-status-report-filed-4-7-23-re-aha-hospitals-sue-to-require-hhs-to-meet-deadlines-for-deciding-appeals.pdf.
5 American Hospital Association v. Sebelius, Order, No. 1:14-cv-00851-JEB (Dist. Ct. D.C. April 10, 2023).
6 Centers for Medicare & Medicaid Services, "COVID-19 Over-the-Counter Tests," page last modified January 18, 2024, https://www.cms.gov/covidotctestsprovider.
7 Centers for Medicare & Medicaid Services, "Over-the-Counter COVID-19 Test Demonstration: Payment and Coverage of COVID-19 Laboratory-Conducted Tests Prior to the Public Health Emergency," April 28, 2023, https://www.cms.gov/files/document/over-counter-covid-19-test-demonstration.pdf.
8 U.S. Department of Justice, Office of Public Affairs, "Justice Department Announces Nationwide Coordinated Law Enforcement Action to Combat COVID-19 Health Care Fraud," news release, April 20, 2023, https://www.justice.gov/opa/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat-covid-19.
9 U.S. Department of Justice, "Justice Department Announces Nationwide Coordinated Law Enforcement Action."
10 U.S. Department of Health and Human Services, Office of Inspector General, "Medicare Part B Payments for Over-the-Counter COVID-19 Tests During the PHE Demonstration," accessed December 14, 2023, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000797.asp.
11 Centers for Medicare & Medicaid Services, "Chapter 2 – Data Analysis," *Medicare Program Integrity Manual*, Rev. 10365, October 2, 2020, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c02.pdf.
12 Dara A. Corrigan and Dara L. Hughes, "CMS is Taking Action to Address Benefit Integrity Issues Related to Hospice Care," Centers for Medicare & Medicaid Services (blog), August 22, 2023, https://www.cms.gov/blog/cms-taking-action-address-benefit-integrity-issues-related-hospice-care.
13 Centers for Medicare & Medicaid Services, "Amniotic and Placental Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound," Local Coverage Determination, DL39575, December 10, 2023, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39575&ver=4.