Know Your Audit! Operational Considerations Under Every Kind of Audit

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I. Understanding the Audit Landscape

A. Introduction: They're All Watching You!

The federal government has well-established mechanisms for identifying potentially inaccurate payments and allegedly fraudulent claims in its health care programs. Generally, government reimbursement operates as a "pay and chase" model whereby most claims that providers submit are accepted and paid with little to no supporting documentation required (though, as discussed further below, there are many documentation requirements that providers must abide by to meet reimbursement criteria under federal and state laws, regulations, and other guidance). Despite these initial payments, the government has the ability to pursue recovery of reimbursement made for those claims that, upon further review, it deems improper or deficient. Claim audits are the most common mechanism through which the government monitors health care providers and determines the accuracy of reimbursement payments from government health care programs, and depending upon the type of claim, the government agency pursuing recovery, and whether potential fraud is involved, such audits may apply to claims that were paid four years, six years, or even ten years ago.

Each year, the government recoups billions of taxpayer dollars through various oversight initiatives which illustrate the government's commitment to pursuing improper payments and ensuring compliance by its health care providers. There is a myriad of audit programs utilized by federal and state governments, and their contractors, that are issued to health care providers each year. Over the years, the number of programs, their lookback periods, and the workload impact on providers have become more and more complex and burdensome. The rules and regulations through which these audits are implemented and monitored have evolved over time.

In this article, we will focus on how the government uses audits to ensure the integrity of the federal health care programs, and to ensure safe high-quality and efficient care. This article will provide the process by which these audits can be appealed by health care providers if you receive a denial of claims related to these audits. Finally, we explore some proactive strategies providers should implement now

to reduce financial exposure in audits but also ensure your organization is properly prepared to respond comprehensively to audits.

B. The Framework of Government Healthcare Audits: The Auditors.

The Centers for Medicare and Medicaid Services ("CMS") is the federal agency responsible for administering Medicare and Medicaid.[1] CMS is responsible for overseeing these programs and must conduct audits to ensure compliance with their standards. CMS outsources the majority of these audits to private contractors. These include:

- Medicare Administrative Contractors, also known as "MACs", are private health care entities that have been awarded contracts by CMS to manage the regional responsibility for processing Medicare claims, for policy and payment. These organizations perform medical reviews consistent with their overarching Medicare guidelines but with significant discretion. Further, MACs can issue requests to providers, known as Additional Document Requests ("ADRs") to seek significant additional medical and financial documentation.[2] Twelve MACs have been awarded contracts to manage Medicare Part A and B, four MACs have been awarded contracts for durable medical equipment ("DME") providers, and four MACs have been awarded contracts for home health and hospice providers.[3]
- Recovery Audit Contractors, also known as "RACs", are independent entities that conduct complex and automated post-payment reviews. Similar to MACs, RACs receive contracts from CMS and have responsibility by region.[4] Currently, there are three contractors assigned

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[1] *See* CMS About Page, https://www.cms.gov/about-cms (last accessed on Feb. 26, 2025).

[2] *See* https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac (last accessed on Feb. 26, 2025).

[3] *See id.*

[4] *See* https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/medicare-fee-service-recovery-audit-program (last accessed on Feb. 26, 2025).

to five regions with RAC responsibility.[5] These private companies are contracted and incentivized by CMS to mine government claims data and identify possibly improper payments or a probability of improper payments to health care providers. RACs also use ADRs to seek additional information from providers.[6]

- Comprehensive Error Rate Testing, also known as "CERT" contractors, are responsible for measuring alleged improper payments in the Medicare Fee-For-Service program.[7] CERTs identify random samples of claims in each reporting period and perform background statistical review of governmental claims data to identify and establish alleged error rates and estimates of improper payments to providers. They can also issue ADRs to seek additional information.[8] Independent medical professionals review the claims to confirm the care was medically necessary and to identify any potential overpayments that can be recouped.[9] Finally, CERTs calculate improper payment rates which are published in the HHS Agency Financial Report.[10]
- Unified Program Integrity Contractors, also known as "UPICs", are independent contractors that investigate and prevent fraud, waste, and abuse in Medicare and Medicaid.[11] Specifically, UPICs perform program integrity functions for Medicare Parts A, B, DMEPOS, Home Health and Hospice, Medicaid, and Medicare-Medicaid data matching. Similar to other programs, UPICs have

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[5]*See* https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/medicare-fee-service-recovery-audit-program (last accessed February 26, 2025).

[6]*See* https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/medicare-fee-service-recovery-audit-program; *see also See* Medicare Program Integrity Manual Chapter 9.

[7]*See* https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/comprehensive-error-rate-testing-cert/background (last accessed on Feb. 26, 2025).

[8]*See id.* As of reporting year 2025, approximately 37,500 claims are reviewed in each reporting period.

[9]*See id.*

[10]*See id.;* see also Medicare Program Integrity Manual Chapter 12.

[11]*See Medicare Program Integrity Manual Chapter 12; Medicaid Program Integrity Manual Chapter 3.*

contractual responsibility by region and uniquely have this responsibility for both Medicare and Medicaid.[12] UPICs are focused annually on CMS priorities related to fraud, waste, and abuse for potential investigations.[13] Similarly, UPICs conduct policy research in each state and communicate with state experts to set priority for investigations.[14] UPICs have the authority to perform both pre-payment and post-payment reviews and support state Medicaid agencies in their reviews, and focus their efforts on targets or leads that federal and state agencies believe put the most dollars at risk or constitute high priority investigations.[15]

- Supplemental Medical Review Contractors, also known as "SMRCs", conduct nationwide medical reviews of Medicaid, Medicare Part A/B, and DMEPOS claims to determine whether claims follow coverage, coding, payment, and billing requirements.[16] The focus of the medical reviews may include vulnerabilities identified by CMS data analysis, the Comprehensive Error Rate Testing (CERT) program, professional organizations, and Federal oversight agencies.[17] At the request of CMS, the SMRC may also carry out other special projects to protect the Medicare Trust Fund. Currently, Noridian Healthcare Solutions has been awarded the SMRC contract.[18] If Noridian identifies issues with claims selected for medical review, the MAC can initiate recoupments through the standard recovery process.[19]

Ultimately, the audit contractors identified above are tasked with determining if a claim must be denied. Reasons for denial include:

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[12] *See id.*

[13] *See id.*

[14] *See id.*

[15] *See id.*

[16] *See* https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/medical-review-and-education/supplemental-medical-review-contractor-smrc (last accessed on Feb. 26, 2025).

[17] *See id.*

[18] *See id.*

[19] *See id.*

- The item or service is not a covered benefit of the healthcare program;
- The item or service is statutorily excluded from coverage by the healthcare program;
- The item or service is not reasonable or necessary; and/or
- The item or service does not meet other program requirements for payment determinations of coverage are governed by health care program policy, including but not limited to, national coverage determinations ("NCDs") or regional local coverage determinations ("LCDs").

LCDs are issued by the regional MAC for the jurisdiction from which the claim is issued and are often updated by that contractor. Specifically, the Social Security Act defines an LCD as "a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A)."[20] On the other hand, an NCD, as its name suggests, applies nationwide regardless of the MAC. The Social Security Act defines an NCD as "a determination by the [Secretary for the Department of Health and Human Services] with respect to whether or not a particular item or service is covered nationally under this subchapter, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this subchapter or a determination with respect to the amount of payment made for a particular item or service so covered."[21] Additionally, State Medicaid agencies define medical necessity through their state Medicaid plan, state rules and regulations and Medicaid manuals. Once claims are denied, health care providers have systematic appeals processes via which the denials can be appealed that will be discussed further herein.

In sum, the type of claim under audit and the jurisdiction where the services were provided largely dictate the applicable coverage criteria that auditors and contractors will

[20] 42 USC § 1395ff(f)(2)(B).

[21] *Id.* at § 1395ff(f)(1)(B).

follow when performing a claims review to determine whether such claims should be reimbursed.

C. The Framework of Government Healthcare Audits: Audit Types

Audit contractors have two types of claim review programs:

i. **Pre-payment review** in which the contractor has identified a provider by their provider number and are reviewing claims prior to payment processing, and;

ii. **Post-payment review** in which payment is made and the contractor can retrospectively review the documentation associated with the claim and determine if the claims were reasonable or necessary.[22]

Providers will typically experience a post-payment review before a pre-payment review. In a post-payment review, the provider has received payment for claims which are subsequently selected for review by an auditor.[23] The auditor may issue an ADR for additional information and re-review the claims, or the auditor may simply issue a claim denial to the provider.[24] The auditor, who may be assisted by a medical provider depending on the complexity of the review, will review the documentation associated with the claims and come to a determination on whether the claims meet the applicable qualifications for payment.[25] These denials should include the reasoning by which the claim was denied.[26] Post-payment reviews resulting in claims denials will also be accompanied by overpayment demands, whereby the contractor requests repayment from the provider based on the claims denials.[27]

On the other hand, a pre-payment review is a review in which the government contractor or auditor informs a provider that they will be reviewing all claims from the

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[22] *See generally* Medicare Program Integrity Manual Chapter 3, Section 3.2.

[23] *See id.*

[24] *See id.* at Section 3.2.3.

[25] *See id.* at Section 3.3.1.1.

[26] *Id.* at Section 3.6.4.

[27] *See id.*

provider's office or facility before payment is made.[28] For many providers, depending on their payor mix, a pre-payment review causes a complete or partial suspension of claims being paid from that payor, which can have a significant financial impact on an organization. As such, the government requires pre-payment reviews only when there exists a "likelihood of a sustained or high level of improper payments", which may be shown where a provider has demonstrated a history of claims errors and/or a history of receiving improper payments (e.g., documentation does not support the provider's coding, services are found not to be medically necessary, billing inconsistencies, etc.).[29] It is also possible that an auditor has performed data mining or used an artificial intelligence ("AI") tool that has detected a potential inconsistency or anomaly in claims, (e.g. a provider is billing a particular service, or more high-level E/M services, more often than other, similar providers in their area). While it is important to defend all audits vigorously, pre-payment reviews typically lead to a more significant financial impact than post-payment reviews (especially given these reviews can last for months, even multiple years) and create the potential for more significant findings against the provider. Thus, providers should ensure their responses to a pre-payment review are robust.

D. Targeted Probe and Educate Audits.

Targeted Probe and Educate ("TPE") reviews are a common type of audit that can be either a pre-payment or post-payment review, or in some instances, combine post-payment and pre-payment reviews into a single audit.[30] These audits focus specifically on providers "who have historically high claim denial rates, who have billing practices that vary from their peers, or when evidence suggests that there is a potential risk to the Medicare Trust Fund."[31] In TPE audits, a MAC will request send a request for medical records for previously submitted claims consisting of 20 to 40 claims per provider per topic (though, in rare circumstances, CMS may

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[28] *See id.* at Section 3.2.

[29] *Id.* at Section 3.4.

[30] *See* Medicare Program Integrity Manual, Chapter 3, Section 3.2.5.

[31] *Id.*

approve a probe sample of other than 20-40 claims).[32] Following its review, the MAC must send the provider its detailed denial reasons for the claims reviewed, if any, and must offer a one-on-one direct educational call with the provider to discuss the denial reasons.[33] Thereafter (and regardless of whether the provider accepts the educational offer), the MAC must allow the provider a minimum of 45 days to incorporate improvements to its claims to cure any alleged deficiencies or issues that the MAC identified in its initial review.[34]

Following the 45-day (or more) waiting period, the MAC may issue a second request for medical records (again limited to 20 to 40 claims per provider per topic) and repeat the process, i.e., the MAC must send the provider a letter detailing the results of the claims reviewed at the conclusion of the round of review, which must include details regarding the provider's specific claim errors.[35] The MAC may perform three (3) rounds of record review, and if the MAC determines the provider has not sufficiently improved its performance after the third round (i.e., the provider continues to have high error rates after three rounds of review), the provider will be referred to CMS for additional action, which may include additional rounds of TPE review, 100 percent prepayment review, extrapolation, referral to a Recovery Auditor, and/or referral for revocation.[36] Conversely, providers who meet the established error rate goal will be released from further review for at least one year, with the caveat that additional review may occur at any time should the MAC identify changes in the provider's billing pattern.[37]

E. Medicare Payment Suspension.

Under federal regulations, CMS may suspend a provider's Medicare payments if any of the following apply: (1) The Medicare contractor possesses reliable information that an

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[32] *Id.*

[33] *See id.*

[34] *Id.*

[35] *Id.*

[36] *Id.*

[37] *Id.*

overpayment exists or that the payments to be made may not be correct, although additional information may be needed for a determination; (2) in cases of suspected fraud, where CMS or a Medicare contractor has consulted with the Office of the Inspector General ("OIG"), and, as appropriate, the Department of Justice, and determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments; or (3) if the provider has been subject to a Medicaid payment suspension under 42 C.F.R. § 455.23(a)(1).[38] In cases where CMS or a Medicare contractor believes that a provider has committed fraud or has instituted a Medicare payment suspension based on credible allegations of fraud, a provider may be barred from receiving Medicare payments for a minimum of 180 days, and such suspension may continue indefinitely upon evaluation every 180 days while the credible allegations of fraud continue to be investigated.[39]

Medicare payment suspensions can arise from a multitude of scenarios, including information gathered during CMS or Medicare contractor on-site reviews, patient interviews or visits, physician interviews or visits, pre-payment reviews (often where 100% of the claims are denied), or post-payment reviews (often where 100% of the claims are denied).[40] Unfortunately, Medicare payment suspensions are frequently a death-knell for providers, particularly smaller providers who rely heavily on Medicare payments as their main revenue source. While providers are permitted to submit a rebuttal statement in response to a Medicare payment suspension within 15 days from the date they were notified of the suspension (if prior notice of the suspension was provided), these rebuttals are typically futile absent clear error by CMS or a Medicare contractor (e.g., the provider was misidentified).[41] Furthermore, a Medicare payment suspension action is not appealable, and the rebuttal is the provider's only opportunity to present information as to why suspension action should not be initiated or should be

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[38] 42 C.F.R. § 405.371(a).

[39] 42 C.F.R. § 405.371(a)–(b); 42 CFR § 405.372(d).

[40] *See* Medicare Program Integrity Manual Chapter 8, Section 8.3.1.1.

[41] *See* 42 C.F.R. § 405.372(b); Medicare Program Integrity Manual Chapter 8, Section 8.3.2.2.5.

terminated.[42] Even if CMS terminates a Medicare payment suspension, such termination is often followed by an overpayment demand by the MAC that creates a new financial burden for providers to navigate.

Therefore, it is imperative that providers work closely with their legal counsel if they receive a Medicare Payment suspension to determine the most appropriate way to respond to and navigate the allegations.

II. Identifying and Returning Overpayments

A. The 60-day Rule.

The 60-day Rule is a requirement originating from a provision in the Affordable Care Act, mandating that providers report and return any overpayments they identify related to claims submitted to Medicare and Medicaid within 60 days of discovering the overpayment. Specifically, an overpayment must be reported and returned by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable.[43] Historically, CMS specified that an overpayment is deemed "identified" when "the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment ***and*** quantified the amount of the overpayment."[44] CMS further clarifies that a person's duty to exercise reasonable diligence arises when that person receives or obtains "credible information" that a potential overpayment exists, and at that point, a provider has up to six months (or 180 days) to investigate the potential overpayment and determine whether it exists (and the amount).[45]

However, under the CY 2025 Medicare Physician Fee Schedule (MPFS), CMS updated it's the 60-day Rule to change the definition of an "identified" overpayment to when a provider "knowingly receives or retains an overpayment. The term 'knowingly' has the meaning set forth in [the

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[42] Medicare Program Integrity Manual Chapter 8, Section 8.3.2.2.5.

[43] 42 U.S.C. § 1320a-7k(d)(2).

[44] 81 Fed. Reg. 7654 (2016) (emphasis added).

[45] *Id.*

federal civil False Claims Act],” which provides that a provider knowingly receives or retains an overpayment when they (1) know about the overpayment, (2) act with deliberate indifference to whether an overpayment exists, or (3) act with reckless disregard of a potential overpayment.[46] Furthermore, under the new rule, a provider does not need to quantify an the provider “overpayment for it to be considered identified under CMS’ new rule.

Importantly, the updated rule also tweaked the time frame that providers have to return and report overpayments. Even though overpayments must still be reported and returned within 60 days from their identification, the 60-day deadline may be suspended for up to 180 days in instances where (1) the provider “has identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment,” and (2) and the provider “conducts a timely, good-faith investigation to determine whether related overpayments exist.”[47] If those two conditions are satisfied, then the deadline for a provider to report and return the initially identified overpayment as well as any related overpayments that arise from the same or similar cause or reason as the initially identified overpayment is the earlier of the (1) date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated, or (2) or 180 days from the date on which the initial identified overpayment was identified.[48]

One crucial part of the 60-day Rule that remains unchanged is requirement that overpayments must be reported and returned only if a person identifies the overpayment within 6 years of the date the overpayment was received (the “Lookback period”), thereby creating a limitation on how far back providers need to investigate potential overpayments.[49] Practically speaking, this means that providers who are investigating the existence of a potential

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[46]42 C.F.R. § 401.305(a)(2).

[47]*Id.* at § 401.305(b)(3).

[48]*Id.*

[49]*Id.* at § 401.305(f); 81 Fed. Reg. 7654.

overpayment should ensure that their internal audit or investigation includes potentially affected claims within and up to the past 6 years.

Notwithstanding, the latest changes to the 60-day Rule do not necessarily mean that providers must conduct extensive investigations every time they are made aware of, or identify, an overpayment. Rather, the reason for the identified overpayment, and whether that reason is likely to apply to other, related claims, is largely determinative for how complex of a review should be performed (if at all). For instance, if a provider identifies an overpayment or receives an overpayment demand from the MAC based on a systemic billing issue that could have or is likely to have affected claims outside of the identified overpayment or overpayment demand claims universe, this reason could warrant a more extensive investigation than, say, an overpayment demand based on medical necessity denials relating to hospice services to various beneficiaries, which are usually very fact-specific and isolated (i.e., limited to the specific date of service or beneficiary and not necessarily suggestive of a larger or widespread issue).

Nevertheless, providers who fail to return an overpayment under the 60-day Rule can face civil charges under the federal False Claims Act and may be excluded from the Medicare program. Therefore, it is essential for providers to conduct thorough internal investigations after identifying an overpayment to confirm whether related overpayments exist and return overpayments and maintain robust compliance programs to help eliminate or reduce overpayments from occurring.

B. Reporting and Returning an Overpayment.

Providers may report and return self-identified overpayments through the OIG Self-Disclosure Process ("SDP") or the CMS Voluntary Self-Referral Disclosure Process ("SRDP") by requesting a claims adjustment or a voluntary offset, by using the credit balance process, or another appropriate process.[50] However, CMS declined to permit providers to offset identified overpayments with underpayments that may be identified in the course of the same review, and such

[50]81 Fed. Reg. 7654; *see* 42 C.F.R. § 401.305(d).

offsetting does not constitute a valid return of an overpayment according to CMS. The 60-day Rule time period will be tolled while a provider is undergoing the SDP or SRDP process. While disclosure and the return of overpayments may be through the SRDP or SDP may resolve a provider's identified overpayment obligations, such disclosure may nevertheless prompt further investigation or intervention from federal and/or state law enforcement agencies (such as the OIG, the Department of Justice, the Medicaid Fraud and Control Unit ("MFCU"), etc.) to the extent they determine there may be additional, unidentified overpayments or potential False Claims Act violations or other fraudulent activity.

Ultimately, CMS views identifying and refunding overpayments as a ministerial task. Specifically, CMS suggests that each overpayment should require about six hours to report and return the overpayment, a task that generally should be completed by "miscellaneous in-house administrative personnel," but sometimes by accountants and auditors.[51] CMS further notes that "[w]e believe only the rarest of circumstances (such as potential fraud or certain investigations of potential violations of the physician self-referral law) would necessitate more costly personnel, such as legal counsel, to comply with the final rule." While CMS may adopt these positions, we disagree that legal counsel would only be necessitated in the rarest of circumstances and that identifying and refunding overpayments are usually (or should be) tasks designated to in-house administrative personnel.

For all these reasons, it is increasingly important for health care providers to (1) proactively respond to initial audit outreaches with complete data to stop audits before they become onerous, and (2) to have proactive processes in place internally with all the appropriate stakeholders to reduce the risk of becoming a target for audits.

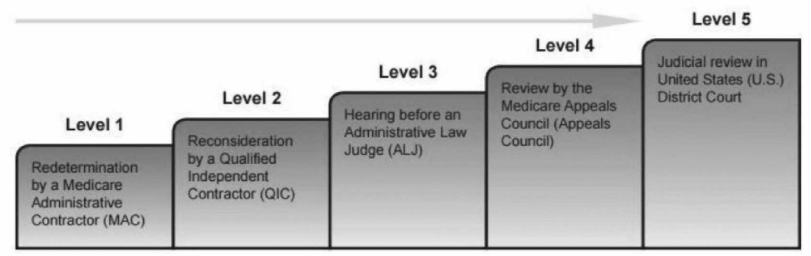
III. Audit Defense

A. Medicare Appeals Process.

After a contractor institutes a pre-payment or post-payment review, the contractor must then decide whether

[51] 81 Fed. Reg. 7654, at *7681.

the claims are reimbursable under Medicare (and the amount payable for each claim). Such a decision is an initial determination. For post-payment reviews involving adverse initial determinations (i.e., the auditor determined claims were paid in error and should be denied), the contractor will issue an overpayment demand seeking payment for the previously-paid claims denied upon review. Providers who disagree with a contractor's initial determination may appeal the decision under the Medicare appeals process, which is proscribed by statute (*see* 42 C.F.R. §§ 405.940–405.1140) and comprises five levels of appeal.



(This graphic is available at https://www.hhs.gov/sites/default/files/omha/files/medicare-appeals-backlog.pdf).

First Level of Appeal: Redetermination

The initial stage of the appeal process is "redetermination" and involves an appeal directly to the contractor who issued the initial determination (the MAC). Appellants have 120 days from the date they receive the initial claim denial or overpayment demand to request a redetermination. There is no minimum amount-in-controversy required for this stage. The Social Security Act stipulates that the MAC must complete the redetermination within 60 days of receiving the appellant's request. Additionally, though Medicare contractors have the general authority to begin recouping Medicare payments from a provider based upon an overpayment demand, such recoupment can begin no earlier than 41 days from the date of the initial overpayment demand; provided, however, that the contractor shall cease recoupment of the overpayment in question upon receipt of a timely and valid request for a redetermination of an overpayment (i.e., prior to the 41-day recoupment grace period).[52] If the recoupment has not yet gone into effect by the time a timely and valid request for redetermination is received, the contractor shall not initiate recoupment.[53] Once the contractor issues its redetermination decision, the contractor may be initiated or resumed on the 60th calendar day after the date of the notice of redetermination was issued.[54]

Second Level of Appeal: Reconsideration

The second appeal stage is "reconsideration." Requests for reconsideration are processed by a Qualified Independent Contractor ("QIC"). If a party is unhappy with the MAC redetermination, they have 180 days from the date they receive the redetermination decision to request reconsideration. This process may include a review of medical necessity issues by a panel of healthcare professionals. No minimum amount-in-controversy is required. The Social Security Act and its regulations state that the QIC must issue a decision within

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[52]42 C.F.R. § 405.379(d)(1).

[53]*Id.*

[54]*Id.* at § 405.379(e).

60 days after receiving a timely reconsideration request. If the QIC cannot meet this timeline, they will inform the appellant of their right to escalate the case to an Administrative Law Judge (ALJ). Upon receipt of a timely and valid request for a reconsideration of an overpayment, the Medicare contractor must cease recoupment of the overpayment in question, and if the recoupment has not yet gone into effect, the contractor must not initiate recoupment.[55] However, following the contractor's issuance of its reconsideration decision, or if the reconsideration request is escalated to the Administrative Law Judge, the QIC may resume or initiate recoupment against the provider.[56]

Third Level of Appeal: Hearing before an Administrative Law Judge ("ALJ")

If a provider is dissatisfied with the QIC's reconsideration decision, they can request a hearing before an ALJ at the Office of Medicare Hearings and Appeals ("OMHA") within 60 days of receiving the QIC's decision. OMHA provides an impartial forum to address disputes regarding CMS Medicare coverage and payment decisions. A minimum amount-in-controversy is required for this stage, which is adjusted annually by a statutory formula. The Social Security Act specifies that the ALJ must conduct a hearing and render a decision within 90 days of receiving the request. If the ALJ fails to meet this deadline, the party requesting the hearing may escalate the case to the Medicare Appeals Council (the "Council") at the United States Department of Health and Human Services ("HHS") Departmental Appeals Board ("DAB"), and the Council must issue a decision or remand the case within 90 days of receiving the request. Historically, OMHA has struggled to meet the 90-day timeline due to an influx of hearing requests, causing a backlog of appeals; however, recent litigation against HHS has effectively resolved the backlog and enabled OMHA to issue timely decisions.[57]

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[55] *Id.* at § 405.379(d)(3).

[56] *Id.* at §§ § 405.379(d)(4), (f).

[57] *See, e.g.*, https://www.policymed.com/2023/06/hhs-significantly-reduces-backlog-of-medicare-appeals-pending-before-omha.html#:~:text=HHS

Fourth Level of Appeal: Medicare Appeals Council Review

The Medicare Appeals Council, which is part of the DAB, reviews ALJ decisions. The Council is independent of both CMS and OMHA and provides the final administrative review for Medicare claim appeals. If a provider is dissatisfied with the ALJ's decision, they have 60 days from the date they receive the decision to request a review by the Council. The Social Security Act requires the Council to issue a decision or remand the case within 90 days of receiving the request. If the Council does not meet this deadline, the appellant may escalate the appeal to Federal district court. Due to a large number of review requests, the Council has also struggled to meet the 90-day deadline, resulting in a backlog of appeals.

Fifth Level of Appeal: Judicial Review in U.S. District Court

A provider may request judicial review in Federal district court if they are dissatisfied with the Council's decision or if the Council has not decided within the required timeframe. A higher minimum amount-in-controversy is required for judicial review, adjusted annually by statute. Providers dissatisfied with the outcome of a Council review have 60 days from the date they receive the Council's decision to file for judicial review in Federal district court. Notably, the Federal district court level of appeal is often a provider's first (and, potentially, only) opportunity to robustly argue and receive a decision on any constitutional or legal process claims they may have raised at the underlying appeal stages, including a due process violation claim.

B. The Importance of Audit Defense.

Government audits can cause significant impact to a provider's revenue cycle systems and can carry additional penalties if audits are directed to prosecutors for additional review are expensive in both internal and external resources to respond to. And if significant fraud is identified related to

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%20Report,pending%20on%20September%2030%2C%202015.&text=Pfizer's%20Subsidiary%20Biohaven%20Settles%20for%20Nearly%20$60M%20Over%E2%80%A6 (last accessed Feb. 28, 2025).

a provider number, that provider could be at risk for individual financial penalties or removal from Medicare or Medicaid entirely. Overall, HHS' OIG recovered $7.13 billion in allegedly misspent funds during fiscal year 2024, and there is little (if any) evidence suggesting that the government will reduce its aggressive auditing and recovery efforts in the near future. Notwithstanding, on June 28, 2024, the United States Supreme Court issued its decision in *Loper Bright Enters. v. Raimondo and Relentless, Inc. v. Department of Commerce*,[58] which overruled *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*,[59] in a 6–3 decision that effectively turned back the clock 40 years to when the landmark agency deference case (i.e., *Chevron*) was first decided. The new *Loper Bright* framework poses many questions to the reimbursement landscape and is likely to result in increased provider challenges to agency action and, potentially, more success for providers in those challenges, as courts across the country are no longer required to afford agencies substantial deference to their interpretations of ambiguous statutes, which often manifests in the form of regulations, rules, and other guidance under which providers are subjected.[60]

In recent years, audit scrutiny has become more intense and complex as the scope and reach of the Medicare contractors has grown. Notwithstanding, audit scrutiny will likely become even more intense under the new presidential Administration. CMS is one federal agency under scrutiny from the Department of Government Efficiency ("DOGE"), which is focused on uncovering fraud, waste, and abuse.[61] Specifically, Elon Musk, who has been tasked with overseeing DOGE, indicated that the "big money fraud" is in

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[58]No. 22-451 and No. 22-1219, 2024 WL 3208360 (U.S. June 28, 2024). These two cases were decided in the same opinion.

[59]Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984).

[60]*See generally Loper Bright*, 2024 WL 3208360.

[61]*See* Donald J. Trump (@realDonaldTrump), TRUTH SOCIAL, https://truthsocial.com/@realDonaldTrump/posts/113472884874740859 (last accessed Feb. 23, 2025); *see also* Executive Order No. 14170, 90 Fed. Reg. 8621 (Jan. 20, 2025); Dominick A. Fiorentino *et al.*, Cong. Rsch. Serv., IN12493, Department of Government Efficiency (DOGE) Executive Order: Early Implementation (2005).

Medicare systems.[62] Therefore, it is imperative that health care providers implement proactive strategies immediately to prepare for this scrutiny.

IV. Proactive Strategies for Successful Audit Defense

A. Implement a Multi-Disciplinary Audit Response Team.

The ability for an organization to identify an overpayment requires the organization to develop strong processes and policies related to its response to overpayments. It is important to ensure all stakeholder groups are knowledgeable, aligned and communicating on government audits. For example, these departments should be included in review of all issues: Revenue Cycle, Internal Audit, Compliance, Legal, Quality/Clinical Review and Finance. As such each organization should have an existing audit response team, potentially governed via the organization's compliance committee.

Ultimately, an organization's identification of and response to an alleged or identified overpayment should be driven by the organization's policies and procedures, especially those that address risk tolerance. Depending on the size of the provider in question, the departments identified above may not exist within the organization, or these teams may not currently regularly communicate regarding what each department is seeing related to government audits. For example, a compliance department might be conducting audits under an annual workplan item, while at the same time the revenue cycle department may have received a MAC denial for the same type of claims and potentially refunded similar claims. Therefore it is imperative to have clear communication across all responsible departments so that all investigations, internal or external, or coordinated and a feedback loop is created so that issues are investigated and potentially remediated quickly.

It is important for health care providers to remember that the government, through their contractors, has the data to analyze trends and identify where alleged overpayments

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[62] Elon Musk (@elonmusk), X https://x.com/elonmusk/status/1887184902543577590?lang=en&mx=2 (last accessed Feb. 23, 2025).

may be occurring. It is essential that health care providers have the same, if not better, systems that allow the organization to track these refunds, denial letters, and potential overpayments *before* the government reaches out. Even if an organization doesn't have the departments listed above, the provider should create an audit defense team with the ability to proactively track these issues, communicate within stakeholder groups, and defend the organization accordingly. Given the relatively short time period for reporting and refunding overpayments under Medicare's directed 60-day Rule (discussed further below), it is vital these groups are knowledgeable of any potential credible overpayments and organized to promptly perform investigations.

Consider the timing of when to bring in internal or external counsel into the audit defense team. There is significant value in including legal counsel in reviews of potential credible overpayments so other departments, including those focused on clinical review, compliance, and audits, can conduct attorney-directed investigations into the often-complex issues that will ultimately determine the course of action to be taken in a manner consistent with attorney-client privilege. Organizations should include counsel consistent with their policies and procedures; however, it is important to remember that documents created in an investigation could be subject to request by the government if not protected appropriately by some means. For organizations to successfully self-evaluate, we recommend that the legal department should be a permanent member of the audit defense team and that all stakeholders communicate with counsel appropriately if issues arise.

B. Inventory internal resources to determine what external resources you may need to respond to an audit.

Depending on the audit, organizations have limited time to review and develop thorough responses to audits. It is highly recommended that leaders, or the audit response team, inventory internal resources including employees, to identify what resources are available, clinical or otherwise, to respond to audits. For example, it is commonplace for audits to evaluate the medical necessity of a service. Often these initial denials are based upon the review of a contrac-

tor's nurse. While some organizations may rely upon the clinical review of the health care practitioner that performed this service, that may be overwhelmingly burdensome or inefficient to obtain that review from your clinical teams. There, it is recommended that the audit response teams have access (or membership) from nurses and physicians knowledgeable about the government rules and regulations of medical necessity but also adept at performing objective reviews. With these internal resources, the audit response team then can identify which audits are worthwhile to appeal.

As appeals move forward in the process, there is always the potential for a nurse or physician reviewer to then be called as a witness, including at the ALJ level of review. It is helpful in appeals that these reviewers have knowledge of your health care system, and knowledge of the company's policies and procedures, to provide more insight into their answers to questions than may be available to outside counsel or external clinical reviewers. It is also a value add to the organization to build up the expertise in these reviews and appeals with these internal reviewers so the audit responses become more sophisticated as these individuals have more interaction with the government contractors.

However, it is not always possible for smaller organizations to have these internal resources. In that instance build strong relationships with external counsel and/or clinical reviewers with expertise in appealing these audits, who can build relationships with the internal teams and who can provide real-time feedback to the internal teams on how processes can be improved to prevent future audits. Often the review and response time for appeals can be short so build these relationships before the audit hits your door.

C. Educate All Employees Regarding Routing of Government Communications.

It is imperative that providers ensure all employees are educated about the potential for receiving government communications and that the employees understand where these communications should be directed so the appropriate stakeholders are timely informed and can institute the appropriate course of action. A provider's failure to respond to a medical record request or other communication from the

government because the communication got lost, sat in someone's desk, was discarded based on a lack of knowledge or understanding, or otherwise failed to get routed to the appropriate person can lead to significant consequences, including a Medicare payment suspension. Therefore, the audit defense team should ensure that all entities are updated with the appropriate contact information for the designated receiving department and ensure that all contractors have the name and phone number of a designated representative. It is also recommended for the organizational representative to build that relationship with the government contractors, especially your local MACs, because often these developed relationships can assist with any inadvertent communication misses.

D. Ensure your organization's full participation in audit processes and vigorously defend all denials.

As noted above, the relationship between your institution and the contractors is vital. Therefore, if you receive a communication that your organization is under review, it is important for the designated employees to engage with the process. Amongst the contractors, the best example of the value of full engagement is in the TPE context designed purportedly to reduce claim denials and appeals through one-on-one help.[63] In the TPE context, the organization can speak with the contractor and communicate about the alleged claims errors rather than solely communicating through emails and writings. Often, it has been our experience, especially when your organizational representative is skilled and experienced in the government audit space, there can be real communication between the contractor and the organization. This process is especially helpful for those providers with complicated claims rules (i.e. ambulance or hospice and home health) to speak in-depth about the basis for the contractor's alleged denials and potentially receive further explanation which may support either the contractor's understanding or support improvements in the organization's documentation or claims processing. While participa-

[63] *See* https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/medical-review-and-education/targeted-probe-and-educate-tpe (accessed Feb. 26, 2025).

tion in the TPE process is mandatory for providers chosen for an audit, it's an example of how it is vital to participate rather than just superficially respond to these government communications.

There is value in participating in all audit processes even if participation isn't mandatory. For example, some organizations may have a denial threshold under which the dollar figure doesn't make sense for the organization to vigorously defend themselves. However, consider the precedents that could be set for failing to participate. Remember, perhaps every dollar that the organization allows to be recouped without defense is a claim that the organization concedes to the government wasn't eligible for payment. It bears consideration that every audited claim should be defended if there is a reason to move forward and appeal.[64] In addition, sometimes small dollar claims should be defended on principle alone or to prevent a bad precedent being set in the eyes of the MAC. What if a small dollar hospital claim was denied for purportedly lacking medical necessity for an inpatient stay? In the cases of claims where the denial reason is repeatedly used to deny large dollar claims against providers, it is important not to miss the opportunities to win these cases and use that possible positive findings to your advantage. Finally, it's also important to ensure these contractors know that your organization is reviewing your claims, has a strong integrity and compliance program, and is prepared to defend itself. As noted above, certain contractors are financially incentivized to recoup eligible overpayments so organizations want to ensure that everyone in this space is aware that you are not an organization ripe for the picking.

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[64]There are obviously going to be claims that are denied, which, upon review, the organization agrees that the denial was valid. In those instances, we would agree allowing the claim to be recouped without denial would be best to maintain the organization's credibility for future defenses.

E. Perform Meaningful Internal Audits.

Everyone knows that the audit contractors are deciding where they place their attention based on CMS priorities.[65] These organizations work closely with CMS to stay informed about the priorities of the agency, and ensure that their investigations are aligned with the agency's critical pressure points or the pressure points identified to the agency from the Office of Inspector General or even Congress. It is vital that health care organization use their resource wisely to ensure that their internal audits are performed in a way that is accretive to the efforts to reduce exposure to government audit, or provide valuable insight to the organization on opportunities for improvement before identified in a government audit.

The HHS OIG publishes its workplan on its website and it is a common first place for organizations to identify what are government priorities for review.[66] In developing its workplan, OIG assesses risk across the Department of Health and Human Services including input from Congress, HHS management, the Office of Management and Budget, the General Accountability Office, and their own management.[67] This workplan is updated monthly.

OIG has also issued new compliance guidance for health care programs, the General Compliance Program Guidance ("GCPG") which is non-binding guidance to support the health care industry in monitoring compliance with laws and regulation.[68] The GCPG included normal focus on important health care laws including Anti-Kickback Statute, Stark Law and False Claims Act, but also focused on non-traditional topics including quality. The GCPG states that their expectation that compliance programs are evaluating quality and patient safety oversight.[69] It is atypical for traditional health care compliance to include quality and

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[65] *See* Medicare Program Integrity Manual Chapter 12; Medicaid Program Integrity Manual Chapter 3.

[66] *See* https://oig.hhs.gov/reports-and-publications/workplan/index.asp (accessed on Feb. 26, 2025).

[67] *See id.*

[68] *See* https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf (accessed on Feb. 26, 2025).

[69] *See id.*

patient safety programs; however, the document states that "OIG and DOJ have long emphasized the importance of quality and patient safety" this review would "enable the entity to mitigate risk of patient harm."[70] The document states that "quality and patient safety concerns . . . can lead to overpayments and may cause False Claims Act liability."[71] Finally, the GPCG makes a direct connection between medical necessity of a claim and patient safety/quality by noting that compliance committees should ensure that these topics—medical necessity, patient safety and quality—are "included in the risk universe."[72] While "non-binding", this document provides clear insight into the thought processes of the government in what it believes health care organizations should be doing in their internal reviews.

Consider what can be gleaned from recent applicable case law in your jurisdiction. As your organization conducts its internal risk assessments, we would recommend that legal departments or outside counsel should review any cases in your jurisdiction from the last year to identify any new cases settled or decided in court that could affect your organization. Ultimately, all Medicare appeals processes can be further appealed to your federal district court so know what the history of that court is on these topics.

It's important to remember that we are at the beginning of a new Presidential administration so priorities published prior to January 2025 may no longer have the same importance. However, there is belief in the current administration there is fraud in federal healthcare programs. There is no reason to believe that the contracts to audit contractors will be converted to new organizations or are likely to be terminated if they are revenue positive for the government. We recommend that organizations continue to identify audit priorities with the resources identified above.

F. Evaluate organizational contracts and agreements.

Evaluating organizational contracts and agreements can

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[70] *Id.* at 76.

[71] *Id.*

[72] *Id.* at 78.

ensure that employees and contracts are in compliance with the same standards for reimbursement and other regulatory requirements. For example, many professional services agreements contain provisions regarding the quality of care provided, service delivery standards, and documentation requirements. Regularly evaluating these elements, including medical records and other documentation prepared by providers, ensures that the services billed for align with the services actually provided, improving both the quality of care and favorable outcomes for patients. Moreover, assessing contracts and agreements, healthcare organizations can ensure they have appropriate internal controls and procedures in place to ensure that claims are processed, submitted, and paid accurately by all of its contractors and partners.

V. Closing Thoughts

Navigating the complexities of health care audits requires not just a deep understanding of the law, but also a strategic approach to operations. As we've explored, audits—whether internal or governmental—differ in scope and focus, but they all share a common thread: the need for accurate documentation, a clear billing practice, and an established audit response protocol. Understanding the nuances of each type of audit is key to minimizing risk and safeguarding your organization's reputation and financial health.

Organizations that proactively prepare for audits—not as isolated events, but as an integral part of their operational workflow—are better positioned to manage the demands of compliance and mitigate the potentially costly consequences of errors or missteps. Operationalizing audit readiness means embedding strong controls, consistent training, and ongoing evaluation into the everyday practices of the organization.

The health care industry is constantly evolving, and so too are the standards and expectations surrounding audits. As regulatory environments tighten and scrutiny increases, organizations must stay ahead of the curve by fostering a culture of compliance and transparency. By "knowing your audit," organizations not only protect themselves from refunds and other penalties but also reinforce their commitment to providing quality care and maintaining trust with patients, providers, and payers alike.