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Kimberly Brandt
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Dear Ms. Brandt:

Once again, thank you for engaging with us on the Office of Inspector General (OIG) hospital audit extrapolation issue. As we discussed at our recent meeting, this issue has plagued our member hospitals and hospital systems for a number of years and, unfortunately, seems to have gotten worse recently with the issuance of a new audit report[1] that a member hospital system brought to our attention.

We detail our concerns about the most recent audit below. We then outline the additional concerns that we have shared with various agencies within the Department of Health and Human Services (HHS) over a number of years.

THE MOST RECENT EXAMPLE OF OIG OVERREACH

A member health system came to us last month because it had gotten a letter from its Medicare Administrative Contractor (MAC) about claims for Hyperbaric Oxygen Therapy (HBOT) services. The letter asked that two of the hospitals in the system conduct a self-audit of hundreds of claims, with dates of service going back to 2012 (essentially, spanning the full six-year lookback applicable to self-reporting of overpayments). The MAC's request is based on a recommendation from the OIG contained in the recent audit report. This report raises serious and, in some cases, new concerns.

Perhaps most concerning, is that *the OIG never presented a draft of the audit report to the Centers for Medicare & Medicaid Services (CMS) for the agency's review and comment*. Rather, the OIG sent a draft to the MAC with "recommendations" for what the MAC should do. This is

[1] OIG, Wisconsin Physicians Service Paid Providers for Hyperbaric Oxygen Therapy Services That Did Not Comply with Medicare Requirements (Feb. 2018), https://oig.hhs.gov/oas/reports/region1/11500515.pdf

highly unusual and significant. Indeed, we saw no other OIG audit of a Medicare item or service in the past three years in which the OIG made its recommendations directly to a MAC or sent the draft audit report for MAC, rather than CMS, review. This matters because *MACs are not the arbiters of Medicare policy* – CMS is. CMS has the final word on whether Medicare coverage criteria are met and, therefore CMS – not the MACs – should have input into and awareness of the OIG's interpretation of coverage rules.

The recent HBOT audit shows why this is a problem. In its report, the OIG attributed alleged overpayments to the fact that the MAC "did not have billing or coding guidelines other than [the HBOT National Coverage Determination (NCD)] for providers to follow." But CMS has consciously chosen to leave it to contractors to decide whether to issue their own, local guidance regarding services covered under an NCD. In faulting the MAC for not having issued its own coding guidance, *the OIG seems to have crossed the line into carrying out Medicare program functions in contravention of the OIG Act*.

Even if HHS takes the position that the OIG Act is not being violated, issuing a report that "recommends" that the MAC take certain actions is highly problematic. Not surprisingly, the MAC largely did what the OIG recommended *without evaluating whether the OIG's coverage decisions on individual claims were correct or whether the audit results should be extrapolated to all 45,000 claims for HBOT services from all hospitals in the MAC's region.* In fact, the audit's findings and recommendations are highly questionable for many reasons:

- The OIG audited a sample of 120 HBOT claims from a universe of just under 45,000 claims from across the entire MAC region and sampled only *a single record* from each of two hospitals in our member's system.
- Of the 120 claims the OIG reviewed, it found 102 to be non-compliant. We understand that whether HBOT meets the requirements of the HBOT NCD often comes down to medical judgment. In the case of our member, it believes the two claims from its hospitals were appropriately billed; it has received no information from the OIG or MAC explaining why its claims might be considered non-compliant
- The coverage criteria for HBOT services are complex and highly patient-specific, but the OIG report includes only two "representative examples" of the 102 claims that the OIG found to be non-compliant, and included only a partial medical record for those claims. As a result, hospitals are unable to see even the general type of error for which they are now being asked to search.
- Despite the fact that hospitals believed they properly billed for covered HBOT services, the OIG extrapolated its findings to all HBOT claims in the region during the audit period. *A hospital might not have had even one claim reviewed in the audit and yet it is being told to review all of its HBOT claims spanning about six years***.** The OIG offered no explanation for why extrapolation was warranted in these circumstances, but we note that it produced a projected overpayment of about $42 million.

- The OIG recommended that the MAC "notify the providers responsible for the 44,820 nonsampled claims . . . so that those providers can investigate and return any identified overpayments." Again, many of these hospitals had only a handful (if any) of their claims actually reviewed by the OIG. The MAC has begun notifying hospitals included in the OIG review even though the MAC is simultaneously doing a separate "Targeted, Probe & Educate" audit of these same services at some of the same hospitals.
- The OIG's report indicates that it is performing a similar audit of another MAC, which would compound the problems identified here. This amplifies the need for swift action to address these problems.

Conducting a 100 percent retrospective review of all HBOT services at all these hospitals is enormously time and resource-intensive and thereby adds even more to the cost of health care. It will tie up hospitals' auditing staffs for months and cost the hospitals tens of thousands of dollars. Yet the hospitals believe that is what they must do; otherwise, they risk some type of adverse action by CMS, owing significant amounts of interest on alleged overpayments, further scrutiny by the OIG or even a potential False Claims Act action.

LITANY OF THE ERRORS IN PRIOR OIG AUDITS

- The OIG improperly relies on post-admission outcomes to conclude that inpatient admissions were wrongly billed. The OIG regularly relies on post-admission patient outcomes, such as actual length of stay or actual rehabilitation outcomes, to conclude that inpatient hospital admissions and inpatient rehabilitation facility admissions were not medically necessary.[2] This directly violates Medicare regulations, which dictate that an admission is covered by Medicare if the physician reasonably *expects* at the time of the patient's admission that the relevant requirements for admission are met.

- The OIG has required hospitals to meet admission order requirements that were not in effect when the admission occurred – or that simply do not exist.

    - In multiple audits, the OIG found that a hospital wrongly billed for an inpatient admission because there was no written physician order at or before the time of admission, as required by an October 2013 regulation that CMS now has rescinded. Even if that regulation were consistent with the Medicare statute – and we strongly believe that it was not – the OIG required at least one hospital to have a physician order for admissions that occurred *before the regulation took effect*.[3]

[2] *See, e.g.*, OIG, Medicare Compliance Review of Mount Sinai Hospital for 2012 and 2013, at 28-37 (Apr. 2017), https://oig.hhs.gov/oas/reports/region2/21401019.pdf [Mount Sinai Compliance Review]; OIG, Medicare Compliance Review of Abbott Northwestern Hospital for 2013 and 2014 (Dec. 2016), https://oig.hhs.gov/oas/reports/region5/51500043.pdf [Abbott Northwestern Compliance Review].
[3] *See* Mount Sinai Compliance Review at 38-39.

- In one audit, the OIG found that the hospital should not have billed for an inpatient admission, even though Medicare lists the procedure that the hospital performed as "inpatient only."[4] The OIG reached this conclusion simply because the patient's medical chart showed that the patient was formally admitted after the "inpatient only" procedure. But there is no law, regulation, or guidance contemplating an admission order before the "inpatient only" procedure begins – the OIG simply made the requirement up.

- The OIG wrongly applies the Medicare rules that determine payment for inpatient stays, resulting in repayment demands for diagnoses that were justified by clinical evidence and CMS coding guidance. For example, the OIG has concluded that a hospital should not have listed Diagnosis Code 261 for severe malnutrition because the patient did not have Nutritional Marasmus (a rare malnutrition disorder associated with that diagnosis code).[5] But CMS coding guidance shows that Diagnosis Code 261 is valid for several different forms of severe malnutrition, not just Nutritional Marasmus. For other patients, the OIG found that the medical record did not justify any malnutrition diagnosis. But it reached this conclusion only by ignoring evidence of severe malnutrition from registered dietitians, which is accepted as relevant evidence to support medical necessity under CMS guidance.

- The OIG misapplies Medicare rules that allow providers to bill certain services separately because the OIG misunderstands or ignores the clinical evidence that the providers submit.

  - CMS guidance permits providers to use modifier -59 to bill separately for "distinct procedural services" that would otherwise be bundled together. A procedure is "distinct" if it is performed, for example, in a "different session or patient encounter, different procedure or surgery, different site, or organ system, separate incision/excision, or separate injury."[6]

  - The OIG regularly misapplies this guidance. For example, one hospital used modifier -59 to bill separately for inserting a catheter into the heart in conjunction with a heart biopsy.[7] The hospital submitted clinician statements and coding guidance supporting its conclusion that these were not "distinct" procedures because in many cases – including those reviewed by the OIG – a catheter is inserted for an independent diagnostic reason (e.g., to measure arterial pressure)

[4] *See* Mount Sinai Compliance Review at 39-40.
[5] OIG, Vidant Medical Center Incorrectly Billed Medicare Inpatient Claims with Severe Malnutrition (Jan. 2017), https://oig.hhs.gov/oas/reports/region3/31500011.pdf.
[6] Medicare Claims Processing Manual, ch. 23, § 20.1.1.B.
[7] *See* Abbott Northwestern Compliance Review.

and not simply to obtain the heart biopsy. The OIG ignored this evidence and wrongly concluded that the hospital should not have billed separately for the procedures. In a later nationwide review of the same issue, the OIG repeated its mistake of assuming that a catheterization is simply part of a heart biopsy, even when there is a separate diagnostic reason for the catheterization.[8]

- In one audit, the hospital used modifier -59 to bill separately for two genetic laboratory tests for breast cancer.[9] The hospital provided coding guidance showing that the procedures are distinct because they test for different genetic alterations – one test looks for "common" breast cancer gene alterations and the other looks for "uncommon" alterations. The OIG ignored that coding guidance and found that the hospital should not have billed separately.

- In still other audits, the OIG found that a hospital should not have billed separately for services related to intensity-modulated radiation therapy (IMRT) because those services were part of developing the IMRT plan. The Medicare manual and AMA coding guidance allow providers to bill separately for any services "not provided as part of developing the IMRT treatment plan."[10] In at least one audit, the hospital furnished evidence that the services provided were separate from the IMRT plan, but the OIG disregarded this evidence.[11] In another audit, the OIG suggested that certain services were always part of the IMRT planning service and could never be billed separately, even though this interpretation directly contradicted CMS guidance.[12]

- Even when CMS corrected the OIG's errors in interpreting CMS coverage policy, the OIG insisted on its own interpretation. In a recent review,[13] the OIG misinterpreted CMS coverage policy for outpatient physical therapy, requiring audited claims to show an expectation that physical therapy will significantly improve the patient's condition, to include functional reporting codes and severity modifiers in all cases, and to list the same therapist on the claim and on the medical record. Each of these "requirements" goes beyond the actual CMS coverage policy, as CMS recognized by responding that the

[8] *See* OIG, Hospitals Nationwide Generally Did Not Comply with Medicare Requirements for Billing Outpatient Right Heart Catheterizations with Biopsies, at 4-5 (Mar. 2017), https://oig.hhs.gov/oas/reports/region1/11300511.pdf.
[9] *See* Abbott Northwestern Compliance Review.
[10] Medicare Claims Processing Manual, ch. 4, § 200.3.1; AMA, CPT Assistant 09:11 (Nov. 2009).
[11] *See* OIG, Medicare Compliance Review of NorthShore University Health System, at 23-24 (Dec. 2016), https://oig.hhs.gov/oas/reports/region5/51500044.pdf [NorthShore Compliance Review].
[12] Mount Sinai Compliance Review, at 41-42.
[13] OIG, Many Medicare Claims for Outpatient Physical Therapy Services Did Not Comply with Medicare Requirements (Mar. 2018), https://oig.hhs.gov/oas/reports/region5/51400041.pdf.

OIG's interpretations were "inaccurate" and "do not appear to align with Medicare outpatient physical therapy payment policy." CMS's response helpfully clarified Medicare policy and caused the OIG to correct certain errors in its report. In other respects, the OIG insisted – in the face of CMS statements to the contrary – that its own interpretation was more accurate than the interpretation of the agency that created the rule. For example, the OIG rejected CMS's statement that a significant improvement in the patient's condition is not required, and held to its original interpretation.[14]

- The OIG fails to follow a process that allows for consideration of all evidence submitted by a provider.

    - The OIG refused to consider clinical documentation that a hospital submitted, even when the submission was timely and relevant. In one audit, the OIG stated that it knew evidence submitted by the hospital was duplicative – and, therefore, would not review the evidence.[15] In another audit, the OIG had difficulty navigating the hospital's medical records, so the hospital made resources available to help the OIG reviewers and directed them to previously provided documentation to support the claims. The OIG responded that its medical reviewers had completed their review and would not consider the supporting documentation, and advised the hospital to use the appeals process to reverse the reviewers' findings.[16]

    - CMS payment policies, the OIG's own audit protocols, and basic due process principles require that the OIG establish and actually follow a process that results in the OIG's consideration of all relevant and timely evidence that a provider submits.

- The OIG has extrapolated in nearly every audit, regardless of whether extrapolation is statistically or legally sound. The OIG has stated that it now extrapolates from its findings in all hospital audits, even when extrapolation is statistically unjustified due to low error rates, which often get even lower due to providers' high rate of success on appeal. As noted, in one recent review, the OIG went a step further and extrapolated its findings to an entire MAC jurisdiction, including hospitals that had only a handful of claims (if any) actually reviewed by the OIG. The OIG routinely casts aside concerns about the statistical and legal validity of its decision to extrapolate, arguing that it isn't bound by any need for a sustained or significant error rate – even though the Medicare contractor, which is bound by such a requirement, will adopt the OIG's extrapolation

[14] *Id*. at 12.
[15] Abbott Northwestern Compliance Review, at 20-21.
[16] NorthShore Compliance Review, at 24.

wholesale. Even in the context of a claim review under a Corporate Integrity Agreement, which would involve a provider charged with fraud or other misconduct, the OIG requires the review entity to extrapolate only if the error rate is 5 percent or higher.[17]

- The OIG repeatedly identified claims as wrongly billed when a hospital did not report a medical device credit, even when the hospital never actually received the credit. CMS regulations require hospitals to report the value of device credits only if the hospital *receives* a credit or a replacement device at no cost.[18] Yet the OIG refused to follow the language of the regulation.[19] It appears to have changed its interpretation on this point only after CMS clarified its policy on device credits, at the AHA's request.

- The OIG repeatedly identified claims as overpayments even when the claim fell outside the applicable reopening period. The OIG repeatedly identified claims as improperly billed and recommended that the Medicare contractor demand repayment of claim amounts even when the claim was submitted outside the period during which the contractor was authorized to reopen the claim.[20] Again, the OIG appears to have stopped this practice only after CMS instructed its contractors not to demand repayment for claims identified by the OIG that fall outside the reopening period.

- The OIG has repeatedly concluded that claims were billed to the wrong diagnosis code even when the code was appropriate under CMS coding guidance. In multiple audits,[21] the OIG found that hospitals wrongly billed claims for various forms of protein malnutrition under ICD-9 code 260, which the OIG has said is exclusively for a specific form of malnutrition called Kwashiorkor. The OIG relied on AHA Coding Clinic Guidance from October 2009 to support its conclusion and stated that coding related questions were handled by the AHA Coding Clinic. Not only is AHA Coding Clinic guidance not a basis for Medicare payment decisions or the equivalent of binding CMS guidance, but CMS's *actual* ICD-9 coding guidance supports use of code 260 for multiple types of protein malnutrition (not solely Kwashiorkor). At the time the claims at issue were filed, the ICD-9's tabular list indicated that code 260 was used for Kwashiorkor but the ICD-9's alphanumeric index stated it could be used for protein

[17] OIG, Corporate Integrity Agreement FAQ, https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp.
[18] 42 C.F.R. § 412.89 (a hospital must report a credit on its claim if "(1) a device is replaced without cost to the hospital; (2) The provider received full credit for the cost of the device; or (3) The provider receives a credit equal to 50% or more of the cost of the device").
[19] *See, e.g.*, Mount Sinai Compliance Review at 37-38; Abbott Northwestern Compliance Review at 29-31.
[20] *See, e.g.*, Mount Sinai Compliance Review at 43-45.
[21] *See, e.g.*, OIG, CMS Did Not Adequately Address Discrepancies in the Coding Classification for Kwashiorkor (Nov. 2017), https://oig.hhs.gov/oas/reports/region3/31400010.pdf.

malnutrition. CMS ICD-9 guidance expressly instructed providers to use *both* the Alphabetic Index and the Tabular List to identify appropriate codes and stated that the instructional notations in the index and the list should be used to select codes. The OIG does not appear to have ever addressed this guidance and the issue ultimately became moot only because the entry to code 260 was revised in the 2012 version of the ICD-9 (and, in 2015, the ICD-10 was introduced).

- The OIG has misapplied CMS regulations and guidance on post-acute transfers to penalize hospitals that treat beneficiaries with ongoing home health needs. CMS regulations treat the discharge of certain inpatients with qualifying DRGs as a "transfer" (rather than a "discharge") if the discharge is to home pursuant to a written plan of care for the provision of home health agency services that begin within three days after discharge.[22] The OIG has misapplied this regulation by concluding that a discharge also counts as a transfer if the patient was receiving home health services under a written plan of care *before* the inpatient admission and continues to receive home health services after the discharge—*even when no new interventions or updates to the plan of care are added as a result of the inpatient admission*. The OIG unreasonably interprets Medicare regulations, which clearly contemplate home health services "beginning" between the date of discharge and three days subsequent. In doing so, the OIG penalizes hospitals simply for treating beneficiaries who have ongoing home health needs.[23]

As you can see, the HBOT audit report is just another in a series of problematic OIG audits. We look forward to discussing further with you how growing concerns among our membership about these audits can effectively be addressed. The pervasive errors in audit findings exacerbated by extrapolation to thousands are unfair and exceedingly burdensome on hospitals and health systems, whose resources are already stretched thin. Perhaps it is axiomatic to observe that we may never be able to effectively address the cost of the health care if unfair and inaccurate audit results subjected to punitive extrapolation are allowed to continue unabated.

We look forward to working with you to address these concerns. I can be reached at mhatton@aha.org or 202-626-2336.

Sincerely,

/s/

Melinda Reid Hatton
General Counsel

[22] 42 C.F.R. § 412.4.
[23] *See* OIG, Medicare Compliance Review of Carolinas Medical Center (Jan. 2018), https://oig.hhs.gov/oas/reports/region4/41604049.pdf.