American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

March 25, 2021

Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445–G
Washington, DC 20201

Dear Acting Administrator Richter:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) writes to express our concerns about the recent denials of our members' requests for a "mid-build exception." These denials result in inappropriately reduced payment rates for items and services furnished by certain off-campus provider-based departments (PBDs) that first billed Medicare for services furnished on or after Nov. 2, 2015.

The 21st Century Cures Act authorizes the Centers for Medicare & Medicaid Services (CMS) to deny a mid-build exception request only if the agency completed its audit of the provider by Dec. 31, 2018. In a March 23, 2021 email, CMS said that it "performed all audit activities in accordance with the requirements set forth in the" law when, in fact, the agency did not meet the Dec. 31, 2018 deadline: The audits were completed and hospitals were notified of the results *more than two years after this statutory deadline.* And, the issuance of these denials could not have come at a worse time for hospitals that are struggling both financially and with staff and resource shortages due to the pandemic.

As such, the denial determinations should be rescinded. Specifically, providers that submitted mid-build exception requests must be excluded from the definition of "off-campus outpatient department of a provider" in all instances where CMS has failed to timely render a contrary determination as part of a mid-build audit completed on or before Dec. 31, 2018.

In addition to the denials being time-barred, many of the denials are simply incorrect; of the 334 providers that requested the mid-build exception, CMS startlingly found that only 132 (40%) qualified, meaning that 202 (60%) failed to qualify. However, our members tell us that they actually did satisfy the statutory "mid-build" requirements. As explained in greater detail below, the denials were based on Medicare Administrative Contractors' (MACs) misunderstandings of the information that the provider submitted or their interpretation of what the statute requires.

The Mid-build Exception Denials Exceed CMS' Authority and Should be Rescinded. Beginning Jan. 1, 2017, Medicare cannot make payment under the hospital outpatient prospective payment system (OPPS) for items and services furnished by off-campus PBDs that first billed Medicare for services furnished on or after Nov. 2, 2015. These PBDs are referred to as "nonexcepted." Instead of being paid under the OPPS, nonexcepted PBDs are paid at 40% of the OPPS rate. However, off-campus PBDs that did not bill for OPPS services prior to Nov. 2, 2015, but were under construction (i.e., "mid-build") as of this date, were allowed to apply for an exception by submitting specified materials to their MAC by Feb. 13, 2017.

A hospital that submitted the specified materials became "excepted" from the lower payment rate unless CMS both audited the provider's compliance with the requirements for the exception by Dec. 31, 2018 and found that the requirements were not met. Specifically, the Medicare statute at 42 U.S.C. 1833(t)(21)(B)(vii), as amended by the 21st Century Cures Act, provides:

> "(vii) AUDIT.—Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. … If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term 'off-campus outpatient department of a provider' under such clause."

However, CMS did not begin to share the results of these audits with providers until Jan. 19, 2021, *more than two years after this statutory audit deadline*. Specifically, the audit determination letters sent to providers by Cahaba, CMS' audit contractor, state "*As required by section 1833(t)(21)(B)(vii) of the Act*, CMS has audited [provider's name] compliance with the requirements of clause (iv) of section 1833(t)(21)(B)." (Emphasis added). However, CMS was not in compliance with this section of the statute because it did not complete the audits by the statutory deadline. Thus, the agency exceeded its authority in denying mid-build exception requests in 2021.

CMS' own "Medicare Mid-Build Off-Campus Outpatient Departments Exception Audit Results Fact Sheet" provides evidence that the agency did not meet the Dec. 31, 2018 deadline:

> "CMS conducted the audits to determine if the providers met the mid-build exception requirements and reviewed the applications along with supporting documentation. CMS worked hard to ensure that the mid-build audits were completed correctly, including implementation of the secondary quality assurance review to ensure the audit determinations were appropriate. *Soon after the reviews were completed, the COVID-19 public health emergency began.*" (Emphasis added)

The effective date of the public health emergency was Jan. 27, 2020. If the audits were completed shortly before this date, the audits must have been completed toward the end of 2019 – already approximately one year past the statutory deadline. Inexplicably, CMS then waited over an additional year to inform the 334 providers of their audit results.

Moreover, CMS never justified the reason for the delay in conducting the audits and notifying providers. The agency was aware of the AHA's concerns about the timing of the audits and the negative financial implications any delay would have for providers. The AHA has expressed concerns about audit timing since early 2017, when the agency issued its preliminary guidance about the mid-build exception. Ultimately, the AHA brought such concerns to CMS' attention in a Dec. 14, 2017 letter in which we stated:

> "As such, the AHA is very concerned about the risk hospitals will have to take on by assuming that they meet the requirements for the exception until the time their audit occurs. Indeed, for this very reason, several of our members have inquired with their MACs about the status of their application, but to no avail. Since reimbursement under Section 603 results in payment at 40 percent of the OPPS, hospitals are anxious to know whether they meet the requirements for being excepted from Section 603 beginning Jan. 1, 2018. This decision is essential for accurate and sound financial forecasting."

These communications informed CMS of the significance of the audit deadline for hospitals. Thus, not only are the exception denials contrary to the statute, but they also are unfair. While awaiting their audit results, providers were permitted to bill for their off-campus PBDs at the full OPPS rate. **The two-year delay has serious negative consequences for these providers**. They did not learn until sometime after Jan. 29, 2021 that they had failed the audit. As a result, if the audit results stand, they would owe the agency far more than what they would have if the audits had been concluded by the statutory deadline. The reverse also is true – certain providers that applied for the exception decided to hold their claims until they learned of their mid-build audit results. Yet, they did not learn until sometime after Jan. 29, 2021 that they had passed the audit. However, the one-year timely claims filing deadline has passed, potentially precluding them from billing at the higher rate. Finally, providers that passed the audit, but acted conservatively by billing as nonexcepted PBDs also are worried that they will not be able to re-bill those underpaid claims that are beyond the one-year timely filing

deadline. And, even if they are able to re-bill, the agency's fact sheet does not address how these providers should rebill.

Application of Interest. As explained above, all mid-build exception denials that hospitals received after Dec. 31, 2018 exceed CMS' authority and should be rescinded. If, however, CMS declines to do so, we ask that in order to mitigate the harm to hospitals, CMS address interest accrual consistent with past precedent. Specifically, it is our understanding that for a MAC-identified overpayment, interest typically begins to accrue only after the issuance of a demand letter. These same regulations would not permit CMS to go back to the date the claim was filed for purposes of the interest calculation. We ask CMS to confirm that interest for purposes of mid-build audit overpayments would not begin to accrue until 30 days after the provider receives a demand letter.

Provision of an Informal Review Process. As previously stated, all mid-build exception denials that hospitals received after Dec. 31, 2018 exceed CMS' authority and should be rescinded. If, however, CMS declines to do so, we ask that CMS also mitigate the harm to hospitals by following another past precedent to establish an informal review process to correct errors in the audit determinations. As previously noted, many providers that failed the mid-build audit have reason to believe that their audit results were faulty. While the 21st Century Cures Act makes no provision for formal administrative or judicial review of individual audit determinations, this does not preclude CMS from establishing an informal review process to determine whether the MACs, the CMS Regional Offices and the secondary quality assurance reviewers applied the law correctly when conducting audits. **As such, we ask that the agency create an informal review process to ensure that the mid-build requirements were applied correctly, with the possibility of an appropriate remedy.**

There is precedent for this. CMS' determination of inpatient prospective payment system (PPS) uncompensated care payment (UCP) amounts are precluded from administrative and judicial review. However, CMS set up a process to review and modify UCPs for hospital mergers if the data CMS used to determine UCPs in the inpatient PPS final rule did not reflect a hospital merger that happened at a later date. CMS gives hospitals a specific period of time to identify a merger not incorporated into its final rule UCP payments.

Indeed, there is ample reason for CMS to provide an informal review of the mid-build audit results. Specifically, a number of AHA's members failed the mid-build audits due to an overly strict and inappropriate interpretation of the mid-build definition that is not consistent with congressional intent. For instance, several providers failed because they leased the space from a landlord and the landlord held the contract for the construction or renovation of the facility. Another hospital failed the audit because, despite owning the property, the health system "parent" of the hospital had the contract for construction, rather than the hospital itself. Cahaba asserted that the statute requires the provider itself to have the contract for construction.

The AHA also has heard from hospitals that have failed their audits for other concerning and inappropriate reasons, such as not having a CEO or COO sign the mid-build attestation because those titles did not exist at their facility. This occurred despite the fact that the equivalent titles are explicitly permitted in CMS' preliminary guidance. Hospitals also failed for other minor technicalities involving missing dates or signatures on fully executed contracts where the provider can show that an agreement was binding and that they were financially liable. Providers receiving these and other kinds of overly strict or faulty bases for failing their mid-build audits should be permitted to have the audit findings reviewed, and as appropriate, reversed by CMS.

Again, we thank you for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, director of policy, at rschulman@aha.org or 202-626-2273.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President