EXHIBIT 9

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Advanced Medical Technology Association

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Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1813

Re: Office of Medicare Hearings and Appeals (OMHA) Decision to Suspend Assignment of New Requests for Administrative Law Judge (ALJ) Hearings for Adjudication of Appeals

Dear Secretary Sebelius and Administrator Tavenner,

The Advanced Medical Technology Association (AdvaMed) is writing regarding the Office of Medicare Hearings and Appeals' (OMHA) recent policy decision to suspend for two years the assignment of new requests for Administrative Law Judge (ALJ) hearings for adjudication of appeals. AdvaMed member companies produce the medical devices and diagnostic products used by many Medicare providers who will be adversely impacted by this policy. We oppose OMHA's decision and are very concerned that the policy will create significant harm for both patients and providers. Given our concerns, we request that (1) the Department of Health and Human Services (HHS) and Centers for Medicare & Medicaid Services (CMS) take immediate action to relieve the current Medicare appeals backlog and the financial strain OMHA's decision places on providers, and (2) CMS work with OMHA to develop and put in place long-term improvements to the Medicare audit and appeals processes.

I. The current backlog and OMHA's decision contradict both the language and the intent of the Social Security Act, and results in significant financial strain on providers, suppliers, and patients

The Medicare appeals process was established to provide Medicare beneficiaries with the opportunity to appeal a Medicare decision without resorting to the courts.[1] Section 1869 of the Social Security Act (SSA), added by the Beneficiary Improvement and Protection Act, establishes deadlines for the review of Medicare appeals at all levels.[2] Where the reviewing body misses a statutory deadline, the appellant is permitted to proceed to the next level of appeal. ALJ hearings must be adjudicated within 90 days under section 1869(d)(1) of the Act. OMHA's decision to ignore these requirements so that no new requests for ALJ hearings would exceed the 90-day statutory deadline, even if the suspended status takes years, plainly violates the statute and contradicts the purpose of the Medicare appeals process.

The current backlog across the review levels for appeals cannot be reconciled with the goals of the statutory scheme for Medicare appeals. If a hospital were to appeal a Medicare Part A coverage decision and then exercise its right to proceed to the higher level of review at the end of each missed deadline at each level of review, the case is virtually certain to end up in queue for a review by a federal court without having been reviewed by an ALJ or the Medicare Appeals Council, and likely without having been reviewed by a Qualified Independent Contractor (QIC). The result would be the absence of an administrative record when the appeal reached the federal courts, leading to precisely the result that the Supreme Court warned about in *Heckler v. Ringer* and that the enactment of section 1869 was designed to prevent. In practice, the current backlog renders the statutory deadlines irrelevant, thus contradicting the statutory mandate. OMHA's decision to suspend the assignment of requests for ALJ hearings only perpetuates the backlog that eliminates the statutory schedule of appeal reviews. OMHA failed to offer any legal authority that permits OMHA to defer the assignment of timely filed ALJ appeals.

In addition to contradicting the mandate of the SSA, OMHA's decision undermines the financial stability of Medicare providers, who have already seen significant revenues tied up in pending appeals as the backlog for ALJ adjudication has grown. Stated simply, the accumulation of appealed claims at OMHA leads to the accumulation of providers' funds at CMS and is unfair to providers who are partners with Medicare in ensuring beneficiaries access to the care they need.

AdvaMed therefore opposes OMHA's proposed stop-gap measure, and offers several suggestions for the resolution of the backlog and the long-term improvement in the efficiency of review. In the short term, HHS should find additional funding for OMHA's budget, beyond the increase established for FY 2014, to provide the resources OMHA needs to adjudicate appeals in

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[1] *See Heckler v. Ringer*, 466 U.S. 602, 627 (1984) (holding that Congress did not intend a process whereby there could be "premature judicial intervention in an administrative system that processes literally millions of claims every year.").

[2] Pub. L. No. 106-554 § 522, 114 Stat. 2763A-1, 543 – 47 (Dec. 21, 2000).

the timeframe required by law. As we recommend below, additional funding would become available if CMS were to put in place a temporary moratorium on audits until much of the backlog of pending appeals requests was eliminated. HHS should also implement long term solutions, including separating appeals by categories, establishing default judgments for providers in some cases, and establishing a clinical inference review in the redetermination and reconsideration levels.

II. CMS should take immediate action to relieve the appeals backlog

CMS can take a number of interim steps to reduce the financial strain faced by providers as a result of a large backlog of appeals requests and OMHA's decision to suspend the assignment of new requests for ALJ hearings:

- CMS should impose a ***moratorium of all pre- and post-payment audits of claims until the backlog is reduced*** to not more than six months. The increase in appeals cases is driven largely by the expansion of post-payment audits, specifically, Recovery Audit Contractor (RAC) and Zone Program Integrity Contractor (ZPIC) audits.[3] Pausing all audits until improvements are made to the Medicare appeals system would allow OMHA to reduce the backlog by preventing the flood of the anticipated new appeals. At the very least, CMS should impose a moratorium on complex medical reviews that have higher rates of appeal. It is a legitimate agency response that would bring balance and sanity to the current situation.

- HHS should use its budgetary authority to ***redirect funding that would be available from the temporary suspension of new audits to OMHA for the hiring of additional resources to reduce the backlog of appeals requests***.

- ***Providers should be excluded from pre- and post-payment audits for one-year if they have a low payment error rate***. This measure would allow CMS to target its audits more efficiently.

- With the significant delay in adjudication of appeals, ***CMS should not recoup disputed funds until after the provider has received an ALJ determination***. Currently, if a provider loses the second level of appeal (QIC), it must remit the funds to CMS even if the provider appeals to the ALJ level. In the wake of OMHA's decision, these funds will remain unavailable to the provider for years following the appeal to the ALJ level. The growing backlog drains an increasing amount of funds for an increasing duration from providers. Until CMS improves the appeals process, these funds should remain with the

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[3] According to a statement by Chief ALJ Nancy Griswold at a 2/12/2014 public hearing entitled "Medicare Appellant Forum." *See* Epstein Becker Green Client Alert, OMHA's Medicare Appellant Forum Offers Few Meaningful Answers for Frustrated Medicare Providers and Suppliers, February 28, 2014, at http://www.ebglaw.com/showclientalert.aspx?Show=18414.

providers through the ALJ appeals process. This is especially fair in the context of hospitals, where providers have been highly successful at the ALJ level, and have won the majority of ALJ appeals.

III. CMS and OMHA should develop and put in place long-term improvements to the Medicare audit and appeals processes on all levels of appeals

MAC Part A/B contractors have historically been expected to match denials, audits, and their appeal (redetermination) capacity; by missing the corresponding performance metrics, they are penalized or risk contract termination. The agency as a whole should follow the same practice. CMS should improve the efficiency of the audit and appeals processes by taking the following steps:

- CMS and OMHA should ***separate appeals streams by source of the payment denial*** to show whether they originate from Medicare Administrative Contractor (MAC) audits or from the RAC program. This breakdown would provide discrete information about the effectiveness of individual contractor audit processes and comparison of performance once the results of adjudication of appeals have been considered.

- CMS should also ***separate pre- and post-payment audits at the appeals level*** so that RAC post-payment audits do not overwhelm the appeals process. This would also allow CMS and OMHA to focus on solutions that target RAC audits and the resulting appeals.

- ***A default judgment should be entered in favor of the provider if an appeal has not been heard within the required time period.*** Providers that miss appeals deadlines lose their right to pursue the claim through the appeals process. However, the only remedy that currently exists for providers when the contractors or ALJs miss their appeals deadlines is to escalate the claim to the next level of appeal. For the provider, this is no remedy at all, since significant backlogs exist at all levels of the appeals process.

- ***CMS should require RACs to request fewer medical records for review*** in order to improve the accuracy with which they select claims for review. Doing so may also encourage RACs to conduct a more thorough review that results in an accurate determination of approval or denial, thereby avoiding the need for an appeal.

- ***CMS should permit clinical inference at the redetermination and reconsideration levels of review, before the appeal for an ALJ hearing***. A comprehensive review of a claim by a clinician is a key aspect of the appeal review for claim appropriateness. Since clinical inference is currently not available until the ALJ hearing, claims ascend past the first two levels of review with little clinical feedback. If claims were examined through a clinical inference earlier in the appeal process, fewer would proceed to the cases up the appeals ladder.

We appreciate the opportunity to comment on the OMHA decision to suspend assignment of new requests for appeals for ALJ hearings. If you have any questions about our recommendations, please contact me at dmay@advamed.org or Richard Price at rprice@advamed.org.

Sincerely,

Donald May
Executive Vice President
Payment & Health Care Delivery Policy
AdvaMed