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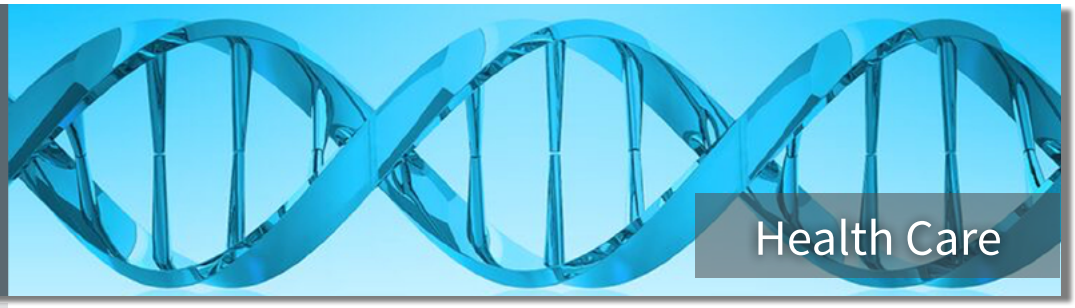

In this Alert:

HHS Finalizes Appeals Backlog Rule in Wake of Judicial Order

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The U.S. Department of Health and Human Services (HHS) released a Final Rule aimed at reducing and eventually eliminating the backlog of more than 650,000 claims currently awaiting adjudication by an administrative law judge (ALJ) at the Office of Medicare Hearings and Appeals (OMHA). The Final Rule, published January 17 and titled "Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures," comes in the wake of U.S. District Court Judge James Boasberg's order to HHS requiring it to reduce the backlog of cases pending before ALJs by 30 percent by the end of 2017, by 60 percent by the end of 2018, by 90 percent by the end of 2019, and completely by the end of 2020.

Unfortunately, by HHS's own admission, the initiatives contained in the Final Rule alone will not eliminate the appeals backlog in accordance with the timeline dictated by Judge Boasberg. And, as a further blow to HHS's plans, the Trump Administration issued memorandum freezing new and pending regulations until such a time as newly installed agency heads can review them; this could potentially delay the implementation of the Final Rule, currently scheduled for March 20, 2017, or possibly kill it altogether, pending such review.

What You Need to Know:

The Final Rule focuses on modifying the third level of appeal (ALJ Review) by:

- Allowing decisions issued by the Medicare Appeals Council (considered to be the final decision of the Secretary of HHS) at the fourth level of review to be designated as precedential, so long as they meet specific enumerated criteria.

- Allowing attorney-adjudicators to decide appeals where a decision can be issued without a hearing, review dismissals issued by a Qualified Independent Contractor (QIC) or Independent Review Entity (IRE), issue

remands to Centers for Medicare & Medicaid Services (CMS) contractors, and dismiss requests for hearing when an appellant withdraws the request.

- Simplifying proceedings by limiting the number of entities (CMS or its Contractors) that can be a participant or party at the hearing.

- Reducing unnecessary appeals to the Medicare Appeals Council by clarifying areas of the regulations that currently cause confusion, streamlining appeals procedures by eliminating unnecessary steps in the process which cause inefficiencies, and requiring appellants to provide more information on the issues on appeal and who will be attending a hearing.

- Revising the rules for appeals of claims involving statistical sampling and extrapolation by requiring that the provider enumerate its reasons for disagreeing with the sampling methodology or extrapolation calculation in its request for ALJ hearing, and that all claims involved in a disputed statistical sample be appealed to the ALJ at the same time.

Precedential Decisions

Perhaps the biggest change being implemented through the Final Rule is granting the DAB Chair the authority to designate a final decision of the Secretary issued by the Council as precedential. HHS's stated goal with this initiative is to improve the predictability and consistency in council and lower-level decisions, thus allowing appellants to better determine whether to seek appeals, and to assist adjudicators at all levels of appeal by providing clear direction on repetitive legal and policy questions.

Based upon this goal, HHS laid out several factors which the DAB Chair will consider in designating a precedential decision; namely:

1. Whether a decision analyzes or interprets a legal issue of general public interest;

2. The state of the record developed at the lower levels of review;

3. Whether the decision has general application to a broad number of cases; and,

4. Whether designation as precedent is likely to materially contribute to improving predictability and consistency in decisions prospectively.

These factors are similar to the factors federal circuit courts typically consider in designating precedent.

In addition to being binding for specific legal issues and for interpretation of applicable authorities, precedential decisions will also, in more limited circumstances, be binding with regard to factual questions where the relevant facts are the same and where evidence is presented that the underlying factual circumstances have not changed since the Council issued the precedential final decision. However, precedential decisions will be limited to Council decisions in which significant legal or factual issues are fully developed in the record and are thoroughly analyzed in the decision. Meaning that decisions that are not as fully developed or analyzed, or which may only have limited application beyond the particular case at issue, will not be proper for precedential designation. Furthermore, the Council's legal analysis and interpretation of authorities or provisions that are binding or owed substantial deference will be determinative for future appeals in which the same authority is applied and is still in effect. This means that if a precedential decision interprets a CMS manual instruction, for instance, that interpretation is then binding on all pending and future appeals and initial determinations to which that manual instruction applies. If CMS then disagrees with this interpretation, it will have to revise the manual instruction in question. Additionally, the findings of fact in precedential decisions will be binding in any future determinations or appeals involving the same parties and evidence.

Precedential decision will be binding on CMS and its contractors in making initial determinations, redeterminations, and reconsiderations. The decisions will also be binding on all HHS and SSA components that adjudicate matters under CMS's

jurisdiction; meaning that the decisions will be binding on OMHA ALJs and on the newly created attorney adjudicators. It should also be noted, however, that should a federal court later reverse a precedential decision, it would lose its binding authority. Similarly, the effect of a decision by a federal court involving a later case applying a precedential decision will depend on the court's commentary and application of the precedential decision in question. The possibility of an appeal decision being designated as precedential will likely encourage appellants to be more strategic in choosing the cases that they will pursue to the DAB appeal level.

Decisions designated as precedential will bind all lower-level decision makers from the date that the decisions are posted on the HHS website. Precedential decisions will also be published in the Federal Register and will otherwise be made available to the general public. In order to promote uniform application of precedential decisions, CMS, OMHA, and the Council anticipate including education on precedential decisions into joint training sessions.

Attorney Adjudicators

HHS adopted its proposed provisions regarding attorney-adjudicators without modification. This new program is intended to alleviate the appeals backlog by allowing to attorney adjudicators to decide appeals for which a decision can be issued without a hearing, review dismissals issued by a QIC or IRE, issue remands to CMS contractors, and dismiss requests for hearing when an appellant withdraws the request. HHS argues that by relieving the ALJs of the non-hearing-related work that they currently must manage, they will be able to better focus their efforts on conducting hearings and adjudicating the merits of more complex cases. Specifically, HHS estimates that OMHA will be able to redirect approximately 24,500 appeals per year to attorney adjudicators.

Attorney adjudicators will have to be licensed attorneys and will be employed by OMHA. They will also undergo the same training that OMHA requires for its new ALJs to help ensure that their decisions are consistent with Medicare law and guidance. With this training, attorney adjudicators will be able to issue decisions when a decision can be issued without an ALJ conducting a hearing under the regulations, to dismiss appeals when an appellant withdraws his or her request for an ALJ hearing, and to remand appeals for information that can only be provided by CMS or its contractors or at the direction of the Council, as well as to conduct reviews of QIC and IRE dismissals. These dismissals and decisions will be subject to the same reopening and appeals rules as those made by ALJs, and appellants will have all the same rights they would otherwise have if their appeal was heard by an ALJ, including the right to escalate the appeal to the next level if they have not received a decision within the required timeframe. Appellants will also receive a Notice of Assignment when their cases are referred to an attorney adjudicator for review. In response to concerns raised by commenters regarding the quality of attorney adjudicator decisions, HHS stated that these decisions will be subject to the same Quality Assurance Program currently in place to retrospectively review ALJ decisions and identify opportunities for training and policy development. Finally, ALJs will be able to refer appeals to attorney adjudicators that they believe are within the scope of their authority to decide, and attorney adjudicators will also be able to refer appeals to ALJs which they believe are outside of their authority.

Revise the Amount-in-Controversy Calculation

By statute, appellants are procedurally blocked from access to ALJ hearing, Council review, or appeal to a United States District Court if their claims fall below a specified amount-in-controversy (AIC). Under the current regulations, the AIC is equivalent to the actual amount charged to the beneficiary for the items or services in question, also commonly referred to as billed charges. HHS proposed revising the methodology for calculating the AIC "in order to arrive at an amount that more accurately reflects the amount at stake for appellants." According to the Proposed Rule, AIC, in most cases, would be calculated according to the Medicare allowable amount for items and services with a published Medicare fee schedule or published contractor-priced amount. Typically, the Medicare allowable amount represents 80 percent of the billed amount, but can fall as low as 30 to 40 percent of the billed amount depending on the item or service. By moving to this new methodology, HHS estimated that over 2,600 "low-value Part B claims" will be removed from the ALJ hearing process. However, after conducting further analysis in response

to public comment on the Proposed rule, HHS determined that the cost of implementing this new methodology would be roughly twice the cost of any benefit; therefore, HHS did not finalize the proposed rule and will continue to calculate the AIC according to the actual amount charged to the beneficiary. However, despite retaining the current methodology, HHS did revise some of the language related to AIC to clarify calculation of the AIC and to remove the deductible and co-insurance amounts in instances where the provider cannot collect these amounts, or must refund them.

CMS Involvement in Hearings

Recognizing that ambiguities in the current rule governing CMS and CMS contractors' participation and party status in ALJ proceedings has led to confusion and administrative inefficiencies, HHS elected to both limit the number of parties that may participate in, or become a party to, ALJ proceedings and to revise the notice requirements when CMS or its contractors elect to participate in, or become a party to, an ALJ proceeding. Under the Final Rule, CMS may elect to participate in an appeal either within 30 days after notification that a request for hearing has been filed with OMHA, if no hearing is scheduled, or within 10 calendar days after receiving the notice of hearing. Participation in the ALJ proceedings may come in the form of filing position papers and/or providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining a party's witnesses. However, under the current rule, when CMS or its contractor participates in an ALJ proceeding, it may not be called as a witness, and is not subject to examination or cross-examination by the parties. To address this situation more equitably, the Final Rule allows parties to the hearing to provide testimony to rebut factual or policy statements made by CMS or its contractor, and allows the ALJ to question the participant regarding the testimony being disputed. The Final Rule further requires that CMS or its contractor must submit any position papers or written testimony within 14 calendar days of its election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the scheduled hearing, unless the ALJ permits more time. In addition, these submissions must be sent to all parties copied on either the reconsideration decision or the notice of hearing within the same timeframes. Any position papers and/or written testimony filing to meet these criteria will not be incorporated into the ALJ or attorney-adjudicator's deliberation and decision.

HHS stated in its proposed rule that not having any limit on the number of entities that may elect to be parties to an ALJ hearing has "resulted in hearings for some appeals being difficult to schedule and taking longer to conduct due to multiple elections." The Final Rule therefore states that if multiple entities elect to participate in the proceedings prior to the issuance of a notice of hearing and they want to participate in the oral hearing, they will need to indicate this in their response to the notice of hearing; however, only the first entity to file its response will be permitted to participate in the oral hearing. The remaining entities will only be permitted to file position papers and/or written testimony, unless the ALJ determines in its discretion that additional participation is necessary for a full examination of the matters at issue; for instance, if an appeal involved LCDs from multiple Medicare Administrative Contractors, or a statistical sample and extrapolation which was conducted by a CMS contractor.

For matters where CMS or its contractor is electing to become a party to the ALJ appeal, the same same basic rules for election and participation will apply; only the first entity to file its election to become a party after a notice of hearing is issued will be made a party. However, the other entities may still file position papers and/or written testimony. Also, in response to concerns raised by the QICs and MACs in comments to the proposed rule, HHS will allow an entity that has been precluded from participating in the oral hearing to still be called as a witness at the hearing by CMS or its contractor that is a party. CMS will still be barred from becoming a party or participating if the appeal is brought by an unrepresented beneficiary.

Finally, an ALJ or attorney adjudicator is empowered under the Final Rule to determine when an election to either participate or become a party is invalid. This may occur when the request for hearing was filed by an unrepresented beneficiary, the election was not sent to the correct parties, the election was not timely, or CMS or its contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination of the matters at issue.

Appeals Process Efficiencies & Changes to Appeals of Statistical Samples and Extrapolations

HHS's Final Rule establishes a series of measures to eliminate procedural inefficiencies currently encumbering OMHA officials and appellants. These measures include allowing ALJs to vacate their own dismissals and to conduct hearings over the telephone regardless of whether special or extraordinary circumstances exist. HHS has also included provisions in the Final Rule which require appellants to provide more information on what they are appealing and who will be attending a hearing. Importantly, providers appealing a statistical sample methodology and/or extrapolation must now assert their reasons for disagreeing with the statistical smpling methodology and /or extrapolation within the request for a hearing itself, which may be in the form of a position paper or other documentation to better explain the reasons for the challenge. However, for separately appealed claims that are part of a statistical sample/extrapolation, the appellant must now file its statistical sample challenge within 60 calendar days of the date that the party receives the last reconsideration for the sample claims. In this instance, the appellant may wait to file a request for ALJ review until it receives the last reconsideration without losing the right to appeal the earlier-decided claims. Similarly, providers that anticipate that they will be submitting further evidence not included in the lower-level appeals must state what the nature of the additional evidence, the good cause basis for not submitting it at the lower levels, and when the additional evidence will be submitted.

However, HHS declined to finalize some of the provisions in the Proposed Rule aimed at creating efficiencies and streamlining the appeals process. For instance, the Proposed Rule included a provision requiring that providers requesting a hearing must include a statement disclosing any pending investigations or proceedings by law enforcement, including the HHS OIG. This provisions was originally intended to provide the adjudicators with information related to the appellants' systemic issues which, according to HHS "may have a bearing on the credibility of evidence or testimony presented to the adjudicator in an individual claim appeal[.]" However, in response to comments that this proposal would be unduly burdensome especially for large hospitals or health systems and may unfairly prejudice the adjudicator in the case of pending investigations which have not reached a final determination, HHS elected to not finalize the provision.

Lastly, the Final Rule contains provisions that allow a party to correct defects and missing information in incomplete ALJ requests within a specified time-frame before the request is dismissed.

Address Stakeholder Concerns and Regulations Clarifications

The Final Rule has taken modest steps to remedy some of the many frustrations voiced by stakeholders regarding inconsistencies and confusion found in the current regulations. These efforts include establishing an adjudication time frame for cases remanded from the Council and providing more specific rules for what constitutes good cause for new evidence to be admitted at the ALJ level of appeal. The Rule also attempts to streamline the language and clarify terms in the current regulations to aid in readability and reduce confusion.

In July 2016, Polsinelli published an E-Alert discussing the proposed rule to eliminate the Medicare claims appeal backlog.

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