ReedSmith

Client Briefing

Life Sciences Health Industry

If you have questions or would like additional information on the material covered in this Briefing, please contact one of the authors:

Scot T. Hasselman
Partner, Washington, D.C.
+1 202 414 9268
shasselman@reedsmith.com

Rahul Narula
Associate, Washington, D.C.
+1 202 414 9270
rnarula@reedsmith.com

…or the Reed Smith lawyer with whom you regularly work.

CMS Finalizes Regulations with Hope of Reducing Medicare Appeals Backlog

At a Glance:

On January 17, 2017, CMS published the final rule titled "Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures," whereby CMS introduces the concept of precedential decisions to the Medicare appeals program, delegates certain administrative law judge tasks to "attorney adjudicators," and clarifies various procedural aspects within the Medicare administrative appeal process in an effort to better streamline the current appeals process.

In the face of growing scrutiny and now judicial pressure, the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) published a final rule[1] effective March 20, 2017[2] (the "Effective Date"), implementing certain administrative and procedural actions in an effort to reduce the significant Medicare appeals backlog. The final rule comes on the heels of intense criticism from various branches of the federal government[3] – including most recently a December 5, 2016, judicial order[4] from the D.C. district court for HHS to achieve the reduction thresholds below from the current backlog of cases pending at the Administrative Law Judge (ALJ) level, and file status reports to the district court every 90 days:

- 30% by December 31, 2017
- 60% by December 31, 2018
- 90% by December 31, 2019
- 100% by December 31, 2020[5]

While not specifically referencing the court order in the final rule, according to CMS, the Office of Medicare Hearings and Appeals (OMHA) had more than 650,000 pending appeals as of September 30, 2016, while it has only a maximum adjudication capacity of 92,000 appeals per year.[6] Given the current backlog, the statutory 90-day limit[7] for a decision at the ALJ level (the third level of the administrative appeal process) is routinely ignored by OMHA – the current average wait time is more than five times this congressionally mandated time limit.

CMS finalized a majority of the administrative and procedural modifications it outlined in its July 5, 2016, proposed rule.[8] Specifically, the final rule:

- Permits designation of certain Medicare Appeals Council Decisions as precedential
- Expands OMHA's available adjudicator pool by allowing attorney adjudicators
- Simplifies proceedings when CMS or CMS contractors are involved by limiting participants
- Clarifies areas of regulation, including when new evidence may be submitted, and rules for filing appeals related to challenging statistical sampling

According to the final rule, these revised appeal procedures, as further discussed herein, are operative as of the Effective Date for all appeals that were filed on or after the Effective Date of the final rule, and for appeals that were filed, but not decided, dismissed or remanded, before the Effective Date of the final rule.

Overview of the Final Rule

According to CMS, in fiscal year 2016, more than 1.2 billion Medicare fee-for-service claims were processed, and on initial determination, more than 119 million claims were denied. Of the denied claims, 3.5 million (2.9 percent of all Medicare denied claims) were appealed. The current backlog of 650,000 pending appeals (at the ALJ level) will take eight years to resolve, assuming no additional appeals are filed. It would take 10 years for the Medicare Appeals Council (the "Council" and the fourth level of appeal) to process the backlog.

In the final rule, CMS reiterates a three-prong approach to addressing the current backlog of claims waiting to be adjudicated – (1) requesting new resources to increase adjudication capacity; (2) taking administrative actions to reduce pending appeals and implement new strategies to alleviate current backlog; and (3) proposing legislative reforms that provide additional funding and new authorities to address the volume of appeals.[9] The final rule focuses on the second prong, with the most significant modifications discussed herein:

- *Implementation of Precedential Decisions*

The final rule grants the Departmental Appeals Board chair (the "DAB Chair") authority to select certain Council decisions from all Medicare program parts

(including parts C and D) in which a significant legal or factual issue was fully developed on the record and thoroughly analyzed as "precedential." CMS explains in the final rule that designating certain decisions as precedential is intended to "increase the predictability and consistency in decision-making throughout the appeals process, and to provide clear direction on repetitive legal and policy questions."[10]

The final rule does not designate all Council decisions as precedential – rather, only those selected by the DAB Chair. While commenters requested specific criteria that the DAB Chair must follow in selecting precedential decisions, CMS concluded it was not "practicable to articulate a comprehensive set of criteria" – rather, CMS opted to broadly specify that the DAB Chair may "take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest."[11] Noting that the majority of commenters supported the concept of precedential decisions, CMS confirmed that precedential decisions would be made available to the public through the *Federal Register* and an accessible HHS website, and such decisions would be effective from the date of posting.[12]

Finally, CMS explains that a precedential decision is binding and must be followed in future determinations and appeals in which the same authority or provision applies.[13] While the decision is binding, the establishment of precedential decisions does not remove an appellant's right to challenge an unfavorable Council decision. Appellants who disagree with the Council's legal interpretation or analysis in a decision may appeal the decision to federal district court in accordance with 42 C.F.R. section 405.1136, regardless of whether the decision is designated as precedential.[14] To the extent a federal court reverses a precedential decision, the individual case would no longer be binding on the parties and would no longer serve as precedent. In order to ensure that this situation rarely arises, however, CMS explains that the DAB Chair may choose to wait to designate certain decisions as precedent until the time for appeal expires, or until a federal court renders a final, unreviewable, decision on judicial review.[15]

- *Granting Decision-Making Authority to Attorney Adjudicators*

Citing a significant strain on ALJ workloads with respect to matters not requiring a hearing, the final rule grants authority for "attorney adjudicators" to issue decisions (1) when a decision can be issued without an ALJ conducting a hearing (where such right to a hearing is waived by the parties or the record supports a fully favorable finding for the appellant on every issue and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing), (2) to dismiss appeals when an appellant withdraws his or her request for an ALJ hearing, (3) to remand appeals under section 405.1056 or at the direction of the Council, and (4) to conduct reviews of Qualified Independent Contractor (QIC) and Independent Review Entity (IRE) dismissals.[16]

CMS anticipates that the use of attorney adjudicators would reduce the wait time for appellants to receive decisions in cases in which no hearing is required, and would help to address the volume of appeals by "channeling some of those appeals through a less costly adjudicator."[17] The final rule defines "attorney adjudicator" as a "licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance."[18] CMS further explains that attorney adjudicators would have full responsibility for reviewing the record, assessing the pertinent facts in the record and identifying the relevant authorities, conducting the necessary analysis, and drafting and issuing the decision, remand, or dismissal under the attorney adjudicator's signature.[19]

In response to commenters expressing concern regarding qualifications of attorney adjudicators, CMS noted that attorney adjudicators would undergo the same training as new OMHA ALJs to help ensure that their decisions are consistent with Medicare law and guidance.[20] The final rule specifies that attorney adjudicator decisions would be treated in the same manner as an ALJ decision. Specifically, a party with an unfavorable attorney adjudicator decision would have a right to request review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision.[21]

- *Admission of New Evidence at the ALJ Level of Appeal*

The final rule clarifies the criteria for when "new evidence" may be submitted at the ALJ level of appeal. Current regulations specify that evidence not submitted during the first two levels of appeal may not be admitted at the ALJ level, unless a party can demonstrate "good cause" for its admission.[22] CMS explains that new evidence may be admitted where (1) the ALJ or attorney adjudicator finds that the new evidence is material to an issue addressed in the qualified QIC's reconsideration decision, and the issue was not identified as a material issue prior to the QIC's decision; (2) the new evidence is material to a new issue identified in the QIC's decision; (3) the party was unable to obtain the evidence before the QIC issued its reconsideration decision, and the party submits evidence that establishes the party's reasonable attempts to obtain the evidence before the decision was made; (4) the evidence was submitted by the party to the QIC but it was not included in the administrative record; and (5) the ALJ or attorney adjudicator determines the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration.[23] Notably, CMS dismissed commenters' concerns related to attorney adjudicators not having the necessary skills to determine if good cause is present.[24]

- *CMS and Contractor Participation in ALJ Hearings*

The final rule also provides some clarity regarding who may participate at an ALJ hearing. Referencing commenter confusion regarding CMS and its contractors' participation in ALJ hearings, CMS explains that an ALJ may request but may

not require CMS and/or one or more of its contractors to participate in any proceedings before the ALJ. CMS specifies that the ALJ "cannot draw any adverse inferences if CMS or the contractor decides not to participate in the proceedings."[25]

The final rule also implements a formal timeframe for when CMS or its contractors must notify the ALJ and parties of its participation at a hearing. In order to participate, CMS or its contractors must provide advance notice before the hearing. The final rule states that CMS or its contractors must make an election no later than 30 calendar days after the notification that a request for hearing was filed, or, if a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing.[26] CMS believes that the 30-calendar-day and 10-calendar-day timeframes provide adequate time for all contractors to receive notice and to file an election to be a participant.

- *Requests for ALJ Hearing Involving Statistical Sampling and Extrapolations*

CMS finalized regulations to address appeals in which an appellant raises issue regarding a statistical sampling methodology and/or or extrapolation that was used in making an overpayment determination.[27] Citing concerns related to reassigning appeals to avoid multiple adjudicators, the regulations now adopt specific filing provisions for statistical sampling appeals. The new rules require appellant's challenging statistical sampling to include the name, address, Medicare health insurance claim number of the beneficiary whose claim is being appealed for each sample claim that the appellant wishes to appeal, and file the request for hearing for all sampled claims within 60 calendar days of the date the party receives the last reconsideration for the sample claims, if they were not all addressed in a single reconsideration.[28] The appellant must also assert the reasons as to why the statistical sample and/or extrapolation was not conducted properly.

- *Proposals Related to Modifying the Amount in Controversy and Regarding Disclosure of Governmental Investigations and Proceedings Not Finalized by CMS*

Citing administrative costs for implementation, CMS declined to finalize its proposal to use the Medicare allowable amount as the basis for the amount of controversy for items and services that are price-based on a published Medicare fee schedule or published contractor-priced amount.[29] Additionally, in response to several commenters objecting to a proposal that appellants disclose any and all investigations and proceedings by any law enforcement agency, CMS declined to finalize such proposal, citing the validity of commenter concerns, such as potential for unfair prejudice and inability to disclose.[30]

Reed Smith Comments and Analysis

The revisions to the Medicare appeals process will take CMS time to implement and require additional sub-regulatory guidance. As a stand-alone resolution, the modifications within the final rule will not alleviate the shortcomings of the Medicare appeals process; however, in combination with additional resources and funding, the changes may allow CMS to eliminate the backlog in the coming years. CMS hopes that with the administrative authorities set forth in the final rule, in combination with proposed funding increases and legislative actions outlined in the 2017 President's Budget, the backlog of appeals could be reduced to just 20,000 appeals by FY 2019 and eliminated by FY 2020.[31]

To the dismay of providers, some of whom have been waiting more than two years to have their requests for hearings adjudicated, the final rule does not advance any provision that includes a right for default judgment or right to dismiss where a case has not been adjudicated timely. Consistent with its position in the AHA litigation, CMS reiterates in the final rule that any such provision would "be inappropriate because Medicare may only pay a claim if the item or service is a covered benefit and coverage is not excluded by statute, and any applicable conditions of payment are met…."[32] Noting that "there is no statutory limitation on liability or overpayment waiver provision that permits payment to be made if adjudication time frame is not," CMS states that requiring payment to be made on a claim only because the adjudication timeframe is not met, could increase the appeals workload and raise program integrity risks.[33]

The most significant modification to the appeals process is the adoption of precedential decisions, though following the final rule, questions remain regarding its implementation. CMS declined to specify a timeframe in which the DAB Chair must designate a decision as precedential because "resource and procedural constraints may limit how quickly the designation process may be completed."[34] In addition to not knowing when and which decisions the DAB Chair may select, the final rule leaves open several questions regarding implementation and its overall benefit to providers. Citing consistency across the board as one of its major benefits, questions remain regarding whether Medicare contractors will be able to properly apply precedential decisions at the first two levels of appeal. In response to commenter concerns, CMS said it expects to provide training sessions on applying precedential decisions as an effective means of educating all levels of adjudicators, as well as to issue additional sub-regulatory guidance.[35] Furthermore, if a party believes that its claim has been inappropriately denied because of the application of a precedential decision, the party must still exhaust the administrative appeals process as statutorily required[36] – as such, it remains to be seen whether this initiative will provide any timely recourse to providers or will overly complicate the appeals process.

With respect to how judicial review may affect precedential decisions, CMS candidly states that there are "many different possibilities, we do not believe we can address in advance the possible effects of federal court decisions on later cases applying precedential decisions."[37] CMS does, however, state that if it disagrees with a precedential decision and the Council's legal interpretation and analysis, CMS has the right to change the policy or rule, or issue a later clarification or rule.[38] While it is unclear what decisions the DAB Chair may select as precedential, providers that often deal with Medicare claims relating to medical necessity will likely not be implicated by precedential decisions, as CMS recognizes that many claim appeals turn on evidence of a beneficiary's condition or care at the time discrete items or services are furnished, and therefore the final rule on precedential decisions is unlikely to apply to findings of fact in these appeals.

Conclusion

Providers with pending appeals must continue to wait and see if CMS is able to convince Congress to allocate resources to resolve pending Medicare appeals. Unfortunately, the final rule appears to signal that CMS is content with its current model for adjudicating appeals – as the inclusion of attorney adjudicators and precedential decisions does little to remedy the underlying issues with appeals process. Rather than improving transparency at the first two levels of appeal so that "rubber-stamping" of appeals is minimized, or adopting an alternative dispute resolution model to more timely resolve provider issues such as pre-payment reviews that can severely jeopardize provider cash flow under the current lengthy appeals process, the emphasis is on controlling precedent in a way that can potentially limit the right to any meaningful review at all. The ability to obtain a fair and timely ALJ hearing and decision, in accordance with the 90-day timeframe mandated by statute, should be at the forefront of CMS' initiatives to reduce the backlog, and should be the primary focus of providers seeking change in the current system. Providers should be alert for additional CMS guidance on this rule, and should advocate for additional adjustments to the Medicare appeals program, such as additional oversight of Medicare contractors at the first two levels of appeal, and expansion of the 2016 settlement program[39] CMS adopted only for hospitals to other provider types.

---

1 82 Fed. Reg. 4974 (January 17, 2017).

2 The rule is effective March 20, 2017, although this date may be impacted by the Trump administration's recently announced regulatory review.

3 Reports from other government agencies regarding the appeals backlog have increased pressure on CMS, including a Government Accountability Office Report identifying issues with the appeals process titled "Opportunities Remain to Improve Appeals Process," GAO-16-366 (May 10, 2016), a Senate Finance Committee hearing in April 2015 titled "Creating a More Efficient and Level Playing Field: Audit and Appeals Issues in Medicare," and OMHA's own "Medicare Appellant Forum" in 2014. *See* Full Committee Hearing Transcript, *available at*: http://www.finance.senate.gov/hearings/creating-a-more-efficient-and-level-playing-field-audit-and-appeals-issues-in-medicare; *see* Medicare Appellant Forum, *available at*: http://www.hhs.gov/omha/files/appellant_forum_presentations.pdf.

ReedSmith

[4] Since 2014, the American Hospital Association (AHA) has been litigating (the "AHA litigation") with HHS regarding HHS' failure to meet statutorily imposed deadlines for Medicare administrative appeals. On remand from the D.C. Circuit with instructions for further proceedings, the D.C. district court determined that there were equitable grounds to issue a writ of mandamus. The court reasoned that even with certain good faith efforts made by HHS to reduce the backlog, the appeals backlog was "still unacceptably high." In its decision, the district court found that HHS did not "point to any categorically new administrative actions," and continues "to promise the elimination of the backlog only 'with legislative action'—a significant caveat." *See American Hospital Association, et al. v. Burwell*, case number 1:14-cv-00851, in the U.S. District Court for the District of Columbia; *see also Am. Hosp. Ass'n v. Burwell* (AHA II), 812 F.3d 183, 192 (D.C. Cir. 2016).

[5] *Id.*

[6] 82 Fed. Reg. 4974.

[7] Section 1869(d)(1)(A) of the Social Security Act; 42 C.F.R. § 405.1046.

[8] 81 Fed. Reg. 43790 (July 5, 2016).

[9] 82 Fed. Reg. 4974

[10] *Id.* at 4978.

[11] *Id.* at 4979.

[12] *Id*. at 4981.

[13] *Id*. at 4980.

[14] *Id.*

[15] *Id*.

[16] *Id*. at 4981-82.

[17] *Id*. at 4983.

[18] *Id.*

[19] *Id.* at 4983.

[20] *Id*. at 4984. In response to concerns related to the legitimacy of attorney adjudicators, CMS was adamant in the final rule that "OMHA will afford attorney adjudicators with a similar level of qualified decisional independent that is afforded to ALJs, to help ensure an impartial and fair adjudication process for all parties to an appeal before an OMHA adjudicator."

[21] *Id.* at 4986.

[22] 42 C.F.R. § 405.1028.

[23] 82 Fed. Reg. at 4992, 5043.

[24] *Id.* at 5043.

[25] *Id.* at 5026.

[26] *Id.* at 5027.

[27] *Id*. at 5033.

[28] *Id*.

[29] *Id.* at 5011-5012.

[30] *Id*. at 5032.

[31] *See* CMS Medicare Appeals Fact Sheet (January 17, 2017), *available at*: https://www.hhs.gov/sites/default/.../medicare-appeals-final-rule-fact-sheet-jan2017.pdf.

[32] *Id.* at 5040.

[33] *Id*.

[34] *Id.* at 4980.

[35] *Id.*

[36] *Id.* at 4981.

[37] *Id*. at 4981.

[38] *Id*. at 4980.

[39] From December 1, 2016 to January 31, 2017, CMS made available an administrative settlement process for inpatient status claims. This process allowed eligible hospitals to withdraw certain pending appeals in exchange for timely partial payment (66% of the net allowable amount). *See* Hospital Settlement Appeals Process 2016, *available at*: https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Hospital-Appeals-Settlement-Process-2016.html.