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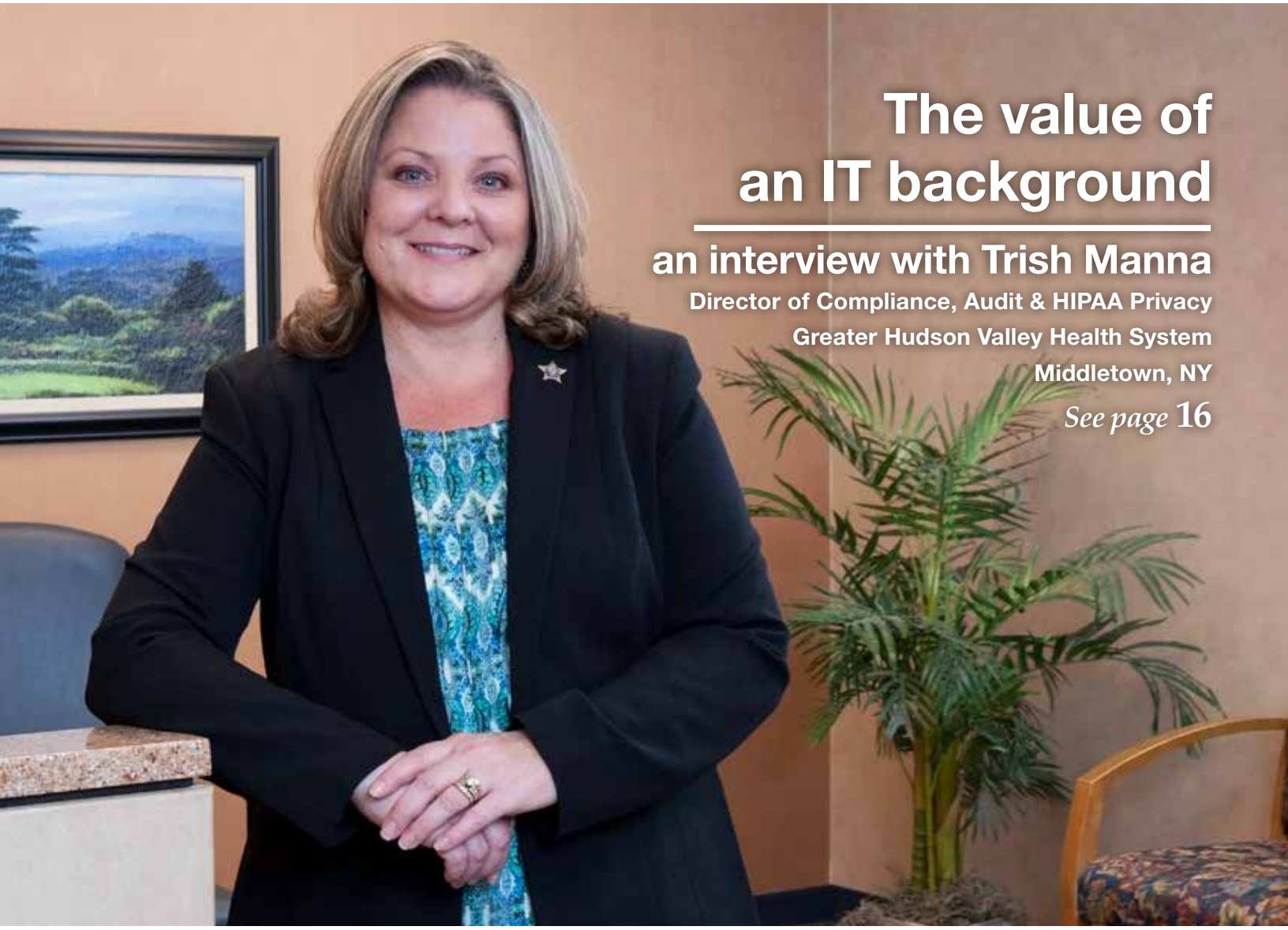

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by Andrew B. Wachler, Esq. and Jessica C. Forster, Esq.

Medicare appeals process: CMS publishes final rule revising regulations

» Federal court ruling requires HHS to take action to reduce the Medicare appeals backlog.

» Additional efforts to reduce the Medicare appeals backlog are helping, but not completely relieving the Medicare appeals backlog.

» The final rule implements changes that will improve efficiencies throughout the Medicare appeals process, but are insufficient in themselves to respond to the backlog.

» The final rule provides important regulatory clarification to longstanding components to the Medicare appeals process.

» The final rule will impact providers' and suppliers' strategic approaches to audits and appeals.

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On January 17, 2017, the Centers for Medicare & Medicaid Services (CMS) published a final rule that seeks to improve the efficiency of the Medicare appeals process. 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," follows a variety of initiatives imposed by the Department of Health and Human Services (HHS) in an attempt to reduce the increasing number of appeals and the increasing backlog of claims at the administrative law judge (ALJ) level of hearing.[1] The reforms announced in the final rule may streamline efforts and increase efficiencies, but its overall impact on the appeals backlog will take time to evaluate.

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Background

Various efforts by the Office of Medicare Hearings and Appeals (OMHA) and CMS to reduce the Medicare appeals backlog at the ALJ level of appeal include alternative settlement options for eligible claims pending ALJ hearing. These settlements, referenced as the Settlement Conference Facilitation (SCF) program, apply OMHA's resources very efficiently and have the potential to resolve a large volume of claims. The ALJ settlements are also potentially excellent opportunities for providers, because the backlog of ALJ appeals has caused an extreme delay for ALJ hearings despite the statutory requirement that ALJs hold hearings and issue decisions within 90 days of receipt of the ALJ hearing request. However, HHS has projected that the SCF process will reduce the number of appeals pending before OMHA by 27,000 by the end of fiscal year (FY) 2020. Under current resources (and without any additional

appeals), it would take 11 years for OMHA to process the pending appeals. Therefore, it is clear that additional efforts are required to continue reducing the appeals backlog in meaningful ways.

Other efforts to reduce the backlog include reopening the 2016 Hospital Appeals Settlement to allow hospitals with claims denied for incorrect setting (i.e., allegedly should have been provided in outpatient setting as opposed to inpatient), which may be settled at 66% of the value of the claim. Hospitals had until January 31, 2017 to engage in the reopened settlement process, and it will take time to know its impact on the appeals backlog. The 2014 Hospital Appeals settlement that permitted hospitals to settle their inpatient hospital claims for 68% of the claim value resolved 346,000 inpatient hospital claims. CMS undoubtedly hopes that the 2016 reopened Hospital Appeals Settlement will yield similar results.

However, the vast backlog requires additional resources and initiatives. This is especially true in light of the recent federal court decision in *American Hospital Association (AHA) v. Burwell*.[2] In the most recent decision from AHA's challenge of the unprecedented backlog of appeals, the DC District Court stated that, absent any intervention, the OMHA backlog at the end of FY 2020 will be over 1,900,000. However, the DC District Court also stated that "significant progress toward a solution" cannot mean that things will get worse more slowly than they would otherwise; rather it must mean "real movement towards statutory compliance." The DC District Court's conclusion was that the proffered administrative fixes as offered now do not demonstrate "real movement towards statutory compliance."[3] As such, the DC District Court accepted reduction in appeal thresholds that were proposed by AHA. The thresholds require CMS and HHS to reduce the backlog of ALJ appeals by certain intervals over the next several years: 30% by 2018; 60% by 2019; 90% by 2020; and 100% by 2021. The court retained jurisdiction over the matter and required that CMS file progress reports every 90 days in regards to what changes were being made. Failure to comply with the decision has the potential to lead to harsh consequences for CMS, and therefore, the implementation of the Rule is an important component to CMS's efforts to reduce the backlog.

The final rule

Published on January 17, 2017, the final rule comes as a response to the growing pressure directed at the Medicare appeals system by providers, beneficiaries, and courts to take meaningful action to make "real movement" towards statutory compliance and resolve the appeals backlog.

The final rule is comprised of a number of reforms and changes to the Medicare appeals process to encourage efficiency, with some reforms being more significant than others. All of the reforms are in step with the HHS's three-prong approach to addressing the increasing number of appeals and the backlog of appeals at the ALJ level of appeal. Specifically, HHS's approach is to:

1. Request new resources to invest at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog;
2. Take administrative actions to reduce the number of pending appeals and implement new strategies to alleviate the current backlog; and
3. Propose legislative reforms that provide additional funding and new authorities to address the volume of appeals.

HHS explains in the final rule that it pursues the three-prong approach in the final rule by "implementing rules that expand the pool

of available OMHA adjudicators and improve the efficiency of the appeals process by streamlining the processes so less time is spent by adjudicators and parties on repetitive issues and procedural matters."[4]

The final rule includes a variety of changes to language within the Code of Federal Regulations that help to streamline the Medicare appeals process and clarify the regulations and their applicability. However, portions of the Rule include impactful changes to the Medicare appeals process that will affect providers' strategic approaches to audits and appeals. These impactful changes include:

- granting precedential authority to certain Departmental Appeals Board (DAB) and Medicare Appeals Council (Council) decisions;
- introduction of "attorney adjudicators" at the ALJ level;
- changes regarding when evidence can be introduced into the appeal; and
- changes to CMS contractors participation in ALJ proceedings.

Although these major changes have been discussed in other settings along with options to reduce the Medicare appeals backlog, the final rule finalizes them for implementation in the Medicare appeals process.

Precedential authority to selected Medicare Appeals Council decisions

Under previous rules, Council decisions were binding on the parties to the particular appeal, meaning that the parties are obligated to follow the adjudicator's action or decision unless a party exercises its appeal rights and the next level of appeal changes the decisions.[5] However, under the revised rules, 42 C.F.R. §401.109 would provide that the Chair of the DAB would have authority to designate a final decision of the Secretary issued by the Council as precedential. HHS's decision to issue precedential authority to the Chair of the DAB was based on a belief that it would provide appellants with consistent precedential decisions to utilize in seeking appeals, assist appeal adjudicators at all levels of appeal by providing clear direction on common legal and policy issues and, in some circumstances, factual questions. In addition, where precedential decisions apply to a factual question, it would apply only in limited situations where the relevant facts are the same and the evidence presented demonstrates that the underlying factual circumstances have not changed since the Council issued the precedential final decision.

> ...where precedential decisions apply to a factual question, it would apply only in limited situations where the relevant facts are the same...

The final rule concludes that the discretionary authority to issue a Council decision as precedential will rest with the DAB Chair. The basis for this decision is that the DAB Chair will render decisions as precedential, but respects the independence of the Council as an adjudicative body. The scope of the precedential effect of a Council decision will include the Council's legal analysis and interpretation of an authority that is binding or owed substantial deference will be binding in future determinations/appeals in which the same authority or provision is applied and is in effect.[6] However, the final rule clarifies that if CMS revises an authority or provision that is addressed in a precedential decision, the Council's decision would not be binding on claims to which the revised authority or provision applies. HHS's rationale for this decision was that it would help ensure that CMS has the "ultimate authority to administer

the Medicare program and promulgate regulations, and issue subregulatory guidance and policies on Medicare coverage and payment."[7]

In the final rule and in response to commenters' concerns regarding the considerations that will guide the DAB Chair in selecting a precedential Council decision, HHS identified factors that the DAB Chair may consider in determining to designate a specific decision as precedential. HHS clarified that the primary goal is for the DAB Chair to identify Council decisions that have wide applicability where the precedent is likely to materially improve predictability and consistency in decisions. The DAB Chair may also factor whether the precedential decision would have wide applicability to a broad number of cases or if the decision analyzes a legal issue of general public interest. Lastly, the final rule suggests the DAB Chair could consider whether the appeal's record was fully developed at lower levels of review, suggesting that records with facts fully analyzed or legal arguments fully raised and argued are better options for precedential designation.

Notice of the DAB Chair's selection of precedential decisions will be provided within a "reasonable amount of time after the issuance of the decision" and will be provided through publication in the *Federal Register* as contemporaneously as possible to the time the decision is actually selected to be precedential.

The precedential decisions selected by the DAB Chair could have significant impacts on providers and suppliers across the spectrum of healthcare. Although precedential decisions will very likely have a streamlining effect on decision-making throughout the Medicare appeals process, they also could have significant impacts on providers' and supplier's compliance activities. Regularly reviewing precedential decisions from the DAB Chair could be an important protocol for providers and suppliers to implement to continue to be updated on the HHS's analysis and conclusions regarding the applicability of Medicare regulations and policies.

Attorney adjudicators at OMHA

The second matter addressed by the final rule is the introduction of "attorney adjudicators" at the ALJ level of appeal.[8] Because the number of appeals has expanded dramatically over the past several years, ALJs have been unable to cope with the increasing workload, causing extreme backlogs of appeals in violation of statutory time limits. Many of the matters handled by the ALJs are substantive legal and medical issues, but a great quantity of matters do not require hearings and are purely administrative in nature. The final rule finalizes its proposal to provide authority to attorney adjudicators to render decisions when an ALJ hearing is not necessary because the decision can be issued without one, to dismiss appeals when an appellant withdraws his/her request for an ALJ hearing, to remand certain appeals pursuant to regulatory standards or at the direction of Council, or to conduct reviews of qualified independent contractors' (QICs) and independent review entities' (IREs) dismissals.

> By introducing attorney adjudicators, the final rule looks to decrease the workload handled by ALJs by transferring the processing of non-hearing, non-substantive claims to attorneys trained in the Medicare system.

HHS reasons that ALJs are specially trained and qualified to hear cases on merits, including fact-finding and reaching conclusions of law. The aforementioned administrative matters, on the other hand, do

not require the same level of expertise, and could be similarly handled by other actors. By introducing attorney adjudicators, the final rule looks to decrease the workload handled by ALJs by transferring the processing of non-hearing, non-substantive claims to attorneys trained in the Medicare system. HHS stresses that these attorneys will still be experienced in the appeals system in all its facets, but will simply not have the same expertise in holding hearings and fact-finding as ALJs. The attorney adjudicators will be specifically trained to handle appeals concerning issues only within the written record that do not require an active oral hearing. The final rule states that cases can be decided without an oral hearing "when the record supports a finding in favor of the appellant(s) on every issue; all of the parties have waived the oral hearing in writing; or the appellant lives outside of the United States and did not inform the ALJ that he or she wishes to appear, and there are no other parties who wish to appear."[9]

The final rule institutes a further safeguard as well, which allows for attorney adjudicators to refer a case for an oral ALJ hearing, if the facts of the case tend to show that such a hearing is warranted. A matter can be referred even in cases such as where parties agree to waive a hearing. After receiving the facts and information on the case, the ALJ will then independently determine if an oral hearing is actually necessary. Therefore, if an attorney adjudicator is faced with an issue which he/she is either not qualified or not prepared to handle, it is hoped that the new system will still allow such cases to be heard by an ALJ.

Another concern for Medicare beneficiaries and providers regarding attorney adjudicators is that ALJ hearings are a statutory right of Medicare providers that meet the eligibility criteria. However, the final rule finds that it is not required that an ALJ handle matters which do not involve a QIC reconsideration, nor where the cases involve a remand or there is a withdrawal by the provider of a request for an ALJ hearing. The final rule further assures that Medicare participants will not lose any of the rights they are entitled to in connection with the ALJ appeal level—any final determination at the ALJ level will still be eligible for appeal to the Council level. As the right of appeal is paramount to the operation of the Medicare system, it is important that appeal rights are protected by the final rule and any other future regulations.

Submission of evidence Medicare appeals

The final rule also changes the evidentiary rules regarding the appeals process. Prior to the final rule, the regulations reflected that ALJ appellants are allowed to submit new evidence at an ALJ hearing if they demonstrate good cause for the submission. The regulations specifically stated that the appellant must submit a good cause explanation with the new evidence. The final rule's revised regulations reinforce the good cause showing requirements. In the final rule, CMS stated that the:

> …regulations as finalized in this rule clearly indicate that providers and suppliers should submit all evidence that is relevant to their appeal as early in the appeal process as possible, and the circumstances in which an ALJ or attorney adjudicator may find good cause for the introduction of new evidence at the OMHA level.[10]

The new regulations under the final rule include that if the provider or supplier fails to include the statement explaining why the evidence was not previously submitted, the evidence will not be considered. Furthermore, unlike the previous version of the regulations addressing this issue, the newly finalized

regulations include specific instances when an ALJ or attorney adjudicator may find good cause for the introduction of new evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is submitted for the first time at the OMHA level. However, the final rule specifies that the ultimate discretion to admit the new evidence will rest with the ALJ or attorney adjudicator.

The four criteria listed in the final rule to be considered by an ALJ or attorney adjudicator for the submission of new evidence are:

- The evidence is material to an issue which was not identified as a material issue prior to the reconsideration decision being issued;
- The new evidence is material to an entirely new issue addressed in the reconsideration decision;
- The party was unable to obtain the evidence prior to the reconsideration decision, and the party has supplied evidence to establish its reasonable attempts to obtain the evidence prior to reconsideration; and/or
- The evidence was submitted before reconsideration and the party can show evidence to prove the submission and the fact that it was not included in the administrative record.[11]

HHS's basis for refining the "good cause" submission requirements at the OMHA level of appeal is to further encourage providers and suppliers to submit evidence at earlier stages of appeal process. HHS believes that this will help further streamline the appeals process. Although it is important for providers to submit all relevant evidence as early as possible in the appeals process, it can be challenging to do so under the current appeal deadlines, particularly if providers and suppliers are filing appeals to prevent recoupment of the alleged overpayment. Therefore, it is important for providers and suppliers to consider that the "evidence gathering" process must begin at the very first notice of an audit. This means that providers and suppliers should consider retaining experts and gathering additional evidence as soon as possible to be prepared for the evidentiary submission requirements.

Appointed representatives

The final rule also clarifies regulations regarding appointed representatives.[12] Upon the election of an appointed representative, a beneficiary or provider/supplier must document the election in a form that is signed by both the representative and the party being represented. The CMS-authorized form for appointing representatives included a section for either the beneficiary's health insurance claim number (HICN) or the provider's/supplier's national provider identifier (NPI) to be entered. Although logic supported the conclusion that the beneficiary's HICN should be entered if the beneficiary was the represented party and the NPI should be included if the provider/supplier was the represented party, in our experience representing providers and suppliers, appeal review contractors would dismiss appeals on the basis of invalid appointed representative forms because the patient's HICN was not included on the form. CMS attempted to clarify the requirements through subregulatory guidance, but the final rule's regulatory change will help further effectuate the clarified requirement. Therefore, pursuant to the new regulation, the appointed representative form will include the Medicare NPI of the provider that furnished the service when the provider is the one who appointed the representative. When the beneficiary is the one appointing representation, the beneficiary's HICN will be included on the form. On its face, this regulation may not appear to have an

impact on the Medicare appeals process, but preventing unnecessary dismissals and efforts to have appeals reopened for incorrect denials is an important component to streamlining the efficiency of the Medicare appeals process.

CMS contractors' participation in ALJ proceedings

The final rule further addresses issues regarding the participation of CMS contractors in ALJ proceedings. Currently regulations allow for CMS and CMS contractors to participate in ALJ hearings, with the only exception being hearings for unrepresented beneficiaries. Complaints from Medicare providers have consistently stated that this has made scheduling hearings difficult and, that even once the hearing was scheduled, the ALJ hearing itself would be too extensive. The final rule addresses this point by limiting participation in ALJ hearings to either CMS *or* a single CMS contractor, unless the ALJ itself finds that the participation of both parties is "necessary for a full examination of the matters at issue."[13] If multiple CMS entities file for participation in an ALJ hearing where only one party is eligible, "only the first entity to file a response to the notice of hearing… may participate in the oral hearing."[14]

However, the final rule does not limit the participation of CMS and/or multiple contractors from submitting position papers or other written testimony for the ALJ hearing. So, while the actual participation in the hearing will be limited by the final rule, there is no limitation on the amount of written material which CMS and its contractors may submit.

The final rule further clarifies that while CMS or contractor participation in an ALJ hearing is beneficial to the appeals process, such participation is not and cannot be required. An ALJ may request that a CMS representative appear, but an ALJ cannot make attendance mandatory and cannot "draw any adverse inferences if CMS or the contractor decides not to participate."[15]

Conclusion

- The *AHA v. Burwell* case mandated improvements to the Medicare appeals system.
- CMS responded by releasing a new final rule to address the appeals backlog.
- The final rule will introduce a precedential system for certain Council decisions in hopes of improving efficiency and consistency.
- The final rule will allow for attorney adjudicators to process administrative matters, hoping to decrease the workload currently placed on ALJs.
- The final rule provides more specifically defined criteria for the introduction of new evidence at the ALJ level for good cause.

The final rule demonstrates HHS's efforts to take steps to improve the appeals process and, in turn, respond to the requirements set forth in the *AHA v. Burwell* case. The overall impact of the final rule's regulatory changes on the backlog at the ALJ levels of appeal remains uncertain. Furthermore, it could impact providers' and suppliers' audit and appeals strategies. It is important that providers and suppliers carefully review the provisions of the final rule and adjust their processes as necessary in response to the final rule's implementation on March 20, 2017.

1. 82 Fed. Reg. 4974 (January 17, 2017)
2. *American Hospital Association et al.* v. *Burwell*, Case 1:14-cv-00851-JEB (September 19, 2016)
3. *Id*
4. 82 Fed. Reg. 4974 (January 17, 2017)
5. *Id*. at 4977
6. *Id*. at 4978
7. *Id*
8. *Id*. at 4981
9. *Id*
10. *Id*. at 5000
11. *Id*. at 5115
12. *Id*. at 4995
13. *Id*.at 5020
14. *Id*. at 5017
15. *Id*. at 5026