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August 29, 2016

Office of Medicare Hearings and Appeals
Department of Health and Human Services
Attn: HHS-2015-49
5201 Leesburg Pike, Suite 1300
Fall Church, VA 22041

Re: 81 Fed. Reg. 43790 (July 5, 2016); HHS-2015-49: Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedure

Ladies and Gentlemen:

The Health Law Section of the American Bar Association (the "Section") respectfully submits the following comments on the proposed rule issued by the Centers for Medicare & Medicaid Services ("CMS") entitled "Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedure" and published in the July 5, 2016 Federal Register (HHS-2015-49; 81 Fed. Reg. 43790).

This letter expresses the Section's views.[1] No government attorneys or government professionals participated in the drafting or submission of these comments. These comments have not been approved by the House of Delegates or the Board of Governors of the ABA and are not the position of the ABA as a whole. These comments do not represent the policy or views of any government employee who is a member of the Section, its Council, or the Managed Care and Insurance Interest Group.

[1] These comments were prepared by a working group of the Health Law Section's Managed Care and Insurance Interest Group. The contributors to these comments are Harsh P. Parikh and Peter Roan from Crowell & Moring LLP's Los Angeles office, and Jessica Guobadia of the Law Offices of Joseph V. Gibson, P.C. In addition, Anthony Choe, Melissa Hulke, and Heather Baroni served as reviewers of the Task Force's work and participated in the preparation of the final comments. Although members of the Section who participated in the preparation of these comments represent clients who may be affected by the proposed rule, no such member has been engaged by a client to participate in the drafting or submission of these comments.

The ABA is the largest voluntary professional association in the world. The Section, with nearly 8,000 attorney members, is a prominent voice of the organized healthcare bar within the ABA. Its members represent clients in all aspects of the healthcare industry, including physicians, institutional providers, clinical researchers, academic institutions, clinical laboratories, pharmaceutical companies, public health entities, non-profit institutions, government healthcare programs and regulatory bodies, device manufacturers, and healthcare and medical application developers. The Section respectfully submits the comments and suggestions below for consideration by the Department of Health and Human Services ("HHS") with regard to the proposed rule.

I. Summary of the Section's Comments

The Section recognizes CMS and the Office of Medicare Hearings and Appeals ("OMHA") are attempting through these proposed changes to the Medicare appeals processes to address the current backlog of pending matters. In the Section's view, any change or reform of the current processes and procedures of Medicare appeals must ensure that all appellants receive a fair and impartial review of the appeal. To that end, we provide the following comments on the Proposed Rule:

1. Precedential Final Decisions by the Secretary. The Proposed Rule grants the Chair of the HHS Departmental Appeals Board the power to designate a determination of the Medicare Appeals Council as having binding precedential value and these selective decisions will be published in the Federal Register. The Section believes that the proposal may not adequately address the issues of accountability or uniformity and may disadvantage a party to the appeal. The Section suggests the following revisions: (a) that the regulations include guidelines that the Chair utilize in determining whether to designate a decision as binding or not binding, (b) that all decisions of the Council should be made publicly accessible, and (c) that there be a mechanism for participation by the OMHA judges.

2. Amount in Controversy: We provide suggestions in response to CMS's request for comments regarding the required amount in controversy for an ALJ hearing.

3. Consolidated Proceedings: We provide suggestions in response to CMS's request for comments related to Consolidated Proceedings.

4. Other Comments: We also provide some additional suggestions concerning the mechanics of the administrative appeals process.

II. Precedential Decisions

The Proposed Rule adds Section 401.109, which empowers the Chair of the Department of Health and Human Services Departmental Appeals Board ("DAB") to designate certain decisions of the Medicare Appeals Council ("Council") as precedential. Precedential decisions under the Proposed Rule are binding on all levels of HHS and CMS. Thus, the legal interpretation of "Medicare authority or provision" in a decision designated as precedential is required to be followed in future determinations and appeals. These precedential decisions under the Proposed Rule would be published in the Federal Register.

The Section recognizes the need to increase consistency in decisions at all levels of the Medicare appeals process. In that regard, the Section understands that designation of certain decisions as precedential will give those considering making an appeal additional information that may be considered in determining whether an administrative appeal is worth pursuing and provide adjudicators with a body of precedential decisions to reference when deciding new matters. But the Section believes that the need for efficiency and consistency must be balanced with ensuring fair administration of the appeals process so that the precedential effect is uniform, that the Chair maintains accountability for designations and that the Medicare appeals process is fair for all appellants. To that end, the Section proposes the following modifications to the Proposed Rule.

1. Guideposts for Determining Precedential Decisions: The Proposed Rule grants the Chair of the DAB the power to create binding authority – a discretionary action which may impact the rights and obligations of parties to future appeals. The Section recognizes it is helpful to distinguish those decisions that make a meaningful contribution to the existing body of precedent from those that merely apply settled authority to a dispute. Nonetheless, the Proposed Rule does not provide any guidance to the Chair on how to decide which determinations should be designated as precedential. The Section suggests that the regulations should set forth criteria that would be used to determine whether a decision should be designated as precedential or not.

The Section suggests that the agency consider adopting the standards that are currently used by federal Circuit Courts in designating decisions as precedential.[2] For instance, the Chair of the DAB may designate a decision as precedential only if it meets one of the following guideposts:

(a) it establishes, alters, modifies, clarifies or explains a rule of law or Medicare authority,

(b) it involves a legal issue of continuing public interest,

(c) it criticizes or identifies existing Medicare authority,

(d) it contains historical review of authority that is not duplicative, or

(e) it resolves a prior conflict between decisions of the Council or creates a conflict with prior decisions of the Council or other adjudicators.

To promote accountability, the Section recommends that such clear criteria for precedent designation be established.

2. Availability of Non-Precedential Decisions: The Proposed Rule requires that decisions that are designated as precedential would be made available by being published in the Federal Register. The Section concurs that not all decisions need to be designated as precedential. For example, the Section agrees that decisions involving articulation of existing settled Medicare authority applied to particular case-specific facts need not be given precedential designation. But, the Section believes the public should have access to review all decisions of

[2] *See, e.g.*, 4th Cir. R. 36(a) (2016).

the Council – precedential and non-precedential (with the personally identifiable information of the beneficiary appropriately removed). Access to non-precedential decisions may be valuable to potential appellants that are considering whether an administrative appeal is worth pursuing. Transparency of all Council decisions would also enhance consistency across the multiple levels of the appeals process and would also have the potential to increase administrative accountability. The Section, therefore, suggests that all decisions of the Council be made available to the public, including those decisions that are not designated as precedential.

3. Role of OMHA in Precedential Designation: The Proposed Rule grants the Chair of the DAB the power to unilaterally designate precedential decisions. There is no mechanism that would permit Administrative Law Judges to certify or recommend decisions for the Chair's consideration. The Section suggests that in many circumstances, the OMHA may be in the best position to determine which cases might be influential for subsequent decisions or identify areas that are of particular importance in a large number of appeals. Thus, the Section recommends that the agency consider implementing a process by which the Administrative Law Judges of the OMHA may participate in the precedential designation.

III. Amount in Controversy Requirement

CMS requested comments on its proposal regarding the required amount in controversy for an ALJ hearing. As an initial matter, the Section agrees that CMS should clarify that Section 405.1006 sets forth the required amount in controversy for an ALJ hearing and judicial review rather than "to request" an ALJ hearing and judicial review. This will align the title of Section 405.1006 with its corresponding statutory provision and will provide more clarification in the regulations.

The Section is concerned, however, regarding CMS's proposals as to how to determine the amount in controversy. Currently, Section 405.1006 provides that the amount in controversy is calculated based on the billed charges, reduced by any Medicare payments already made or awarded, and any applicable patient responsibility portions (e.g. coinsurance or deductibles). This estimation of the amount in controversy provides a simple method to determine whether a claim submitted by any party will meet the requirements for an ALJ hearing and judicial review.

In what appears to be an effort to streamline the appeals process and limit the influx of appeals by providers, CMS has proposed that the published contracted price amount be used, rather than the billed charges, to determine whether the amount in controversy is met when a provider knows the allowed amount. However, in some instances, such as when a provider cannot determine the allowable amount or a beneficiary requests a hearing, the billed charges may be used to determine whether the amount in controversy is sufficient for an ALJ hearing.

CMS's proposal to use billed charges in some instances and allowable amounts in others will not streamline the requests for hearings. In fact, the Section believes that the different standards will result in confusion among appellants – providers and beneficiaries, alike – as well as among ALJs and attorney adjudicators. In part, the concern stems from the fact that Medicare allowable amounts are not reasonable amounts. If an ALJ is able to determine whether the amount in controversy is met based solely on Medicare allowable amounts, then providers will be denied the ability to challenge legitimate denials, underpayments, and other reimbursement issues, even if the problem is ongoing. For example, a provider may not be able to challenge a

$100 reimbursement dispute because a single $100 claim does not meet the immediate amount in controversy requirement. But if over time, there are 1000, $100 claims that could result from that same issue, the issue becomes much more concerning.

Although CMS purports to address this issue by proposing to amend Section 405.1006(e)(1)(ii), (e)(1)(iii) and (e)(2)(iii) regarding aggregation of claims, these proposed revisions may overcomplicate the process. Under these rules, either an attorney adjudicator will be required to determine that the amount in controversy requirement is met, or, the attorney adjudicator will still need to refer the claim to the ALJ for review, so that the ALJ can deny the request for hearing. Given the new framework, it seems as though this process will make the process to request a hearing less efficient. The role of the attorney adjudicator could be duplicative, since the attorney adjudicator can only approve cases to go forward based on aggregation. If it appears that claims that are aggregated are not properly aggregated and/or do not meet the required amount in controversy, then this matter must be addressed by the ALJ to permit the ALJ to dismiss the request for an ALJ hearing. Furthermore, unless CMS has safeguards in place to guarantee that ALJ's will not merely adopt attorney adjudicators' decisions, without more review, then this may result in improperly denied requests for ALJ hearings based on the amount in controversy.

Furthermore, CMS's proposed revisions could overburden Medicare beneficiaries and their families. As noted by a commenter in a letter dated July 2, 2016, these proposed rules provide CMS with a unilateral means to prohibit providers and beneficiaries from pursuing wrongful denials, without adequate recourse by the provider or beneficiary to challenge any such denial. These concerns could be addressed in more detailed terms in the proposed rules. As such, the Section is concerned that these rules, as proposed, could prohibit providers and beneficiaries from seeking fair adjudications on improper payments from CMS. Given CMS's inclination to provide more lenience to beneficiaries that are requesting ALJ hearings, the Section also has concerns that providers may start to rely on beneficiaries and/or their families to provide increased assistance in the appeals process.

IV. Consolidated Proceedings

CMS is seeking comments regarding proposals related to Consolidated Proceedings. Currently, a consolidated hearing may be held at the request of an appellant or on the ALJ's own motion if the issues to be considered are the same as those pending in another request for hearing(s) pending before the same ALJ and CMS is notified of an ALJ's intention to conduct a consolidated hearing. If a consolidated hearing is held, the ALJ may make a consolidated decision and record or may make a separate decision and record for each claim involved. CMS claims that the current process has resulted in confusion and has limited the circumstances in which no hearing is conducted.

The Section agrees that an ALJ that consolidates proceedings should be required to either consolidate a decision and consolidate the record or maintain separate records and issue separate decisions to permit for more efficient review of appeals. The Section further agrees that, if an ALJ issues a separate decision and record, any audio recordings of any conferences that were conducted and the consolidated hearing must be included in the individual record to ensure completeness of the appeals. Furthermore, the Section commends CMS for taking steps to try to make the adjudication process more efficient when multiple appeals are pending before the same

adjudicator.

The Section has some concerns, though, about the proposed limitations on consolidating proceedings for multiple appellants. CMS's proposed solution to this problem is to add Section 405.1044(c), which would likely complicate the consolidation of proceedings involving multiple appellants unless (1) the multiple appellants' aggregated claims meet the amount in controversy requirements pursuant to Section 405.100 and (2) the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants.

A provider's ability to consolidate proceedings may be hindered if it is unable to secure the necessary permissions from beneficiaries. While the Section agrees that reasonable steps must be taken to protect beneficiaries, there must be a way to mitigate the release of this information, while allowing providers to seek fair adjudication of these issues.

Another concern is that, in some instances, beneficiaries will not provide the consent necessary to pursue these claims. As CMS is aware, HIPAA provides for exceptions to the rule to permit providers to release protected health information in certain circumstances, even absent consent, for the purpose of billing and collection activities and for the purposes of healthcare operations in the course of a legal proceeding. See 45. C.F.R. §164.501 (1)(definition of "Health care operations") and 45 C.F.R. §164.501 (definition of "Payment"); 45 C.F.R. § 164.502(1)(ii); 45 C.F.R. § 506(c). Requiring the provider to obtain additional consents in these situations seems to be an unnecessary hurdle in this process. Given the possible application of these HIPAA exceptions, the Section respectfully requests clarification from CMS as to whether and when these exceptions would not apply, such that beneficiary consent is necessary to release the records at issue.

If CMS is concerned about the release of protected information, then the Section would request that CMS adopt more reasonable rules that require a provider to take "reasonable" steps to obtain any such consent but, if such consent cannot be obtained, that the parties be required to enter into a protective order to prohibit the release of the information and that the parties be required to de-identify the records as much as possible (e.g. remove the patient's name, address, date of birth, and social security number) so that the claims can be consolidated and the provider(s) and beneficiaries can seek any relief to which they are entitled.

By adopting a rule as described as these comments, CMS will permit multiple appellants to be able to consolidate proceedings, thereby allowing for more efficiency in the appeals process. At the same time, CMS will be able to ensure that beneficiary information is as protected as possible in these circumstances.

V. Other Comments

The Section also provides the following comments regarding the Proposed Rule:

- Submission of Untimely Evidence (§ 405.1018): The Proposed Rule in Section 405.1018 establishes a specific time frame within which a party must submit written evidence or other evidence prior to a hearing. If evidence is untimely, the Proposed Rule requires an explanation of the reasons why the evidence was not

timely submitted. If a provider or a supplier fails to include a statement explaining why the evidence was not previously submitted, the evidence would not be considered. The Section comments that this rule should be amended to provide a certain degree of flexibility. The OMHA ALJs and staff should be permitted to review evidence – in their discretion – even if a party fails to provide an explanation for the untimely submission of evidence.

- Review of Submitted Evidence (§ 405.1028): The Proposed Rule in Section 405.1028 mandates that the ALJ or the attorney adjudicator "must exclude" new evidence unless the party can show that good cause exists. The regulations provide certain examples of when good cause may be found. The Section believes that the ALJ or the attorney adjudicator should be given discretion to admit new evidence even if a party is unable to satisfy the enumerated criteria for "good cause." To do so, the Section suggest that this rule be amended to provide additional flexibility and that the "good cause" standard may be satisfied if the ALJ or the attorney adjudicator determines that "review of additional evidence is necessary in the interest of justice."

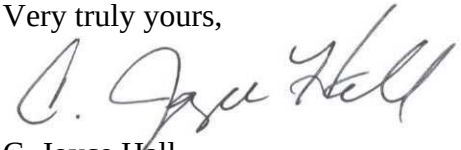
- Administrative Record (§ 405.1042): Section 405.1042(a)(3) permits a party to review a copy of the administrative record prior to or at the hearing, or if a hearing is not held, at any time before the notice of decision is issued. The Section suggests that parties be permitted to review a copy of the administrative record at any time, including after the hearing or after the notice of decision is issued. The Section believes that permitting such review of the administrative record would permit parties to assess the record to determine whether to pursue a subsequent appeal or judicial review.

VI. Conclusion

Thank you for the opportunity to submit these comments. The Section appreciates CMS and OMHA's efforts to address the increase in the number of appeals and efficiently process the current backlog. We provide these comments in order to encourage the agency to thoroughly consider the impact of the Proposed Rule on appellants and ensure that each appeal is reviewed on its merits in a fair and transparent manner.

If you have any questions or would like any additional information, please contact C. Joyce Hall, Chair of the Health Law Section, at (601) 965-1982 (jhall@watkinseager.com) or Simeon Carson, Director of the Health Law Section, at (312) 988-5824 (simeon.carson@americanbar.org).

Very truly yours,



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