THE NEW MEDICARE APPEALS PROCESS

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In the March 8, 2005 Federal Register, at 70 FR 11420, the Centers for Medicare and Medicaid Services ("CMS") issued its interim final rule regarding changes to the Medicare appeal procedures. The new interim final rule with comment period (hereinafter referred to as "final rule" or "final regulations") responds to comments on CMS' November 15, 2002 proposed rule, establishes the implementing regulations for the new appeals process, explains how the new procedures will be implemented, and sets forth the provisions necessary to implement the new statutory requirements enacted in Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). The final rule is effective May 1, 2005; however, due to numerous changes that impact the appeals procedures and the complex nature of implementing the changes because of various timing and related issues, all of the final rule provisions will not be implemented at one time. This article primarily focuses on the changes to the Medicare Part A and Part B appeal procedures as they impact providers and suppliers who submit claims to the Medicare program.

Background of the New Appeals Process

In 2000, Section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA") amended the Social Security Act to require revisions to the Medicare appeals process for Medicare Part A and Medicare Part B (see Pub. L. 106-554). Specifically, Section 521 required, among other features, the establishment of a uniform appeals process for Medicare Part A and Part B appeals, revised time frames for

filing appeals and issuing decisions, and the establishment of a new appeal entity, the Qualified Independent Contractor ("QIC") to conduct reconsiderations. In response to BIPA, CMS published a comprehensive proposed rule on November 15, 2002, at 67 FR 69312. On December 8, 2003, the MMA was enacted, which also contained a number of provisions impacting the Medicare appeals process including, among other requirements, revisions to the Medicare appeals process requiring: (a) full and early presentation of evidence in the appeals process; (b) specific requirements that must be met for appeal notices issued at various levels in the appeals process; (c) specific eligibility requirements for QICs and a reduction in the number of QICs from twelve to a minimum of four; and (d) revisions to the appeal time frames and amount in controversy requirements for appealing (see Pub. L. 108-173).

The Medicare regulations for Part A and B appeals have been contained in 42 CFR Part 405 subparts G and H, respectively. These regulations will continue to exist for an indefinite transition period until all appeals have been completed that resulted from initial determinations made before the new procedures set forth in the final rule go into effect.

The new regulations governing both the Part A and B appeal process are now contained in new subpart I of 42 CFR Part 405. Subpart I is comprised of the following:

- General Rules (42 CFR Sections 405.900-912).
- Initial Determinations (42 CFR Sections 405.920-928).
- Redeterminations (42 CFR Sections 405.940-958).
- QIC Reconsiderations (42 CFR Sections 405.960-405.978).
- Re-openings (42 CFR Sections 405.980-405.986).

- Expedited Access to Judicial Review (42 CFR Section 405.990).
- ALJ Hearings (42 CFR Sections 405.1000-1064).
- Medicare Appeals Council Review (42 CFR Sections 405.1100-1140).

In summary, the new five (5) step appeals process for both Part A and B providers is structured so that once a contractor makes an initial determination, a provider has 120 days to file a redetermination with the contractor. Following the contractors' redetermination decision, and within 180 days of receiving the determination, the provider may then file for reconsideration by a QIC. Following the QIC's decision, if the amount in controversy is met (i.e., \$100 increased by the percentage increase in the medical care component of the consumer price index), the provider is then afforded the right to file a request for an ALI hearing. This request must be made within 60 days from receipt of the QIC's decision. If the provider is dissatisfied with the ALJ hearing decision, the provider has 60 days to file the fourth level of appeal with the Medicare Appeals Council. The final level of appeal is the federal district court. In order to exhaust the final level of appeal, the provider must submit the request within 60 days and meet the amount in controversy requirement of \$1,000 or more. The amount in controversy requirement will be adjusted in accordance with the medical care component of the consumer price index.

Expansion of Appeal Rights (42 CFR Section 405.912)

Prior to the final rule changes, under the Part A appeals procedures, a Part A provider was only permitted to appeal claims when certain conditions were met. Part A providers were not

afforded the direct right to appeal claims when services failed to meet the requirements of a covered benefit (e.g., technical denials such as failure to have the appropriate physician certification for home health and hospice services). In such situations, Part A providers were only able to get around the restriction by acting as the beneficiary's appointed representative if the provider was able to get the beneficiary to sign the appropriate forms. Thus, without obtaining the appropriate signatures on the required appointment of representative form, a Part A provider was left without any appeal mechanism when claims were denied for technical reasons.

In keeping with the goal of having a uniform appeals process for Part A and Part B, the new regulations allow providers to have direct appeal rights with regard to all Medicare initial determinations. The new regulations do not alter the available reasons for denying a claim; rather, the regulations change the status of providers and participating suppliers by affording them the opportunity to appeal all denied claims in their own right.²

Initial Determinations (42 CFR Sections 405.920-928)

As part of the uniform appeals process, CMS proposed to continue to require that parties be notified of initial determinations in writing. The content of the notice must include the basis for the determination and notification to the parties of their right to a redetermination if dissatisfied with the decision on the initial claim determination. The proposal provided that the Remittance Advice (i.e., to providers) and the Medicare Summary Notice (i.e., to beneficiaries) would continue to be the mechanism to satisfy the written notification requirement.

In the final rule, CMS formally adopted the notice provisions requiring the notice to contain: (i) the basis for any full or partial denial; (ii) information

on the right to a redetermination if the provider or supplier is dissatisfied with the outcome of the initial determination; (iii) all applicable claim adjustment reason and remark codes to explain the determination; (iv) the source of the Remittance Advice and who may be contacted if the provider or supplier requires further information; (v) all content requirements of the standard adopted for covered entities under The Health Insurance Portability and Accountability Act ("HIPAA"); and (vi) any other requirements specified by CMS.³

With regard to initial determination time frames, per 42 CFR Section 405.922, contractors must issue initial determinations on clean claims within 30 days; otherwise interest will accrue on the claim. Consistent with the proposed regulations, and despite certain commenters' requests, the final regulations do not impose interest when contractors fail to process non-clean claims within the 45-day statutory time period. CMS received several comments regarding establishing procedures for escalation, and for imposing interest or penalties when contractors fail to meet the 45-day statutory time frame for issuing initial determinations on non-clean claims. Some commenters suggested that an escalation provision would enable parties to proceed to the redetermination level of the appeals process when contractors did not timely satisfy the time frames.

CMS noted that while it understood the concerns regarding the need for contractors to process claims timely, it also believed it was important for contractors to employ appropriate medical review procedures to ensure proper payment of claims. CMS stated that it is not always possible for the contractor to pay a claim within 45 days, particularly in situations wherein the provider does not timely submit the additional documentation needed on the claim. CMS opined that protecting the Medicare Trust Funds through medical review of claims flagged by the system was preferable to making inappropriate payments without having the appropriate information.⁴

First Level of Appeal -Redetermination (42 CFR Sections 405,940-958)

The first level in the new appeals process is the redetermination stage. Part A and Part B providers are required to file redetermination requests within 120 calendar days of receiving the notice of the initial determination. There is no amount in controversy requirement for exercising this first level of appeal. Under the prior system, upon receiving an initial determination, dissatisfied Part A providers filed reconsideration requests with the fiscal intermediary and Part B providers were afforded a carrier review.

In developing the new regulations, CMS proposed that all redetermination requests would have to be submitted in writing. The previous Part B appeal mechanism allowed providers to make requests for carrier review via telephone. In response to the proposed rule, CMS received several comments regarding whether redetermination requests should be accepted orally for purposes of offering a convenient and simple method to appeal.

According to the final rule, redetermination requests must be submitted in writing. In the final rule commentary, CMS stated that although allowing telephone requests would provide a faster appeals process in some cases, requiring a written process offers advantages of efficiency and accuracy. CMS opined that requiring written submissions promotes early submission of evidence (i.e., providers are able to submit evidence when filing the written request), which may lead to resolving appeals at lower levels. CMS also noted that it believed that requiring written submissions would promote more accurate decision-making.

Per 42 CFR Section 405.950, the contractor is required to mail or otherwise transmit notice of its decision within 60 calendar days of receiving

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the request for redetermination. The contractor is permitted to extend the 60-day time frame an additional 14 days if the provider submits additional evidence to the contractor after filing the redetermination request. The 60-day time frame can be extended an additional 14 days for each submission of evidence.

Some commenters advocated that CMS should impose penalties on carriers and fiscal intermediaries who failed to meet the 60-day time period. CMS also received other comments suggesting that providers be permitted to escalate their case to the next level of appeal for a contractor's failure to meet the regulatory time frame. In response, CMS opined that it did not believe it was appropriate to permit escalation of redetermination cases to the next level of appeal. CMS noted that it believed that Congress weighed the merits of escalation and specifically chose only to implement an escalation option at the QIC reconsideration level of appeal and higher. CMS did state, however, that it is required by law to monitor timeliness of contractor decisions and that the time frames will be enforced through corrective action plans and other tools that CMS has available to ensure carriers and fiscal intermediaries are meeting their contractual responsibilities.⁵

Second Level of Appeal - Reconsideration (42 CFR Sections 405.960-978)

Both Part A and Part B providers who are dissatisfied with a redetermination decision of a contractor are permitted to file a request for reconsideration to be conducted by the QIC. This second level of appeal must be filed within 180 calendar days of receiving notice of the redetermination decision and does not include an amount in controversy requirement.

Prior to the establishment of the new uniform appeals process, upon

receiving a decision from the carrier review process, Part B providers were afforded a Carrier Hearing. The QIC reconsideration stage of the appeal replaces the previous Carrier Hearing stage in the appeals process. Unlike Part B providers, Part A providers were not afforded a hearing level appeal prior to the Administrative Law Judge ("ALJ") level. Upon receiving a decision on the fiscal intermediary's reconsideration, the next stage in the appeals process was the ALJ hearing. Accordingly, this second level of appeal now affords Part A providers an additional step in the appeals process.

In an important change for Part B providers, the QIC reconsideration stage is an "on-the-record" review as opposed to an in-person hearing review. The on-the-record review consists of a review of the initial determination, the redetermination, and all issues related to the payment of the claim. In conducting the review, the QIC reviews the evidence and findings upon which the initial determination and redetermination were based as well as any additional evidence submitted by the parties or that the QIC obtains on its own.

CMS received comments to the proposed regulations that would change the QIC reconsideration stage to an on-the-record review. CMS noted that although a few commenters agreed with the proposal, most opposed the on-the-record review. The opposing commenters stated that appellants should be afforded the opportunity for a hearing as had been the case under the Part B hearing process. In response to such comments, CMS noted that the BIPA and MMA amendments do not require nor do they reference a "hearing" at the QIC level of appeal. CMS stated that the law refers to a review which includes consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and that such decisions shall be based on

applicable information, including clinical experience and medical, technical and scientific evidence.

In supporting its position, CMS noted that the law specifically provides for "hearings" at the ALJ level. CMS opined that its proposal was consistent with the substantially revised appeals process including "faster decision-making time frames, physician reviewers, and lower amount in controversy thresholds" and that "Congress was fully aware of the historical meaning of the terms 'reconsideration' and 'hearing' and did not use them lightly in the new statute."

As the ability to present a case in a hearing context has proven valuable for many Part B providers over the years, particularly in the context of large postpayment audit cases, Part B providers could be greatly impacted by the lack of hearing at this new stage. For example, in large Part B post-payment audit cases involving medical necessity denials, legal counsel often presents expert testimony from a qualified physician in the specialty at issue to advocate the provider's case. The inability to advocate a case through in-person expert testimony will likely impact the postpayment audit cases focusing on medical necessity. Legal counsel representing Part B providers in such cases will have to be prepared to handle the cases in a different manner, which may include submission of written affidavits from qualified experts.

The lack of hearing may also have an impact on providers with regard to being subject to recoupment of overpayments prior to the exhaustion of the appeals process. In the December 2003 MMA amendments, in a departure from the prior recoupment process, Congress placed limitations on CMS' ability to recoup alleged Medicare overpayments from providers and suppliers until after the reconsideration decision is rendered. Many thought this could have a significant impact if providers

were able to have an actual hearing prior to being subject to recoupment, as the hearing process could yield favorable results to the provider, avoiding potentially devastating recoupment. Unfortunately for providers appealing the large post-payment audit cases, however, the favorable MMA recoupment limitation may not prove as beneficial as first thought, given the QIC reconsideration is not a "hearing."

Of particular note in the reconsideration stage is the requirement under 42 CFR Section 405.968 that when the initial determination at issue involves a finding on whether an item or service was reasonable and necessary, the QIC's reconsideration must involve consideration by a panel of physicians or appropriate health care professionals and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record. Where the claim pertains to physician services, the reviewing professional must be a physician. The regulations do not require, however, the physician reviewer to be in the same specialty as the physician whose claims have been denied based on medical necessity.

As part of the reconsideration review process, 42 CFR Section 405.968(b) provides that QICs are bound by National Coverage Decisions, CMS Rulings, and applicable laws and regulations but are not bound by Local Coverage Decisions, Local Medical Review Policies or CMS program guidance such as program memoranda and manual instructions. Although not bound by the latter authorities, the final rule does require the QIC to give substantial deference to such authorities if applicable to a particular case. According to the final regulations, a QIC's decision to not follow one of the non-binding authorities only applies to the specific claim being reviewed and has no precedential effect.

Consistent with Section 933(a) of the MMA, in the final regulations CMS included a requirement in the reconsideration stage for full and early presentation of evidence. Specifically, 42 CFR Section 405.966 requires that when filing a reconsideration request, an appellant should present evidence and allegations of fact or law related to the issues in dispute and explain the reasons for the disagreement with the initial determination and redetermination. Notably, absent good cause, failure of a provider to submit evidence, including documentation requested in the notice of redetermination, prior to the issuance of the notice of reconsideration, precludes subsequent consideration of the evidence. Similar to the earlier stage in the appeals process, the QIC can extend its 60-day mandatory decision making time frame up to 14 calendar days each time a party submits additional evidence after initially filing the request for reconsideration. Accordingly, providers must understand that they may not be permitted to introduce evidence in later stages of the appeals process if such evidence was not presented at the reconsideration stage.

In response to concerns regarding this requirement, CMS did establish an exception to the full and early presentation of evidence requirement applicable to beneficiaries (but only those beneficiaries who are not represented by providers or suppliers) exercising their appeal rights.

Many issues are raised by the early presentation of evidence requirement. For example, in large post-payment audit cases involving statistical sampling and voluminous claims that have historically taken considerable time to prepare, will the provider be able to submit all evidence in the required time frame? Moreover, if in-person expert testimony cannot take place at the QIC level, will the provider be required to submit affidavits or other written testimony at the QIC level in order to introduce expert testimony at the ALJ hearing?

Health care counsel representing providers in the large post-payment audit cases and other cases must be mindful of these requirements. Given that these cases take considerable time to work-up, including securing appropriate experts to review the case, counsel may evaluate various strategic considerations, such as whether to wait until the end of the 180-day appeal time period to file the reconsideration request. Moreover, upon receiving a redetermination decision, providers would be well advised to make immediate Freedom of Information Act requests for the carrier file in order to begin working-up the case as soon as possible in the process.

In order to provide appellants appropriate notice of the full and early presentation of evidence requirement, per 42 CFR Section 405.956, any redetermination that affirms an initial determination, in whole or in part, must contain a number of items including, among other requirements: (a) a statement of any specific documentation that must be submitted with the request for reconsideration; and (b) a statement that all evidence that the appellant wishes to introduce during the remainder of the appeals process must be submitted with the request for reconsideration.

In general, 42 CFR Section 405.970 requires that within 60 days of receiving the request for reconsideration, the QIC must take one of the following actions: (1) notify all parties of its reconsideration decision; (2) notify the appellant that it cannot complete the reconsideration by the deadline and offer the appellant the opportunity to escalate the appeal to an ALJ. The QIC is required to continue to process the reconsideration unless it receives a written request from the appellant to escalate after the adjudication period has expired; or (3) notify the parties that it has dismissed the reconsideration request in accordance with the dismissal regulation. If an appellant exercises the option to escalate by submitting it in writing to the QIC, the QIC then (within five days of receiving the written notice or within five days from the end of the adjudication period) must either complete the reconsideration and notify all parties of the decision or acknowledge the

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escalation notice in writing and forward the case to the ALJ.

CMS received comments in this area, including concerns that the time frame was not sufficient for postpayment audit cases involving statistical sampling ("big box cases") that require individual consideration of numerous claims. In such cases, the commenters feared that the limited time could force OICs to rubberstamp redeterminations in order to meet the time frames. In response, CMS stated that Congress did expect that there would be some situations in which the time frame could not be met, as evidenced by its inclusion of the escalation provisions. Accordingly, CMS stated that if the QIC fails to meet the time frame in big box cases, an appellant is given the option to wait for the decision or is permitted to escalate the case to the ALJ level.⁷

An important issue that remains unknown at this point is the impact of taking advantage of the escalation provisions in the context of the overpayment recoupment process. As discussed earlier in this article, per Section 935(b)(2) of the MMA. Medicare carriers and fiscal intermediaries are prohibited from recouping alleged overpayments from a provider "until the date the decision on the reconsideration is rendered." If a provider opts to escalate a case due to the QIC's failure to meet the decision time frame, will the carrier or intermediary be permitted to begin recoupment action at that time? Health care counsel representing providers in the appeals process should consider and thoroughly analyze such issues when advising clients on decisions involving whether or not to escalate a case.

Third Level of Appeal-ALJ (42 CFR Sections 405.1000-1054)

The third level of appeal under the new uniform appeals process is the ALJ

hearing. A provider dissatisfied with a reconsideration decision may request an ALJ hearing. Also, a provider who has properly exercised the escalation provision at the reconsideration stage is entitled to request an ALJ hearing. Similar to the old process under Parts A and B, the request must be filed within 60 days after receipt of notice of the QIC decision and must meet the \$100.00 amount in controversy requirement.

Under the final regulations, ALJ hearings can be conducted in-person, by video-teleconference ("VTC") or by telephone. As noted in the regulation's preamble comments, however, CMS revised 42 CFR Section 405.1020 in the final rule to require that ALJ hearings be conducted by VTC if the VTC technology is available. The ALJ is also permitted to offer a telephone hearing if the request for hearing or the record reflects that it would be more convenient for one or more of the parties.

In discussing the comments received expressing concerns regarding VTC and telephone hearings, CMS noted that the regulations do allow the appellant to object to the VTC and request an in-person hearing, which will be granted upon a finding of good cause. In such cases, the appellant is required to waive the 90-day time frame for holding a hearing and rendering a decision. According to 42 CFR Section 405.1020 of the final regulations, an ALJ may determine to hold an in-person hearing if VTC is not available or if special or extraordinary circumstances exist.

If a party objects to a VTC hearing or a telephone hearing offered by the ALJ, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and must request an in-person hearing. The notice must be in writing, set forth the reason for the objection, and state the time and place desired for the hearing. An ALJ may grant the request with the concurrence of the Managing Field

Office ALJ, upon a finding of good cause. In the preamble commentary, CMS noted that an ALJ could find good cause to grant an in-person request when the party demonstrates that the case presents complex or challenging issues that necessitate an in-person hearing. CMS also noted that a party's objection to a VTC or telephone hearing may only be made with respect to the party's own testimony and not with respect to the entire hearing.

After the ALJ sets the time and place for the hearing, a notice must be sent to the parties setting forth a statement of the specific issues. If a provider objects to the issues described in the notice, the provider must notify the ALJ in writing at the earliest opportunity before the hearing and no later than five days before the hearing. The written objection must set forth the reasons and be sent to all parties to the appeal.

Per 42 CFR Section 405.1037, discovery is only permitted in ALJ hearings when CMS elects to participate in the hearing as a party. In such cases, the ALJ may permit limited discovery as set forth in the regulation. CMS noted in the preamble commentary that BIPA does not explicitly provide for discovery and thus limited discovery is only available for adversarial hearings (i.e., when CMS or its contractor is a party to the case). CMS also stated that the limited time frames for adjudication of the ALJ hearings set forth in BIPA do not envision that discovery will be included in most cases.10

In presiding over hearings, the final regulations provide that ALJs are bound by National Coverage Decisions but not Local Coverage Determinations, Local Medical Review Policies, or CMS program guidance. ALJs must, however, give the non-binding authorities substantial deference if applicable in a case. An ALJ's decision to not follow a non-binding authority must be set forth and will not have any precedential

effect in other cases.

In issuing the final regulations, CMS also added 42 CFR Section 405.1064 to address ALJ decisions in cases involving statistical sampling. Specifically, CMS noted that a decision based on only a portion of a statistical sample does not accurately reflect the entire record; thus when an appeal from the QIC involves an overpayment in which the QIC relies on a statistical sample in making its decision, the ALJ must base his or her decision on a review of all claims in the sample.

An ALJ is required to issue a decision, enter a dismissal order, or remand to the QIC, as appropriate, no later than 90 days from the date the request for hearing is received. Similar to the escalation clause in the QIC reconsideration stage, a provider who timely files for an ALJ hearing and whose appeal continues to be pending after the adjudication time period has ended has the right to request that the case be escalated for Medicare Appeals Council review. In such cases, if the ALJ is unable to issue a decision or remand to the OIC, as appropriate, within the later of five days from receiving the escalation request or within five days from the expiration of the adjudication time period, the case can be escalated.

MAC and Judicial Review Stages (42 CFR Sections 405.1100-1140)

The fourth level of the uniform appeals process is the Medicare Appeals Council Review ("MAC") stage. The MAC is within the Departmental Appeals Board of the U.S. Department of Health and Human Services. The MAC review is not a hearing level of appeal. A MAC review request must be filed within 60 days after receipt of the ALJ's decision or dismissal. A party does not have the right to seek MAC review of an ALJ's remand to the QIC or an ALJ's affirmation of a QIC's dismissal on a request for reconsideration. Per 42 CFR Section 405.1100, the MAC

reviews an ALJ's decision de novo. As noted by CMS in the regulation's preamble commentary, as the MAC must review the decision de novo, it will not apply a substantial evidence standard when it considers the ALJ's findings of facts. However, an ALJ's findings and conclusion on factual issues will still carry weight, particularly with respect to credibility of witnesses.¹¹

The MAC may decide on its own motion to review a decision or dismissal by an ALJ. CMS or any of its contractors may also refer a case to the MAC anytime within 60 days after the date of an ALJ's decision or dismissal of a case, if in its view the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect public interest. CMS can also request that the MAC take a case on its own motion if (i) CMS or its contractor participated in the appeal at the ALJ level; and (ii) in CMS' view, the ALJ's decision or dismissal is not supported by the preponderance of evidence in the record or the ALI abused his or her discretion.¹² CMS' request must be made in writing, must state the reasons why the MAC must review the case, and must be sent to all parties as well as the ALJ. A party who receives CMS' request is also entitled to file a written exception with the MAC within 20 days of receiving the referral notice request.

Per 42 CFR Section 405.1110(c), when CMS refers a case to which it or its contractors participated at the ALI level, the MAC exercises its own motion authority if there is an error of law material to the outcome of the case, there is an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence, or there are broad policy or procedural issues that may affect the general public interest. In deciding whether to accept the case for review, the MAC will limit its consideration to those issues raised by CMS in the written request. For those cases in which CMS or its contractors did not participate at the ALJ level, the MAC will accept review only if the decision or dismissal contains an error of law material to the outcome or presents broad policy or procedural issues that may affect the public. Again, the MAC will limit its consideration to those issues raised by CMS in the written request.

In filing a request for MAC review, among other standard requirements, the request must identify the parts of the ALJ action with which the party disagrees and explain the reasons for the disagreement. Thus, if the appellant believes that the ALJ action is inconsistent with a regulation or law, the request for MAC review should set forth why the ALJ's action is inconsistent. Importantly, unless the request is from an unrepresented beneficiary, the MAC will limit its review to those exceptions/ issues raised by the appellant in the written request for review.¹³

Upon request, the MAC will grant the parties a reasonable opportunity to file briefs or other written statements. Unless the party submits the brief or written statement at the time of filing the request for MAC review, the time beginning with the date of the request to submit a brief and ending with the date of receipt of the brief will not be counted toward the 90-day adjudication time period imposed on the MAC. Per 42 CFR Section 405. 1124, a party may request to appear before the MAC to present oral argument on the case. The MAC will grant such a request if it decides that the case raises an important question of law, policy or fact that cannot be readily decided based on the written submissions. The MAC also has the authority to decide on its own motion that oral argument is necessary in the case. In such cases, the MAC must provide notice to the parties of the time and place of the oral argument at least 10 days prior to the date. The MAC can also request, but cannot require, CMS or its contractors to appear, but cannot draw any inferences if they decide not to participate in oral argument.

After reviewing all of the evidence in the administrative record, the MAC

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is required to make a decision or remand the case to the ALJ. Similar to the previous stages in the appeals process, the MAC review stage also contains an escalation provision. Specifically, if the MAC fails to issue a decision or remand the case within the 90-day (or longer if the extension provisions apply) adjudication time period, the appellant may request that the appeal, other than an appeal of an ALJ dismissal, be escalated to federal district court. When the MAC receives an escalation request, the MAC may issue a decision or remand the case to the ALJ, if that action is taken within the later of five calendar days of the receipt of the escalation request or five calendar days from the end of the applicable adjudication time period. If the MAC is unable to take the action in the time frames noted above, the MAC must send a notice to the appellant. The appellant may then file an action in federal district court within 60 days after the date of receiving such notice from the MAC.14

The final step in the appeals process is judicial review in the federal district court, which must be filed within 60 days of receipt of the MAC's notice of decision. 42 CFR Section 405.1136(e) provides that a court may not review a regulation or instruction that relates to a method of payment under Medicare Part B if the regulation or instruction was published or issued before January 1, 1991. In a federal district court action, the findings of fact by the Secretary of HHS, if supported by substantial evidence, are deemed conclusive.

The Reopening Process (42 CFR Sections 405.980-986)

The final regulations also provide for a reopening process regarding initial determinations, redeterminations, reconsiderations, ALJ hearings and MAC reviews. A reopening is defined as a remedial action taken to change a final

determination or decision that resulted in either an overpayment or underpayment, even though the determination or decision was correct based on the evidence in the record. According to the regulations, a contractor is required to process clerical errors such as mathematical mistakes, denials of claims as duplicates, inaccurate data entry and similar errors as reopenings rather than as redeterminations.

With regard to duplicate claim denials, CMS noted that when a provider or supplier receives a denial based on the contractor's determination that the claim is a duplicate and the provider or supplier believes that the denial was erroneously identified as a duplicate claim, the contractor should reopen the denial. In the event the contractor believes that the denial was correctly identified as a duplicate, the contractor must dismiss the reopening and advise the party of any appeal rights. If a party files a reopening based on an alleged clerical error and the contractor disagrees that it is a clerical error, the contractor must dismiss the reopening request and advise the party of any appeal rights, provided the time for appeal has not expired. 15 A provider must be cautious not to lose appeal rights in this scenario.

Providers should also be aware that when a party has filed a valid request for appeal of an initial determination, redetermination, reconsideration, ALI hearing or MAC review, no adjudicator has the authority to reopen the claim until all appeal rights have been exhausted. Once the appeal rights have been exhausted, the contractor, QIC, ALJ or MAC can reopen, consistent with the regulations. In the preamble commentary, CMS noted that 42 CFR Section 405.980(a)(4) ensures that the reopening and appeals processes are not engaged at the same time. CMS stated that irrespective of a provider's request for an appeal, a contractor must treat a request for appeal involving a clerical

error as a reopening and that it understands that educational efforts will have to be undertaken in the provider and supplier community to create awareness of the contractors' obligations to solve such issues through reopening. CMS opined that until such education occurs, providers and suppliers may continue to believe that their only recourse is the appeals process. ¹⁶ Notably, a contractor's, QIC's, ALJ's, or MAC's decision on whether to reopen is final and not subject to the appeals process. ¹⁷

The regulations set forth the various time frames applicable to the reopening process, including that a party can request that a contractor reopen an initial or redetermination within one year for any reason and within four years upon a showing of good cause. Good cause may be established when there is new and material evidence that was not available or known at the time of the decision that may result in a different conclusion, or that the evidence that was considered or a decision clearly shows on its face that an obvious error was made. Of particular note, the regulations provide that a change of legal interpretation or policy by CMS in a regulation, CMS ruling or instruction is not a basis for reopening of a determination or a hearing decision.¹⁸ Like the previous reopening provisions, the regulations provide for various time frames in which the adjudicators may reopen. These provisions include the ability to reopen at any time if there exists evidence of fraud. 19

Expedited Access to Judicial Review (42 CFR Sections 405.990)

In order to conform to Section 932 of the MMA amendments, CMS' final regulation makes certain changes to the expedited review process. Specifically, Section 932 requires HHS to establish a process under which a provider, supplier or beneficiary may obtain access to

judicial review when a review entity determines that the MAC does not have the authority to decide the guestion of law or regulation relevant to the matter and there is no material issue of fact to dispute. Accordingly, in order to obtain expedited access to judicial review ("EAJR"), a provider may request EAJR in place of an ALJ hearing or MAC review if certain requirements set forth in 42 CFR Section 405.990(b) are met. In order to be granted EAJR, a review entity (comprised of an entity of up to three reviewers who are ALJs or members of the Department Appeals Board) must certify that the MAC does not have the authority to decide the question of law or regulation and that no material facts are in dispute. If there is more than one party to the reconsideration, hearing or MAC review, each party also has to concur in writing with the request for the EAJR. The review entity has 60 days to issue a certification for EAJR or to deny the request. Notably, a review entity's decision is not subject to review by the Secretary of the Department of Health and Human Services. The regulations also provide that if the review entity fails to act within the required time frame, the requester is permitted to bring a civil action in federal district court within 60 days of the end of the time period.²⁰

Summary

Although the new uniform appeals process contains many of the components and features of the previous Medicare Part A and Part B appeal procedures, there are numerous changes that impact the provider and supplier community, including requirements for full and early presentation of evidence, the lack of a "hearing" at the reconsideration stage, and the inability to have an in-person hearing in most cases at the ALJ level.

In some cases, the new time frames and escalation clauses may prove

beneficial to providers and suppliers who have been frustrated by the slowness of the previous appeals process, particularly given that alleged overpayments are subject to recoupment prior to exhaustion of the appeals process. The new time frames, however, may not be viewed as advantageous in all situations, including the large post-payment audit cases that take considerable time to work-up and should take considerable time to appropriately and thoroughly review. It is unknown whether providers opting for escalation will be negatively impacted by the recoupment procedures. Moreover, the escalation clauses may essentially operate to deprive providers of being able to take advantage of all stages in the appeals process.

Legal counsel representing health care providers and suppliers in the Medicare appeals process should be fully aware of the new requirements and limitations in the process.

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Endnotes

- See, Fed. Reg. Vol. 70. No. 44 at page 11425. As set forth in CMS' implementation table, CMS used a phased-in approach implementing changes to the Part A process first. This approach enables Qualified Independent Contractors ("QIC") to begin carrying out reconsiderations of appealed fiscal intermediary claims beginning in May 2005, which provides the second level reconsideration for Part A claims as soon as possible. This second level of appeal was not available in the previous appeals process for Part A claims. In January of 2006, QICs will then begin carrying out reconsiderations of appealed Part B carrier redeterminations. Moreover, whenever the BIPA and MMA provisions were not fundamentally premised on the introduction of QIC reconsiderations into the appeals process, CMS has already taken steps to implement the new appeals provisions, including the transition to a uniform redetermination process by the fiscal intermediaries and carriers, including the time frame and notice requirements.
- ² See, Fed. Reg. Vol. 70. No. 44 at page 11427.
- ³ See, 42 CFR Section 405.921.
- ⁴ See, Fed. Reg. Vol. 70. No. 44 at page 11434.
- ⁵ See, Fed. Reg. Vol. 70. No. 44 at page 11439.
- 6 See, Fed. Reg. Vol. 70. No. 44 at page 11447-11448.
- ⁷ See, Fed. Reg. Vol. 70. No. 44 at page 11449.
- 8 See, Fed. Reg. Vol. 70 No. 44 at page 11456-11457.
- ⁹ See, Fed. Reg. Vol. 70 No. 44 at page 11457.
- ¹⁰ See, Fed. Reg. Vol. 70 No. 44 at page 11461.
- ¹¹ See, Fed. Reg. Vol. 70 No. 44 at page 11467.
- ¹² See, 42 CFR Section 405.1110
- ¹³ See, 42 CFR Section 405.1112.
- ¹⁴ See, 42 CFR Section 405.1132.
- ¹⁵ See, 42 CFR Section 405.980.
- ¹⁶ See, Fed. Reg. Vol. 70 No. 44 at page 11452.
- ¹⁷ See, 42 CFR Section 405.980(a)(5).
- ¹⁸ See, 42 CFR Section 405.986(b).
- ¹⁹ See, 42 CFR Section 405.980(b) (c) and (d).
- ²⁰ See, 42 CFR Section 405.990(f).

For additional information on the MMA, see "The MMA One Year Later" (a three-part teleconference series, February 2005); available in the ABA's webstore at www.abanet.org/ABA Store