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May 9, 2005

BY HAND

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Attention: CMS-4064-IFC

Dear Sir or Madam:

Enclosed please find one original and two copies of the American Clinical Laboratory's ("ACLA") comments on the proposed changes to the Medicare Claims Appeal Procedures.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Peter Kazon/cj
Peter Kazon

PK:cj
Enclosures

WDC01/167736v1

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**Comments of the
American Clinical Laboratory Association on
Changes to the Medicare Claims Appeal Procedures
CMS-4064-IFC**



American
Clinical Laboratory
Association

The American Clinical Laboratory Association (“ACLA”) is pleased to submit these comments on the proposed changes to the Medicare Claims Appeal Procedures (the “Interim Final Rule”). 70 Fed. Reg. 11420 (March 8, 2005). ACLA is an association representing independent clinical laboratories throughout the United States, including local, regional, and national laboratories. ACLA members utilize the claims appeal process to resolve unfavorable determinations; therefore, ACLA members will be significantly affected by the changes in the Interim Final Rule. ACLA’s comments on the Interim Final Rule focus on the provisions covering: the assignment of beneficiary appeal rights; the submission of evidence requirements; deference to local coverage policies and CMS guidance; reopenings of claims based on clerical errors; and rights to a fair hearing.

Assignment of Appeal Rights

Section 405.912 – Assignment of Beneficiary Appeal Rights. The Interim Final Rule provides new regulatory procedures when a beneficiary assigns his/her appeal rights to providers. To be valid, under Section 405.912(c), the assignment must:

- Be executed using a Centers for Medicare & Medicaid Services (“CMS”) standard form;
- *Be in writing and signed by both the beneficiary assigning his or her appeal rights and by the assignee;*
- Indicate the item or service for which the assignment of appeal rights is authorized;
- Contain a waiver of the assignee’s right to collect payment from the assignor for the specific item or service that are the subject of the appeal (except where the assignee is recovering payment associated with coinsurance or deductibles or an advance beneficiary notice is properly executed);¹ and
- Submitted at the same time the request for redetermination or other appeal is filed.

ACLA supports CMS’s decision to impose regulatory safeguards to protect beneficiary appeal rights; however, the signature requirement on the part of the beneficiary will adversely affect the ability of clinical laboratories to pursue appeals and is unnecessary because the beneficiary has no financial liability. Accordingly, ACLA requests that this signature requirement not be applied to clinical labs.

¹ A provider or supplier is not barred from recovery for any coinsurance or deductible or from claiming payment in full where the beneficiary has signed an Advance Beneficiary Notice (“ABN”) accepting responsibility for payment.

It will be extremely difficult for laboratories to obtain the beneficiary's signature because in most cases, the laboratory has no direct contact with the patient; thus, there is no opportunity to obtain the signature. Furthermore, the beneficiary seldom knows which clinical laboratory is providing the laboratory services. Consequently, beneficiaries will often be confused by the laboratory's request that the beneficiary sign an assignment of appeal rights because the beneficiary has no knowledge of the laboratory's involvement.

Further, the beneficiary does not usually have any financial liability for services performed by clinical laboratories. Clinical laboratory services must be billed on an assignment-related basis and there is no copayment for these services. Therefore, because the beneficiary is not financially liable, there is no reason for the beneficiary to give his or her permission for the appeal.²

As a result, ACLA members will be severely, unfairly, and disproportionately disadvantaged by the requirements set forth under the Interim Final Rule because it will be extremely difficult, if not impossible, for them to obtain the beneficiary's signature to permit the appeal. Thus, ACLA respectfully requests that clinical laboratories be exempted from the beneficiary signature requirement for the assignment of appeal rights. Instead, ACLA urges that clinical laboratories be permitted to appeal claims on their own behalf.

Reconsiderations

Section 405.966 – Evidence to be Submitted with the Reconsideration Request. The Interim Final Rule states that any party to an appeal may submit additional evidence at any time until the qualified independent contractor ("QIC") renders its decision. Any additional evidence that is submitted results in a fourteen (14) day extension of the QIC's decision-making time frame. After the QIC's decision, providers, suppliers, and beneficiaries represented by providers and suppliers are precluded from introducing additional evidence, unless there is a good cause for not presenting the evidence prior to or during the reconsideration.

ACLA generally supports the "full and early" presentation of evidence requirement stated in the Interim Final Rule. *70 Fed. Reg.* 11446. However, Medicare appeals will often involve numerous claims and a variety of complex issues. Thus, it will not be unusual for it to become apparent later in the appeals process that additional information may be necessary or useful. As a result, the introduction of such information should be permitted after the QIC's decision, if it is relevant to a determination of the issues and if there is no prejudice to permitting its submission.

Conduct of a Reconsideration

Section 405.968 – Conduct of a Reconsideration. According to the Interim Final Rule, the QIC must give "substantial deference" to local coverage determinations ("LCDs"), local medical review policies ("LMRPs"), or CMS program guidance, if it is determined that any of these policies are applicable to the particular claim. *70 Fed. Reg.* 11447. The QIC is not required to follow such policies if the QIC believes that the policy is not relevant or legally persuasive. A

² There may be, however, a copayment for physician pathology services, which are also performed by clinical laboratories. Even these services are usually performed on an assignment-related basis; therefore, the laboratory is primarily responsible for the billing.

party may also request that the QIC not follow existing LCDs, LMRPs, and CMS program guidance, provided that the party demonstrates a persuasive reason why the policy should not be followed. However, ACLA does not agree that such deference is required.

CMS suggests that such deference is appropriate because LCDs can be challenged directly under Section 522 of the Benefits Improvement Act ("BIPA"). Section 522 of BIPA, however, only provides an alternative for "aggrieved parties" to challenge the coverage decision. By definition, "aggrieved parties" only includes beneficiaries, not providers such as clinical laboratories. Providers have no opportunity to challenge local coverage decisions other than through the claims appeal process.³ As a result, it is unfair and a denial of due process for the QIC to give LCDs, LMRPs, and CMS program guidance substantial deference because this will be the first opportunity for providers to challenge these coverage decisions.

The QIC should have the opportunity to review the evidence and make its own determinations concerning the appropriateness of local policies. QICs, as directed by the Medicare Modernization Act of 2003 ("MMA"), are required to have sufficient "medical, legal knowledge, and other expertise, including knowledge of the Medicare program" in order to carry out their duties. Therefore, QICs are well-equipped to determine medical necessity on their own accord, without affording substantial deference to local policies. As a result, ACLA believes this requirement should be eliminated to preserve fairness and due process.

Section 405.960 Right to Reconsideration The Interim Final Rule states that all QIC

coding information. As discussed with CMS, in many cases, these resubmissions are necessary because although as many as eight (8) ICD-9 codes are submitted with the claim, the MCS claims processing system only utilizes the first four (4) ICD-9 codes to adjudicate the claim. The only way to have all codes reviewed is to resubmit the claim, and change the order of the ICD codes submitted.

Not only is the Change Request unfair and burdensome, but it is also contrary to the Interim Final Rule, which provides that duplicate claims are to be considered clerical errors and, therefore, resolved through the reopening process. Based on the Change Request, ACLA members are concerned that when carriers are unable to read all eight of the required ICD-9 codes, clinical laboratories will have to initiate an appeal for their claim, instead of the reopening process, which is generally used today. ACLA strongly urges CMS to consider the administrative burdens and costs that this interpretation of the Change Request will cause and to resolve this issue in favor of the Interim Final Rule, which allows for the reopening of duplicate claims.

ALJ Hearings

Section 405.1020 – Time and Place for a Hearing Before an ALJ. The Interim Final Rule states that ALJ hearings must be conducted by videoteleconferencing (“VTC”), if available. An appellant may request an in-person hearing, but it will only be granted on a showing of good cause. Evidence of good cause may include a case that presents complex, challenging, or novel issues.

The opportunity for an in-person hearing is an essential component of the ALJ stage in the claims appeal process. A provider should have the right to an in-person hearing with an ALJ to present its most compelling case in the most efficient way. The Interim Final Rule currently provides only one opportunity for a fair in-person hearing, which is at the ALJ stage.⁴ To propose that the ALJ hearing should now be conducted by VTC deprives providers of this very important element of the hearing process. Moreover, clinical laboratories consistently consolidate multiple claims at the ALJ stage, which is not suitable for VTC. Being able to sit at the same table, point out issues on documents, and pass documents back and forth is efficient and fair. Denying this right of an in-person hearing is inefficient.

Thus, we urge CMS to make the in-person hearing before an ALJ a right of the appellant. This would preserve the one remaining opportunity for clinical laboratories to be heard in-person.

Section 405.1062 – Applicability of Local Coverage Determinations and Other Policies not Binding on the ALJ and MAC. As the Interim Final Rule provides at the QIC stage of the claims appeal process, the ALJ (or the Medicare Appeals Council (“MAC”)) is also required to give substantial deference to LCDs, LMRPs, CMS manuals, and other program guidance. Again, as discussed in our comments on Section 405.968, the ALJ is especially equipped to make his or her own determinations without such deference to local policies. We encourage CMS to allow ALJs to make their determinations based on their own review of the evidence.

⁴ As noted above, ACLA believes a hearing should also be permitted at the QIC stage.

Section 405.1034 – Remand Authority. As discussed earlier, CMS has proposed that providers may not submit additional evidence beyond the QIC level without a demonstration of good cause. Thus, at the ALJ level (or MAC level), providers may not submit additional evidence unless the ALJ (or MAC) determine that the provider has good cause for not submitting such evidence before or at the QIC level. CMS, however, has the opportunity to submit new evidence at the ALJ level without the limitation of the good cause standard.

While we understand that CMS is precluded from submitting evidence prior to the ALJ level, the submission of new evidence by CMS at this level presents a serious disadvantage to providers. Although the Interim Final Rule observes that CMS's introduction of new evidence may be considered good cause for the submission of evidence by providers, the good cause requirement should be eliminated under these circumstances. In the instances where CMS presents new evidence to the ALJ, providers should automatically have the right to present new evidence, without regard to the "good cause" requirement. Thus, clinical laboratories should have the opportunity to present evidence that may counter an introduction of evidence by CMS without having to prove good cause as a matter of fairness and due process.

Conclusion

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the Medicare Claims Appeal Procedures. Please do not hesitate to contact us should you have any questions about this information or need any further information.

American Medical Association

Physicians dedicated to the health of America

MAY 17 2005



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May 9, 2005

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Re: Medicare Program: Changes to the Medicare Claims Appeal Procedures;
Interim Final Rule; 70 Fed. Reg. 11,420 (Mar. 8, 2005); File Code CMS-4064-IFC

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates the opportunity to submit our comments to the Centers for Medicare and Medicaid Services' (CMS) concerning its interim final rule on *Changes to the Medicare Claims Appeal Procedures*, at 70 Fed. Reg. 11,420 (Mar. 8, 2005). The AMA recognizes that CMS addressed a number of our concerns from the proposed rule, and we are appreciative of your response and efforts in that regard. We would like to raise an additional issue, however, stemming from the restructuring of the appeals process. Specifically, we are concerned that CMS has not set forth any deadlines for contractors in issuing decisions on a request for a reopening.

REOPENINGS OF INITIAL DETERMINATIONS, REDETERMINATIONS, RECONSIDERATIONS, HEARINGS AND REVIEWS

The AMA understands that "reopenings" are intended to address minor or clerical errors in claims submissions, while redeterminations and other levels of appeal are for more complex matters. For most levels of appeal, there exist specific timeframes in which the Medicare contractor or other adjudicator must issue a decision. However, no such decision-making timeframe exists for reopenings. This is of great concern to the AMA because a physician or other party has 120 calendar days *from the initial determination* to file for a redetermination (although this may be extended for good cause). Likewise, there are timeframes within which a provider or other party must file for additional levels of appeal. If a physician requests a reopening, we are concerned that in some instances that decision-making process could exceed the timeframe for filing a request for a redetermination or an additional level of appeal. In that case, if the reopening is denied,

Mark B. McClellan, MD, PhD
May 6, 2005
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physicians would not be able to file a request for the next level of appeal, and thus, in effect, would be denied "their day in court."

CMS' rationale for not establishing timeframes under which contractors must issue a decision on a reopening is that contractors may, at any time, reopen claims "for fraud or similar fault," which could take an unpredictable extended amount of time for decision. Thus, the agency believes it cannot establish a reasonable timeframe for issuing a decision on a reopening. **The AMA recommends that CMS specify that a contractor or other adjudicator's failure to issue a decision on a reopening and notify the requestor within a sufficient time to file a request for a redetermination or the next level of appeal, constitutes "good cause" and shall result in an extension of the timeline to file for a redetermination or the applicable next level of appeal.**

The AMA appreciates CMS' efforts to improve the appeals process, and looks forward to continuing to work with you to ensure timely and fair resolution of claims discrepancies. Thank you again for the opportunity to comment on this interim final rule.

Sincerely,



Michael D. Maves, MD, MBA

MAY 17 2005



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May 9, 2005

VIA HAND DELIVERY

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Washington, DC 20201

**Re: Comments on the Section of the Interim Final Rule with Comment
Addressing "Reopenings of Initial Determinations, Reconsiderations,
Hearings, and Reviews"**

File Code: CMS-4064-IFC

Reference: 70 Fed Reg. 11420 (March 8, 2005)

Dear Mr. McClellan:

We are writing in response to the interim final rule with comment for file code CMS-4064-IFC published in the Federal Register on March 8, 2005 (70 Fed. Reg. 11420) (the "**Interim Final Rule**"). The Interim Final Rule responds to comments that the Centers for Medicare and Medicaid Services ("**CMS**") received on the proposed rulemaking published in the Federal Register on November 15, 2002 (67 Fed. Reg. 69312) (the "**Proposed Rule**") regarding extensive changes to the Medicare appeal procedures for claims for payment of services and/or supplies furnished by providers/suppliers for purposes of implementing the changes required by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("**BIPA**"). We represent many types of healthcare providers and suppliers and are writing to comment on the proposed 42 C.F.R. §§ 405.980 to 405.986. Specifically, we are commenting on the interim final regulations addressing the Medicare Program's process for reopening payment

determinations because CMS's responses in the Interim Final Rule to questions addressing reopening issues need further clarification.

REOPENING STANDARDS

We support and commend CMS on its efforts to "establish a unified set of reopening regulations that consolidate and clarify the existing reopening provisions of subparts G and H of part 405." *See* 70 Fed. Reg. at 11450. However, our review of the Interim Final Rule suggests that the Interim Final Rule needs further clarification on the reopening process in order to achieve this goal and to provide all parties with defined closure of the Medicare payment process. In particular, the following comments reflect that the Interim Final Rule needs to have clear criteria for when a reopening under the "similar fault" reopening provisions may occur.

Historically, CMS defined "fraud or similar fault" in the Medicare Carriers Manual, Part 3, § 12100.10(A). This provision, which was recently moved to the Medicare Claims Processing Manual, § 90.9 suggests that "fraud or similar fault" is limited to "deception," "an act that approximates fraud", or "a pattern of program abuse." However, in the Interim Final Rule, CMS's definition of "similar fault" is much broader because it includes situations where the provider/supplier "should have known" that it "received" or "obtained" funds to which it was not legally entitled. Specifically, CMS is proposing to define "similar fault" as:

[T]o obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that it filed a proper claim as defined in part 411 of this chapter."

See Interim Final Regulations § 405.902.

However, CMS does not explain in the Interim Final Rule why the broad "similar fault" definition in the Interim Final Rule deviates from CMS's historical policy. Indeed, a comparison of the new "similar fault" definition to the provisions governing waiver under §§ 1879 and 1870 demonstrate that it would cover any situation where waiver of liability was denied under §§ 1879 and 1870 of the Act because, in such situations, the Medicare Program would have determined that the supplier "should have known" certain applicable Medicare rules and was not "without fault."

As such, we believe that the definition in the Interim Final Rule would be burdensome on providers/suppliers who appropriately received funds from the Medicare Program. With the broad "should be expected to know" standard, we are concerned that contractors could abuse the open-ended time frame (*i.e.*, there is no time-limit) for "similar fault" reopenings. Indeed, the broader definition for "similar fault" would implicitly require providers/suppliers to maintain

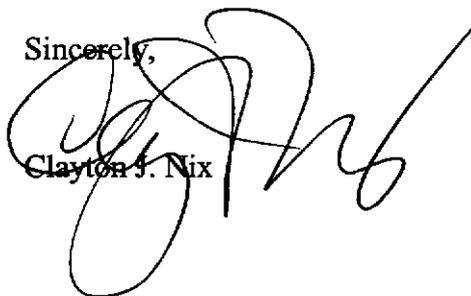
Mark B. McClellan
May 9, 2005
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billing records for an indefinite time and at considerable expense to refute any potential future allegations that they should have known that they were not entitled to receive the funds at issue. Based on the above, we believe that the proposed definition is overly broad and urge CMS to follow its current policy.

* * * * *

We appreciate the opportunity to submit these comments in response to the Interim Final Rule. Please feel free to call us if you have any questions regarding these comments or require further information regarding the issues we have raised.

Sincerely,



Clayton J. Nix

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Congress of the United States MAY 17 2005
Washington, DC 20515

May 9, 2005

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS-4064-IFC

Dear Secretary Leavitt:

As the Ranking Members on the Committee on Ways and Means and the Committee on Energy and Commerce, and as four of the original authors of the provision to transfer Medicare appeals out of the Social Security Administration's system, we respectfully submit the following comments on the Medicare Program: Changes to the Medicare Appeal Procedures, Interim Final Rule, issued in the March 8, 2005, Federal Register.

While we have long been advocates of streamlining the Medicare appeals process and alleviating the historic backlog of cases, the current regulations fail to adequately protect beneficiaries' right to appeal. Specific proposed regulations seriously undermine beneficiary access to in-person appeals and the ability to receive timely decisions at all stages of the process.

We have chosen to focus our comments on three fundamental changes in the regulations. Other provisions have points of concern as well, but would not damage the appeals process as dramatically as do the areas outlined in this letter.

Administrative Law Judge (ALJ) Independence

One of the major legislative challenges regarding the fundamental shift of Medicare appeals from the Social Security Administration (SSA) to the Department of Health and Human Services (HHS) was ensuring the continued independence of ALJs in deciding appeals. Creating an independent appeals office in HHS, organizationally separate from CMS and similar in stature and treatment to the Office of the Inspector General, appears to attain this goal. However, §405.1062 requires ALJs to give "substantial deference" to multiple types of CMS guidance. This section further requires ALJs to explain any decisions that deviate from these policies.

Medicare appeals must be conducted by independent ALJs who review the facts of each case based on the record created by the lower-level reviews. The substantial deference requirement severely limits ALJ independence and may cause them to rubber stamp lower-level decisions. It was not the intent of Congress to turn ALJ hearings into a venue for denying benefits because decisionmakers must give substantial deference to

guidance. This section clearly tilts the process in favor of HHS. We urge you to eliminate the "substantial deference" language.

Beneficiary Access to Timely, In-Person ALJ Hearings

The presumption that all hearings be conducted by videoteleconferencing (VTC) where available, as stated in §405.1020(b), effectively denies beneficiaries their statutory and due process rights to timely, in-person hearings. Although the regulations permit a beneficiary to request an in-person hearing instead of the VTC, the threshold showing of "good cause" that the beneficiary must make as required under §405.1020(h)(5) is vague and potentially difficult to meet. Additionally, the fact that requesting an in-person ALJ hearing constitutes a waiver of the statutorily defined 90-day time frame makes it possible, if not likely, that any person requesting an in-person hearing will go months or even years before receiving a hearing.

The intent of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), as amended by the Medicare Modernization Act (MMA), was to give everyone access to an ALJ hearing, regardless of venue, within the statutorily defined 90-day time frame. In creating only four appeals offices (Cleveland, OH, Miami, FL, Irvine, CA, Arlington, VA), access to in-person hearings is effectively denied. There is no indication in the regulations that ALJs will travel to hear cases, and there is no provision to provide travel allowances for appellants. An appellant may need to travel hours to reach a place where VTC or in-person hearing is possible and the lack of reimbursement for these costs is a de facto denial of a hearing for those who cannot afford to reach the hearing site. Because of these deficiencies in the regulations, there is no guarantee that beneficiaries will have access to timely in-person hearings. This is a serious erosion of current rights that runs contrary to the intention of the statutory language.

Furthermore, we are also very concerned that HHS may not have secured adequate facilities to accommodate the volume of VTC hearings that will be required because of the presumption in §405.1020. The current infrastructure to conduct VTC hearings is wholly inadequate to handle all Medicare appeals. In many cases beneficiaries and providers may be forced to travel hundreds of miles to get to a VTC hearing site. Although providers may be able to handle this, beneficiaries are mostly over age 65, are often ill or disabled, and may not be able to travel long distances.

Timeliness of Lower Level Reviews

Statutory deadlines for reconsiderations, which were clearly defined in BIPA as amended by MMA, are undermined by extensions in the regulations. The unlimited and automatic extensions of up to 14 days upon submission of new evidence, as required by §405.966(b) and §405.970, are unlawful under 42 USC 1395ff(c)(3)(C)(iv), which states that a reviewer may be granted additional time as the individual requesting such reconsideration specifies, not to exceed 14 days.

Additionally, similar unlimited and automatic extensions of up to 14 days upon submission of new evidence, as required by §405.946(b) and §405.950, clearly

undermine the 60-day statutory time frame enacted by Congress within which redeterminations are to be adjudicated.

Although we recognize the need for time to review new evidence, the potential for abuse created under these regulations is unacceptable and deters beneficiaries from continuing to assert their appeal rights. To the extent that such unlawful extensions are implemented, they will be struck down.

Conclusion

The Interim Final Rule thwarts the intent of Congress to provide Medicare beneficiaries with access to timely, independent, in-person appeals. The geographic distribution of ALJs combined with the presumption of VTC hearings will gravely limit the due process rights of beneficiaries. ALJ hearings have historically been independent, and this process has often resulted in beneficiaries receiving coverage for claims that were initially denied. The substantial deference requirement undermines ALJ independence and limits an ALJ's ability to overturn reconsiderations. Finally, Congress created strict time frames for lower-level reviews to expedite the appeals process and avoid the huge backlogs that have plagued the system. Potentially unlimited 14-day extensions are inconsistent with statutory language and should not be implemented as part of the redetermination and reconsideration processes.

Sincerely,



John D. Dingell
Ranking Member
Committee on Energy and Commerce



Charles B. Rangel
Ranking Member
Committee on Ways and Means



Sherrod Brown
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce



Pete Stark
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