**Submitter :** Mr. William Foley **Date:** 08/05/2005

**Organization :** Empire Medicare Services

**Category :** Health Care Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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Act.

Except for reimbursement of legal expenses

The various standards may be summarized as follows:

- FIs and Carriers. Pursuant to their existing contracts, intermediaries and carriers are indemnified for all costs related to judicial proceedings in accordance with the FAR so long as the underlying conduct was not criminal, fraudulent or grossly negligent.
- MACs. Under section 911 of the MMA, CMS has the express authority to indemnify MACs using the same standard currently applicable to intermediaries and carriers (i.e., indemnify so long as the underlying conduct as not criminal, fraudulent or grossly negligent). In addition, the MMA affords MACs immunity from liability unless the contractor acted with reckless disregard of its obligations, or with intent to defraud.

To the extent that a current intermediary or a MAC enters into a contract to perform MAC functions, they should be afforded the same immunity and/or indemnification rights as exist under their intermediary/carrier or MAC contract. Obviously, such rights are much broader than proposed in section 421.316(a). We believe that not only would it be administratively difficult, if not impossible, to impose different immunity/indemnification standards to different FI, carrier, or MAC functions (i.e., MIP vs. others), but that no clear authority exists to do so.

Accordingly, we propose that language be added to section 421.316(a) clarifying the continued applicable of the immunity/indemnification standards in FI and carrier contracts, as well as any such standards ultimately included in MAC contracts, to MIP functions.

In addition, we believe there is a reasonable basis to support a finding by CMS that it is appropriate to adopt a different standard for MIP contractors than the "due care" standard applicable to QIOs. As set forth in section 1893(e) of the Act, CMS may adopt a different limitation of liability standard than the one applicable to QIOs set forth in section 1157 of the Act "to the extent the Secretary finds appropriate."

In particular, the functions performed by MIPs are substantially broader than those performed by QIOs, and include investigations related to potential fraud, cost report audits, and taking actions to recover inappropriate payment. Both the quality and quantity of the functions to be performed by a MIP contractor result in a substantially greater risk of exposure to liability compared to QIOs. Moreover, while the legal concept of "due care" is reasonably related to the medical review functions performed by QIOs, it is not at all clear based upon accepted negligence jurisprudence how this standard would be applied in the context of MIP functions such as potential fraud investigations, cost report audits, and recovery of inappropriate payments. This vagueness risks the rendering of the intended immunity illusory.

Moreover, it is expected that, given both the type and array of functions to be performed by MIPs, liability premiums will be substantial. The uncertainty inherent in a due care immunity standard will likely exacerbate these costs.

For all of the above reasons, we believe that a more appropriate standard would be a "gross negligence" or "reckless disregard" standard similar to the indemnification standard applicable to intermediaries/carriers and MACs, respectively.

In sum, we urge CMS to (1) add language making clear that to the extent MIP functions are performed by intermediaries, carriers, or MACs, the immunity and/or indemnification standards contained in such contracts will continue to apply, and (2) adopt a limitation of liability standard whereby MIP contractors will be afforded immunity unless they were grossly negligent in performing their duties, or acted in reckless disregard of their obligations under the MIP contract.

2. Payment of Legal Expenses (Proposed rule 42 CFR § 421.316[b]).

Section 421.316(b) of the proposed rule provides that a MIP contractor will only be reimbursed for legal expenses related to lawsuits brought against the contractor if the costs are reasonable, as determined by CMS, and only to the extent that funds are available.

We strongly object to both the discretionary reasonableness standard and the funds available condition. Taken together, we believe that these provisions have the potential of substantially undermining the intent of the statute to afford MIP contractor indemnification of their legal expenses.

With respect to the reasonableness standard, we request that the phrase "as determined by CMS" be deleted. Instead, we propose that the reasonableness of legal expenses be determined in accordance with the FAR standards at 31.201-3 (Reasonableness) and 31.205-47 (Legal Expenses). This is consistent with the reimbursement principles contained in current FI, carrier, and MAC contracts.

With respect to the "funds available" condition, we believe this is unprecedented. Neither the current FI or carrier contracts contain such a condition, nor does the MMA with respect to MAC contractors. Perhaps most importantly, we believe the imposition of such a condition exceeds both the intent and the express language of the authorizing statute. In particular, section 1193(e) of the Act requires the same or comparable standard as the QIO statute at section 1157 of the Act. Section 1157 contains no condition that legal expenses will be reimbursed only to the extent that funds are available. Accordingly, we request that the funds available condition be deleted.

3. Recompeting and Transfer of a Business to a Subsidiary (Proposed rule 42 CFR § 421.306).

Under the proposed rule, MIP contracts may be renewed without complying with the FAR competition requirements. In proposed rule 421.306(b), there is an exception to competition requirements for successors-in-interest if certain conditions are established.

Although the proposed rule does not expressly require a transfer of resources (including personnel involved in performing the contract functions) for the exception to apply, the preamble to the proposed rule does state that a transfer of resources and personnel must occur to qualify for an exception to the competition requirements (70 FR 35210).

We request clarification regarding this apparent "transfer of resources" condition. In particular, when transferring Medicare operations to a new subsidiary, contractors may wish to enter into an administrative services agreement with a parent or related entity that employs the staff previously employed directly by the contractor. There are many business reasons why such an arrangement may be advantageous. Accordingly, we request confirmation that a potential successor-in-interest may qualify for an exception to re-competing even if personnel are not transferred, but are provided via an administrative services agreement, provided that all other criteria of the regulation are met.

We appreciate your consideration of these important issues. If you have any questions, please do not hesitate to contact me.

Sincerely,

William E. Foley
Vice President
Empire Medicare Services,
a Division of Empire HealthChoice Assurance, Inc.

**Submitter :** Dr. Michael Maves

**Organization :** American Medical Association

**Category :** Health Care Professional or Association

**Date:** 08/15/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-6030-P-32-Attach-1.PDF

AMA
AMERICAN
MEDICAL
ASSOCIATION

**Michael D. Maves, MD, MBA,** Executive Vice President, CEO

August 15, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

**RE: Proposed Rule, "Medicare Program; Medicare Integrity Program, Fiscal Intermediary and Carrier Functions, and Conflict of Interest Requirements" [CMS-6030-P2]**

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule, "Medicare Program; Medicare Integrity Program, Fiscal Intermediary and Carrier Functions, and Conflict of Interest Requirements," issued on June 17, 2005. Through the Medicare Integrity Program (MIP), CMS is authorized to contract with third parties to perform MIP activities, such as medical and utilization review, identification of potential fraud, and physician and provider education. The AMA recognizes the important role that these contractors play in educating physicians and ensuring Medicare pays appropriately for services. In general, the AMA strongly encourages CMS and its current and future MIP contractors to focus on educational rather than punitive measures toward physicians. Additionally, the AMA offers the following brief comments to improve MIP contractors' efforts under this proposed rule.

**Provisions of the Proposed Rule**

II. A. 4. (a): Medical and Utilization Review

The proposed rule observes that medical and utilization reviews help to ensure that services meet professionally recognized standards of care and that services are used appropriately. The AMA has consistently maintained that individuals conducting such reviews should possess appropriate credentials to adequately assess these factors. It is imperative that the

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MIP reflect the following: medical review and utilization review should be conducted by physicians with the same state licensure, from the same geographic area, and within the same specialty as the physician who provided the service under review.

II. A. 7: Conflict of Interest Rules

The proposed rule leans heavily on conflict of interest guidance in the Federal Acquisition Regulation to safeguard against potential conflicts of interest among its current and potential MIP contractors. Under the current MIP program and this proposal, the government may contract with an organization, even if a conflict of interest exists, if it is in the best interest of the government. The final rule should specifically and expressly state that such contracts may be entered into if they are "in the best interest of the government, even though the conflict exists, *and the conflict has been mitigated to the extent possible*." (Emphasis added.) Clarifying language of this nature emphasizes the government's commitment to minimizing conflicts of interest and adds an additional measure to ensure conflicts are as limited as possible.

To assist CMS' MIP contract officer in resolving conflicts of interest, the proposed rule authorizes CMS to establish a Conflict of Interest Review Board. The AMA believes that if CMS convenes such a board, its membership should include practicing physicians who regularly treat Medicare patients. It should also include other provider representatives as appropriate, representatives from the type of entity experiencing the conflict, and CMS.

II. A. 8: Limitation on Liability

Under the MIP program, it is possible that some contractors will be permitted to perform MIP activities despite potential conflicts of interest. This may include review of competitors, as well as review of physicians and other health care providers that may provide services under both the contractor's commercial and Medicare products. In a program where the potential for abuse is so significant, contractors should not be permitted to escape liability for any actions arising out of the performance of MIP functions unless they can demonstrate that they have complied with necessary safeguards. They must also demonstrate that their actions, relating to MIP activities, are motivated by a contractual obligation to identify and address noncompliance with Medicare rules, regulations, and policies, rather than self-interest. The AMA is concerned that indemnifying MIP contractors from liability as long as they exercise "due care," as proposed by CMS, is too weak a standard. Contractors are more likely to conduct their activities in strict compliance with MIP principles if they cannot so easily avail themselves of immunity from liability.

The AMA appreciates the opportunity to provide these comments.

Sincerely,

Michael D. Maves, MD, MBA

**Submitter :** Mrs. Kathy Reep

**Date:** 08/15/2005

**Organization :** Florida Hospital Association

**Category :** Health Care Provider/Association

**Issue Areas/Comments**

**Provisions of the Proposed Rule**

Provisions of the Proposed Rule

Under the detail of services to be procured, the proposed regulation indicates that the MIP contractor may conduct cost report audits. We are concerned with a different contractor conducting the hospital cost report audits from the contractor responsible for processing the claims for the same providers. While currently the fiscal intermediary in Florida is responsible for processing hospital claims and cost reports, we understand that the hospitals in North Carolina have separate contractors and that there are problems with the two contractors "talking" with each other. Access to PS&R reports, updated claims information, etc. has been a problem and we would not want to see this extended to other states or contractors.

We would urge CMS to discuss the nature of the problems that providers have experienced when dealing with separate contractors for payment vs cost report with the hospital association in North Carolina or with specific providers in order to ensure that existing roadblocks are cleared before any potential expansion of separate contractors across the country.