June 2, 1998

Health Care Financing Administration
Department of Health and Human Services
Room 309 - G. Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Attention: Ms. Brenda Thew


Dear Ms. Thew:

On behalf of the Section of Public Contract Law of the American Bar Association ("the Section"), I am submitting comments on the above-referenced matter. The Section consists of attorneys and associated professionals in private practice, industry, and Government service. The Section's governing Council and substantive committees contain members representing these three segments, to ensure that all points of view are considered. In this manner, the Section seeks to improve the process of public contracting for needed supplies, services, and public works.

The Section is authorized to submit comments on acquisition regulations under special authority granted by the Association's Board of Governors. The views expressed herein have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, therefore, should not be construed as representing the policy of the American Bar Association.
I. INTRODUCTION

The Section supports the goal of the Health Insurance Portability and Accountability Act ("HIPAA") to provide HCFA with authority to contract utilizing the Federal Acquisition Regulation ("FAR") with a broad base of entities capable of promoting integrity in the Medicare program. HIPAA requires HCFA to develop regulations that provide for identifying, evaluating, and resolving organizational conflicts of interest ("OCI") in accordance with the FAR. As explained in these comments, the proposed rule's disclosure requirements impose a level of detail and coverage that is excessive, burdensome, and in excess of what the FAR permits. In particular, the proposed rule's definition of what constitutes an actual or potential OCI is inconsistent with the longstanding acquisition policies that are contained in Subpart 9.5 of the FAR.

The Section recognizes the extensive effort that has gone into developing the proposed rule and commends the agency for the work done to address various competing concerns. However, the Section believes that HCFA can best achieve its acquisition objectives by adhering to the FAR's balanced approach to resolving OCIs. By doing so, HCFA may proceed with its contracting strategy without burdening potential bidders and contractors with the need to disclose excessive and unnecessary amounts of information. The Section believes that HCFA will be better positioned to attract a large number of new contractors anxious to accept the challenge of detecting fraud and abuse in the Medicare program if the contractors are permitted to operate in the manner specified in the FAR.

II. THE STATUTORY AND REGULATORY FEATURES OF THE ORGANIZATIONAL CONFLICTS OF INTEREST PROVISIONS

HIPAA provides that when awarding MIP contracts, HCFA shall enter into contracts and follow procedures that "are generally applicable to Federal acquisition and procurement." § 1893(d)(1) of the Social Security Act. We interpret the preceding language to mean that HCFA must adhere to the OCI provisions in the FAR. These comments explain how the proposed rule exceeds the FAR's OCI requirements in numerous respects. Before proceeding, a brief review of the OCI provisions in the FAR is necessary.

To begin with, FAR 9.501 defines the term "organizational conflicts of interest" in the following manner:

Organizational conflict of interest means that because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the Government, or the person's objectivity in performing the contract work is or might be otherwise impaired . . . .

FAR 9.505(a) restates this definition by proclaiming that an "underlying principle" in this area is, preventing the existence of conflicting roles that might bias a contractor's judgment.

Thus, an agency has a legitimate interest in contracting with entities that are unbiased in their judgment, impartial in their ability to render advice, and objective in their approach to the work in question. Each situation should be judged on the particular factors involved. FAR 9.502(c) says that an organizational conflict of interest "may result when factors create an actual or potential conflict of interest on an instant contract. . . ." (Emphasis supplied.)

FAR 9.504(a)(2) instructs contracting officials to avoid, neutralize, or mitigate important or "significant" issues and to refrain from focusing on the trivial. In that regard, the FAR directs that,

contracting officers shall analyze planned acquisitions in order to

. . . [a]void, neutralize or mitigate significant potential conflicts before contract award.

In deciding whether a "significant" potential conflict exists, as well as how to resolve an actual or potential conflict, FAR 9.505 instructs contracting officers to use "common sense, good judgment, and sound discretion."
Finally, the FAR addresses the question of how much information, by way of the particulars of a contractor's other business interests, ought to be scrutinized by the Government. FAR 9.504(d) states that:

In fulfilling their responsibilities for identifying and resolving potential conflicts, contracting officers should avoid creating unnecessary delays, burdensome information requirements, and excessive documentation.

The FAR OCI rules described above apply to all Federal agencies. If HIPAA had instructed HCFA to develop its own unique OCI rules, FAR 9.502(d) states that the above FAR requirements would not be applicable. However, HIPAA did not envision that HCFA would develop its own unique OCI procedures. In fact, HIPAA expressly said just the opposite when it required HCFA to adhere to the OCI procedures "that are generally applicable to Federal acquisition and procurement." Section 1893(d)(1) of the Social Security Act.

III. DISCUSSION

A. HCFA's Creation of An Apparent Conflict of Interest Standard (§ 421.312(a)(1))

Section 421.312(a)(1) of the proposed rule requires an offeror to provide "[a] description of all business or contractual relationships or activities that may be viewed by a prudent business person as a conflict of interest." The preamble refers to this type of conflict as "an apparent organizational conflict of interest." 63 Fed. Reg. 13596. The Section believes that creation of a new standard that is not included in the FAR-- an "apparent" OCI -- is unnecessary and causes greater uncertainty with an already subjective OCI definition. As with any highly subjective standard, it is an open invitation to disputes, disagreements, and protests, especially where proposed § 421.312(a)(5) requires a contractor to certify that it has not neglected to disclose all actual, potential, and apparent OCI's. More importantly, the addition of this new category does not follow the FAR as required by HIPAA. A significant revision to the FAR, as proposed by HCFA, would require deviation from the FAR.

Thus, for these reasons and others set forth below, the Section is opposed to the creation of an "apparent" OCI standard. The Section recommends that HCFA follow the standards in the FAR at Subpart 9.5.

B. Description of Methods to Mitigate Organizational Conflicts of Interest

Section 421.312(a)(2) of the proposed rule requires an offeror to provide "[a] description of the methods the offeror or contractor will apply to mitigate any situations listed in the [Organizational Conflict of Interest] Certificate that could be identified as a conflict of interest." The Section has several concerns about this requirement. First, as written it requires that the offeror provide a mitigation plan for a potentially large number of situations, since it is required for "any situations . . . that could be identified as a conflict of interest." This violates FAR 9.504(d) which precludes "burdensome information requirements, and excessive documentation." We recommend that mitigation plans should be required only for "significant" conflicts, consistent with FAR 9.504(a)(2), and that the standard for determining what conflicts are significant should be consistent with the standard currently in FAR 9.501 under the definition of "organizational conflict of interest."

Second, Sections 421.310(a)(1) and (c)(2) of the proposed rule are also overly burdensome in requiring the submission of mitigation plans whenever one of the offeror's or contractor's parent companies, subsidiaries, affiliates, subcontractors, current clients, officers, directors or managers has a financial relationship with the offeror or contractor, no matter how many levels removed from a direct interest. Again, this violates FAR 9.504(d) which precludes "burdensome information requirements, and excessive documentation." Mitigation plans should be required only for significant conflicts, and the standard for determining what conflicts are significant should be consistent with the standard currently in FAR 9.501.

Third, the offeror would be required to prepare the mitigation plans essentially in the dark, without any guidance regarding the types of plans the agency will find acceptable or any assurance that the plans it proposes will be acceptable to the agency. This is also a burdensome requirement in violation of FAR 9.504(d), particularly since the mitigation plans prepared may be wholly rejected by the agency, rendering
Fourth, and perhaps most importantly, the FAR implies that the contracting officer, not the offeror or contractor, is responsible for developing the mitigation plan. FAR 9.504(a)(2) and (c). The reason for this requirement is apparent: the contracting officer has the most familiarity with the contract requirements and can therefore best identify significant potential conflicts and the best ways to mitigate them. Clearly, this is the most efficient way to resolve conflicts. HCFA should follow the FAR's well-reasoned approach instead of attempting to compel offerors and contractors, who have neither the familiarity with the contract work nor the training and experience of the contracting officer, to guess what mitigation plans may be appropriate, effective, and acceptable to the agency.

C. Compliance Program (§ 421.312(a)(3))

Section 421.312(a)(3) of the proposed rule requires the offeror to provide

[a] description of the offeror's or contractor's program to monitor its compliance and the compliance of its proposed and actual subcontractors with the conflict of interest requirements as identified in the relevant solicitation.

The post-award requirement that a contractor must resubmit a description of its compliance program whenever the contracting officer requests a revision in the Certificate, as part of a compliance audit by an independent auditor, and 45 days before any change in the information submitted pursuant to paragraph (a) or (b) of proposed § 421.313, is an ongoing requirement that the Section views as unnecessary and burdensome. Once the compliance program is established, it should be left up to the contractor to monitor and revise its program as necessary. This aspect of the proposed rule again is inconsistent with FAR 9.504(d), which precludes "burdensome information requirements, and excessive documentation."

D. Consideration of Other Federal Contracts and Grants

Under § 421.310(c)(4)(ii) of the proposed rule, HCFA may determine that an offeror or contractor has an organizational conflict of interest, or the potential for a conflict exists, based on "[o]ther contracts and grants with the Federal Government." The proposed rule explains that HCFA believes

it is necessary to consider the offeror's or contractor's other contracts and grants with the Federal Government to determine whether the offeror's or contractor's financial dependence upon the Government could influence the likelihood that it would provide unbiased opinions, conclusions, and work products.


HCFA's consideration of other contracts and grants with the Federal Government raises several concerns. First, there is no precedent in the FAR to consider such a factor. Absent an OCI created by performing other Federal contracts or grants, the number of Federal contracts or grants by itself is unlikely to impair a contractor's unbiased opinions, conclusions, or work product.

Second, the proposed mitigation method -- requiring an offeror or contractor to "negotiat[e] a phasing out of other contracts or grants" will either place an offeror or contractor at a competitive price disadvantage or increase the cost of performing a MIP contract. 63 Fed. Reg. 13597. Performing other Federal contracts and grants can reduce the costs of performing a MIP contract by spreading or allocating certain fixed or general and administrative costs over a greater number of Federal contracts and grants.

Third, although HCFA may determine that an impermissible OCI exists based on an offeror's or contractor's other Federal contracts and grants, it is unclear whether an offeror or contractor must disclose those contracts and grants prior to or after award. The Certificate does not expressly provide for such a disclosure. In any event, to the extent HCFA retains the consideration of other Federal contracts or grants, the most that an offeror or contractor should be required to disclose are Federal contracts or grants the performance of which would create or have the potential to create a significant organizational conflict of
E. Updating the Organizational Conflict of Interest Certificate (§ 421.312(b)(4))

Section 421.312(b)(4) of the proposed rule requires that an offeror or contractor submit a new Organizational Conflicts of Interest Certificate "45 days before any change in the information previously submitted in accordance with paragraph (a) or paragraph (b) of this section. Only changed information must be submitted."

As previously discussed, the information required under paragraphs (a) and (b) is burdensome and overly broad, causing the requirement to update such information to be equally burdensome and unnecessary. This requirement is particularly burdensome because HCFA does not appear to limit changes requiring submission of revised information to those changes that are material.

The proposed regulation's requirement to update previously submitted information "45 days before any change in the [previously submitted] information" also creates concerns. Due to the volume and pace of business transactions, many offerors and contractors may not be able to submit the new information in accordance with this timeframe. For example, the financial interest, percentage of ownership or income generated from or in "any other entity" may change in a matter of days. Such a change prevents a contractor from providing 45 days prior notice to HCFA. The requirement to provide 45 days prior notice of any change to the previously supplied information will inhibit the efficient operation of normal business transactions. At the very least, this aspect of the proposed rule should be revised to require a new submission within 45 days from when a offeror or contractor knows or should have known of a material change to previously supplied information.

F. The Requirement to Contract with an Independent Auditor (§ 421.312(a)(4))

Section 421.312(a)(4) of the proposed rule requires, as part of the OCI Certificate, the following:

A description of the offeror's or contractor's plans to contract with an independent auditor to conduct a compliance audit.

The imposition of a requirement that a bidder must develop plans to contract with an independent auditor to conduct a compliance audit to ensure that the information in the OCI Certificate is kept accurate is in conflict with HIPAA and the regulatory requirements imposed on the award of a MIP contract by HIPAA.

The proposed rule's requirement for disclosure of plans to contract with an independent auditor to conduct a compliance audit, and the imposition of a requirement for a compliance audit to be conducted, are "burdensome information requirements" and "excessive documentation" which are expressly required to be avoided by FAR 9.504(d). The Section recommends that the requirement at § 421.312(a)(4) be eliminated and contractors should be allowed to decide on their own how best to comply with the OCI requirements.

G. The Affirmation Requirement (§ 421.312(a)(5))

Section 421.312(a)(5) of the proposed rule requires, as part of the OCI Certificate, the following:

An affirmation, using language that HCFA may prescribe, signed by an official authorized to bind the contractor, that the offeror or contractor understands that HCFA may consider any deception or omission in the Certificate grounds for nonconsideration for contract award in the procurement process, termination of the contract, or other contract or legal action.

HCFA is proposing that contractors submitting an OCI disclosure statement must, in effect, certify as to the accuracy of the information and the potential consequences of any deception or omission. The imposition of a certification or affirmation requirement on contractors is contrary to the procedures generally applicable to Federal acquisition and procurement. Thus, the proposed rule violates the applicable standards set forth in HIPAA.

According to HIPAA, the Secretary shall enter into contracts following procedures, including those that "are

A provision of law may not be construed as requiring a certification by a contractor or offeror in a procurement made or to be made by the Federal Government unless that provision of law specifically provides that such a certification shall be required.

§ 4301 (emphasis added). There is no provision in HIPAA specifically providing for a certification associated with the OCI disclosure statement. Nor is there a certification requirement for the regulatory implementation of the OCI provisions in the FAR at Subpart 9.5. As proposed, the OCI Certificate's affirmation requirement exceeds what is allowed for by applicable acquisition and procurement law and, thus, is contrary to HIPAA.

The certification also places an unnecessary burden and risk on contractors. Whenever a contractor makes a certification or an affirmation like the one proposed by HCFA, the specter of liability under the False Claims Act ("FCA") exists. For example, in United States ex rel. Pogue v. American Healthcorp, Inc., 914 F. Supp. 1507 (M.D. Tenn. 1996) a relator stated an FCA claim against a health care provider that allegedly submitted requests for reimbursement for treatment in violation of federal anti-kickback and self-referral statutes. The court in Pogue recognized that a recent line of cases has held that the submission of claims to the Government represents an implied certification that the claimant has complied with all applicable statutes, rules, and regulations. Id. at 1509. See also United States ex rel. Fallon v. Accudyne Corp., 921 F. Supp. 611 (W.D. Wis. 1995) (ambiguous certification accompanying payment request might be reasonably construed as a certification of full compliance with applicable environmental statutes such that a violation of such statutes would give rise to an FCA violation).

The best-known such case is Ab-Tech Construction, Inc. v. United States, 31 Fed. Cl. 429 (1994), aff'd without opinion, 57 F.3d 1084 (Fed. Cir. 1995). In Ab-Tech, payment vouchers submitted by a small business under an 8(a) contract "represented an implied certification . . . of its continuing adherence to the requirements for participation in the 8(a) program." Id. at 434. Consequently, the small business not in compliance with those requirements was liable for FCA statutory damages, even though the Government had suffered no actual damages as a result of the implied false certifications.

These cases are illustrative of the potential consequences a MIP contractor may face if the information submitted as part of the OCI disclosure statement is incorrect and the Government can prove that when the contractor submitted a claim for payment, it knew or should have known the earlier OCI certification or representation was wrong. We submit that the imposition of such severe consequences merely to assist the contracting officer with identification of potential OCIs is unreasonable and the benefit derived by HCFA is disproportionately small compared to the potential liability to bidders.

In light of the lack of statutory authority and the specter of an FCA violation, the proposed OCI disclosure certification requirement should be eliminated.

H. Financial Interests (§ 421.312(a)(7))

Section 421.312(a)(7) of the proposed rule requires an offeror to provide substantial information about the offeror's financial interests in "other entities." In the context of the prior paragraphs (a)(1) through (a)(5) (which address relationships deemed to be conflicts of interest), the term "other entities" appears to refer to entities that have no association with the Medicare program.

Subparagraphs (i) and (ii) require an offeror holding equity in another company or receiving income from another company to report that interest. Subparagraphs (iii) and (iv) require a listing of "current or known future contracts or arrangements" with any insurance organization or subcontractor thereof, or with providers of health services for which payment may be made under the Medicare program, including dollar amounts of the contracts, the type of work performed, and the period of performance.

The Section believes that these provisions run afoul of FAR 9.504(d), which advises against requiring
"burdensome information requirements, and excessive documentation" when resolving conflicts. In prior provisions, offerors have already been required to detail all relationships that might be viewed as conflicts of interest. Offerors must certify to the inclusiveness of these disclosures, establish an internal compliance program, and contract with an independent auditor. To require the detailing of financial interests in entities where there is deemed to be no potential for conflict of interest (presumably to check on the inclusiveness of the conflict of interest disclosures), is excessive. For large companies, this requirement may also be burdensome, as these companies may have such financial interests in many entities. Moreover, even assuming that HCFA has reason to obtain this information, a threshold should be established such that only consequential percentages of ownership or amounts of income must be reported.

In addition to these general comments, the Section believes that the language of these provisions creates specific, additional problems:

Paragraph (a)(7), while setting out specifically required information in subparagraphs (i) through (iv), does not literally limit the required information to those specifics. Rather, paragraph (a)(7), by using the language "including the following," literally requires offerors to describe all financial interests of any kind in other entities. This would include any contractual relationship for sale of services, purchase of supplies, lease of office space, etc. The literal language of paragraph (a)(7) is thus much too broad, and the Section recommends that the clause "including the following" be deleted and the clause "as set out below" be substituted.

Subparagraph (a)(7)(ii) refers to "income generated from other sources." It is unclear whether this provision is intended to include income from contracts or is limited to holdings of bonds, notes, etc. If contract income is included, the burden of responding might be prohibitive for a large services company with thousands of contracts. Clarification of this requirement is thus necessary.

Subparagraph (a)(7)(iii)(A) requires disclosure of contractual arrangements with insurance organizations or subcontractors of insurance organizations. It is unclear why non-health care insurance organizations have specific relevance. It is also unclear why a subcontractor of a non-health insurance organization has relevance, nor is it apparent that an offeror would know whether a company has a subcontract relationship with an insurance organization.

Subparagraph (a)(7)(iii)(B) requires disclosure of contractual relationships with providers or suppliers furnishing health services for which payment may be made under the Medicare program. This request would appear to duplicate paragraph (a)(1). It is unclear what additional information is intended to be obtained through (a)(7)(iii)(B).

As a complement to the disclosure requirements of paragraphs (a)(1) through (a)(7), Section 421.312(a)(8) of the proposed rule sets out disclosure requirements for the offeror's officers, directors, and managers "who would be or are involved with the performance of the Medicare Integrity Program contract." Disclosure is required of information specified in (a)(1), (a)(7)(iii), and (a)(7)(iv); if required by the solicitation, disclosure is also required of information specified in subparagraphs (a)(7)(i) and (a)(7)(ii).

The Section does not question the need for disclosure by involved officers, directors, and managers of all business or contractual relationships that might constitute actual or significant potential conflicts of interest. Nevertheless, for essentially the same reasons as stated above, the requirement that these personnel also disclose financial interests which are unrelated to the Medicare program is unnecessary, and hence excessive and potentially burdensome. For example, the offeror's personnel would be required under subparagraph (a)(7)(iii)(A) to disclose their automobile and home insurance policies. If disclosure under subparagraph (a)(7)(i) and (ii) is required, the offeror's personnel would be required to disclose all mutual fund and bond holdings. The Section believes that the disclosure requirements for involved offeror personnel should be limited to matters covered by paragraph (a)(1).

I. Conflict of Interest Resolution (§ 421.314)

Section 421.314 of the proposed rule indicates that HCFA will establish a Conflicts of Interest Review Board to decide whether an OCI has been mitigated, whether or not the OCI prevents a contractor from being
awarded the contract, or whether a contract should be terminated because of the OCI. The Section agrees
with the concept of a Board to address these matters because it promotes consistency in applying the OCI
rules. The Section is concerned, however, that the proposed rule does not comply with the due process
requirement contained in the FAR wherein a contractor is permitted an opportunity to respond to a notice of
the proposed action before a contract may be withheld because of an OCI. FAR 9.504(e). HCFA could easily
rectify this omission by allowing a party the opportunity to appear before the Board, preferably in person
but at least through a written submission, to address the reasons the agency believes that adverse agency
action (such as withholding a contract award, and terminating or not renewing a contract) is required.

J. Preclusion of Judicial Review (§ 421.308)

Section § 421.308 of the proposed rule follows HIPAA and permits HCFA to renew contracts from term to
term without the need for an additional competition. Section 1893(d)(3) of the Social Security Act.
However, the proposed rule then departs from HIPAA when it precludes a MIP contractor from seeking
judicial review of HCFA's decision not to renew the contract. The Section recognizes that in most instances,
a contractor whose contract is not renewed will have a difficult time convincing a court that it has
jurisdiction to entertain a challenge to the nonrenewal decision. Nevertheless, there may be instances
where the circumstances surrounding a nonrenewal are such that a contractor may be able to establish a
right to judicial review of the agency's decision.

The case law is clear that there is a presumption favoring judicial review of administrative action, and this
presumption can only be overcome by express statutory language or compelling legislative history that
Congress intended to deprive a party of its ability to go to court. Bowen v. Michigan Academy of Family
Physicians, 476 U.S. 667 (1986). Because there is no authority in HIPAA for depriving an aggrieved party
of the opportunity to seek judicial relief in the event of a nonrenewal, the Section recommends that
proposed § 421.308 be revised to strike the provision stating that a contractor does not have the right to
judicial review of a nonrenewal decision.

K. Continuation of MIP Activities under Intermediary and Carrier Contracts (§ 421.306)

HIPAA endows HCFA with considerable discretion with regard to the timing of when it will conduct a
competitive acquisition for the various activities that are described in the proposed rule. The statute allows
HCFA to begin using competitive procedures even before publication of a final regulation. Section 1893(d)
of the Social Security Act. On the other hand, HIPAA permits HCFA to allow existing intermediaries and
carriers to continue to perform MIP activities without the need to conduct a competitive acquisition. Section
1893(d)(2) of the Social Security Act.

Although the preamble to the proposed rule reflects HCFA's understanding that it may continue to contract
for MIP activities with existing intermediaries and carriers (63 Fed. Reg. 13593), the text of the proposed
rule does not specifically mention this authority. The Section believes that because HCFA will be
implementing its new authority “incrementally” (63 Fed. Reg. 13592), HCFA should clarify § 421.306 to
affirmatively state that it has the right to continue to contract for MIP activities with the existing
intermediaries and carriers. HCFA should also state whether those MIP activities will continue to be
performed under existing contracts or whether HCFA intends to award new MIP contracts to the
intermediaries and carriers.

The need for clarification in this Section of the proposed rule is also exemplified by a provision in § 421.306
whereby HCFA asserts the authority to award a new MIP contract on a noncompetitive basis to a successor
in interest to an intermediary agreement or carrier contract. HCFA should consider whether it is necessary
or appropriate to enter into a new contract with such a successor in interest. Subpart 42.12 of the FAR
contemplates that when the Government recognizes a successor in interest, that entity assumes the
transferor's existing contractual responsibilities. Moreover, the transferor's guarantee of performance under
the standard FAR novation agreement is limited to the specific contract being novated. Therefore, the
Section believes that it would be in HCFA’s interest to clarify the proposed rule to permit HCFA to novate
existing intermediary and carrier contracts to a successor in interest.

CONCLUSION
The Section appreciates the opportunity to provide these comments and is available to provide additional information or assistance as you may require.

Sincerely,

Marcia G. Madsen
Chair
Section of Public Contract Law

cc: David A. Churchill
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