DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400 and 421

[HCFA–7020–P]

RIN 0938–AI09

Medicare Program; Medicare Integrity Program, Intermediary and Carrier Functions, and Conflict of Interest Requirements

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement section 1893 of the Social Security Act (the Act) by establishing the Medicare integrity program (MIP) to carry out Medicare program integrity activities that are funded from the Medicare Trust Funds. Section 1893 expands our contracting authority to allow us to contract with ''eligible entities'' to perform Medicare program integrity activities. These activities include review of provider and supplier activities, including medical, fraud, and utilization review; cost report audits; Medicare secondary payer determinations; education of providers, suppliers, beneficiaries, and other persons regarding payment integrity and benefit quality assurance issues; and developing and updating a list of durable medical equipment items that are subject to prior authorization. This proposed rule would set forth the definition of eligible entities, services to be procured, competitive requirements based on Federal acquisition regulations and exceptions (guidelines for automatic renewal), procedures for identification, evaluation, and resolution of conflicts of interest, and limitations on contractor liability.

In addition, this proposed rule would bring certain sections of the Medicare regulations concerning fiscal intermediaries and carriers into conformity with the Act. The rule would distinguish between those functions that the statute requires be included in agreements with intermediaries and those that may be included in the agreements. It would also provide that some or all of the listed functions may be included in carrier contracts. Currently all these functions are mandatory for carrier contracts. These changes would give us the flexibility to transfer functions from one intermediary or carrier to another or to otherwise limit the functions an intermediary or carrier performs if we determine that to do so would result in more effective and efficient program administration.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 19, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–7020–P, P.O. Box 26676, Baltimore, MD 21207–0519.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–7020–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Brenda Thew (410) 786–4889.

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Medicare Contracting Environment

The current Medicare contracting authorities have been in place since the inception of the Medicare program in 1965. At that time, the health insurance and medical communities raised concerns that the enactment of Medicare could result in a large Federal presence in the provision of health care. In response, under sections 1816(a) and 1842(a) of the Social Security Act (the Act), Congress provided that public or private entities and agencies may participate in the administration of the Medicare program under agreements or contracts entered into with us.

These Medicare contractors are known as intermediaries (section 1816(a) of the Act) and carriers (section 1842(a) of the Act). With certain exceptions, intermediaries perform bill processing and benefit payment functions for Part A of the program (Hospital Insurance) and carriers perform claims processing and benefit payment functions for Part B of the program (Supplementary Medical Insurance).

(For the following discussion, the terms ''provider'' and ''supplier'' are used as those terms are defined in 42 CFR 400.202. That is, a provider is a hospital, rural care primary hospital, skilled nursing facility, home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement to furnish outpatient physical therapy or speech pathology services. Supplier is defined as a physician or other practitioner or an entity other than a ''provider,'' that furnishes health care services under Medicare.)

Section 1842(a) of the Act authorizes us to contract with private entities (carriers) for the purpose of administering the Medicare Part B program. Medicare carriers determine payment amounts and make payments for services (including items) furnished by physicians and other suppliers such as nonphysician practitioners, laboratories, and durable medical equipment suppliers. In addition, carriers perform other functions required for the efficient and effective administration of the Part B program. Section 1842(f) of the Act provides that a carrier must be a ''voluntary association, corporation, partnership, or other nongovernmental entity which is lawfully engaged in providing, paying for, or reimbursing the cost of, health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier, including a health benefits plan duly sponsored or underwritten by an employee entity.'' No entity may be considered for carrier contracts unless it can demonstrate that it meets this definition of carrier.

Section 1842(b) provides us with the discretion to enter into carrier contracts without regard to any provision of the law requiring competitive bidding. Other provisions of generally applicable Federal contract law and regulations, as well as HHS procurement regulations, remain in effect for carrier contracts.

Section 1816(a) of the Act authorizes us to enter into agreements with private agencies or entities (intermediaries) for the purpose of administering Medicare Part A. These entities are responsible for determining the amount of payment due to providers in consideration of services provided to beneficiaries and for making

these payments. We may enter into an agreement with an entity to serve as an intermediary if the entity has first been ''nominated'' by a group or association of providers to make Medicare payments to it. Other portions of section 1816 of the Act provide further details concerning the ''nomination process'' and assignment and reassignment of providers to intermediaries.

Our regulations at § 421.100 require that the agreement between us and an intermediary specify the functions the intermediary must perform. In addition to requiring any items specified by us in the agreement that are unique to that intermediary, our regulations require that all intermediaries perform activities relating to determining and making payments for covered Medicare services, fiscal management, provider audits, utilization patterns, resolution of cost report disputes, and reconsideration of determinations. Finally, our regulations require that all intermediaries furnish information and reports, perform certain functions with respect to provider-based home health agencies and provider-based hospices, and comply with all applicable laws and regulations and with any other terms and conditions included in their agreements.

Similarly, § 421.200 of our regulations, requires that the contract between us and a Part B carrier specify the functions the carrier must perform. In addition to requiring any items specified by us in the contract that are unique to that carrier, our regulations require that all Part B carriers perform activities relating to determining and making payments (on a cost or charge basis) for covered Medicare services, fiscal management, provider audits, utilization patterns, and Part B beneficiary hearings. In addition, § 421.200 requires that all carriers furnish information and reports, maintain and make available records, and comply with any other terms and conditions included in their contracts.

It is within the above context that Medicare intermediary and carrier contracts are significantly different from standard Federal Government contracts.

Specifically, the Medicare intermediary and carrier contracts are normally renewed automatically from year to year, in contrast to the typical Government contract that is recompeted at the conclusion of the contract term. Congress, in providing for the nomination process under section 1816 of the Act, and authorizing the automatic renewal of the carrier contracts in section 1842(b)(5) of the Act, contemplated a contracting process that would permit us to noncompetitively renew the Medicare contracts from year to year.

For both intermediaries and carriers, § 421.5 states that we have the authority not to renew a Part A agreement or a Part B contract when it expires. Section 421.126 provides for termination of the intermediary agreements in certain circumstances, and, similarly, § 421.205 provides for termination of carrier contracts.

Each year, Congress appropriates funds to support Medicare contractor activities. These funds are distributed to the contractors through an annual Budget Performance Requirements process, which allocates funds by program activity to each of the current 69 Medicare contractors. Historically, approximately one-half of the funds have been for payment for the processing of claims; one-quarter of the funds have been for ''payment safeguard'' activities to fund activities such as conducting medical review of claims to determine whether services are medically necessary and constitute an appropriate level of care, deterring and detecting Medicare fraud, auditing provider cost reports, and ensuring that Medicare acts as a secondary payer when a beneficiary has primary coverage through other insurance. The remainder of the funds have been allocated for beneficiary and provider/supplier services and for various productivity investments.

B. The Medicare Integrity Program

The Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191) was enacted on August 21, 1996. Section 202 of Public Law 104–191 adds a new section 1893 to the Act establishing the Medicare integrity program (MIP). This program is funded from the Medicare Hospital Insurance Trust Fund for activities related to both Part A and Part B of Medicare. Specifically, section 1893 of the Act expands our contracting authority to allow us to contract with eligible entities to perform Medicare program integrity activities performed currently by intermediaries and carriers. These activities include medical, fraud, and utilization review; cost report audits; Medicare secondary payer determinations; overpayment recovery; education of providers, suppliers, beneficiaries, and other persons regarding payment integrity and benefit quality assurance issues; and developing and updating a list of durable medical equipment items that, under section 1834(a)(15) of the Act, are subject to prior authorization.

Section 1893(d) of the Act requires us to set forth, through regulations, procedures for entering into contracts for the performance of specific Medicare program integrity activities. These procedures are to include the following:

(1) A process for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement.

(2) Competitive procedures for entering into new contracts under section 1893 of the Act, a process for entering into contracts that may result in the elimination of responsibilities of an individual intermediary or carrier, and other procedures we deem appropriate.

(3) A process for renewing contracts entered into under section 1893 of the Act.

Section 1893(d) also provides that we may enter into these contracts without publication of final rules.

In addition, section 1893(e) of the Act requires us to set forth, through regulations, the limitation of a contractor's liability for actions taken to carry out a contract.

Congress established section 1893 of the Act to strengthen our ability to deter fraud and abuse in the Medicare program in a number of ways. First, it provides a separate and stable long-term funding mechanism for MIP activities. Historically, Medicare contractor budgets had been subject to wide fluctuations in funding levels from year to year. The variations in funding did not have anything to do with the underlying requirements for program integrity activities. This instability made it difficult for us to invest in innovative strategies to control fraud and abuse. Our contractors also found it difficult to attract, train, and retain qualified professional staff, including auditors and fraud investigators. A dependable funding source allows us the flexibility to invest in innovative strategies to combat fraud and abuse. It will help us shift emphasis from post-payment recoveries on fraudulent claims to prepayment strategies designed to ensure that more claims are paid correctly the first time.

Second, to allow us to more aggressively carry out the MIP functions and to require us to use procedures and technologies that exceed those currently being used, section 1893 greatly expands our contracting authority. Previously, we had a limited pool of entities with whom to contract. This limited our ability to maximize efforts to effectively carry out the MIP functions. Section 1893 now permits us to attract a variety of offerors with potentially new and different skill sets and will allow those offerors to propose

innovative approaches to implement MIP to deter fraud and abuse. By using competitive procedures, as established in the FAR, our ability to manage the MIP activities is greatly enhanced, and the Government can seek to obtain the best value for its contracted services.

Third, section 1893 requires us to address potential conflicts of interest among potential MIP contractors before entering into any contracting arrangements with them. By requiring offerors/contractors to report situations that may constitute conflicts of interest, we can minimize the number of situations where there is either an actual or an apparent conflict of interest. This is a concern particularly when intermediaries and carriers processing Medicare claims are also private health insurance companies.

From the inception of the Medicare program, intermediary and carrier contracts have contained provisions that have precluded contractors from using their Medicare contract to benefit their private lines of business. These conflicts of interest were rarely a problem in the early years of Medicare because these companies did only health insurance business within prescribed market areas. In recent years, however, Medicare intermediaries and carriers, like most health insuring organizations, have expanded their businesses and product lines to become large integrated health care delivery systems. Some organizations have diversified into corporations with many subsidiaries and a variety of arrangements. These range from overlapping ownership of other insurers, third party administrators, providers, and managed care entities to the marketing of management services and software products. This creates a conflict of interest when the contractor reviews claims, identifies Medicare secondary payer instances, and performs other payment safeguard activities for its own providers and suppliers as well as for its provider's and supplier's competitors.

We have been criticized for the lack of effective mechanisms to mitigate these conflicts of interest. Even when we are assured that proper mechanisms are in place, the appearance of a conflict remains in the eyes of competitors. An even more difficult problem arises with respect to program integrity activities. Medicare contractors exercise considerable discretion in their audit functions, the use of prepayment screens, the conduct of fraud investigations, and referrals to law enforcement agencies regarding incidences of fraud and abuse. These activities depend upon the ability of the contractor to conduct independent reviews, negotiate disputes, and to manipulate data with great sophistication to discover situations where providers and suppliers are engaged in fraudulent activity. These activities would be largely ineffective if contractor-owned providers and suppliers benefit from bias or forewarning.

When a Medicare contractor owns a provider or supplier, it necessarily finds itself in a situation in which potential conflicts of interest could arise. On the one hand, it has a fiduciary duty to its stockholders to use its best efforts to capture market share and to maximize profits. On the other hand, it has an obligation to Medicare and to the public not to take advantage of its position as a Medicare contractor. For example, the Medicare contractor—

- Has access to information about beneficiaries, providers, and suppliers that would be enormously useful in marketing and other business decisions, including provider/supplier information that is considered ''proprietary.''
- As the claims administrator for an area, it has extraordinary leverage over providers and suppliers. That leverage could be used, implicitly or explicitly, to persuade providers and suppliers to join a network or to agree to business arrangements that are favorable to the Medicare contractor.
- Has knowledge and experience as a Medicare claims administrator that would give it a competitive advantage in knowing how to submit claims to avoid payment screens and in having other information that is not available to other providers/suppliers that could assist in maximizing payments to its own providers/suppliers.
- May also offer other health insurance coverage that is primary or supplemental to Medicare. In this situation, there is always the temptation to let Medicare pay first, knowing that even if the mistaken Medicare payment is later discovered and reimbursed, the contractor has received a temporary interest free loan from the Government.

The MIP, however, allows us to separate payment safeguard functions from all of the functions now being performed by current intermediaries and carriers. This allows current contractors that are performing important functions such as beneficiary and provider/supplier services well to continue to do so, or possibly to review claims from providers/suppliers with which they have no financial relationship.

Conflict of interest situations can also occur when Medicare contractors own managed care entities, for example health maintenance organizations (HMOs). The mere ownership of an HMO by a Medicare contractor would seem to create no conflict of interest concerns since the HMO would be dealing directly with the Government. However, in the situation in which a physician both works for a contractor-owned HMO and maintains a fee-for-service practice, the contractor could give the physician a ''bonus'' by doing a less thorough review of his or her claims. Additionally, the contractor-owned HMO could use its Medicare beneficiary database to perform health screening of beneficiaries, or its utilization data, marketing information, etc. for its commercial benefit. It could also influence the HMO market by promoting itself as the local intermediary or carrier.

Medicare contractors also provide management services and develop software to facilitate the filing of claims and compliance with Medicare requirements. Since Medicare contractors have an intimate knowledge of Medicare claims systems and administration, they may derive an unfair competitive advantage if they were to sell information that is not generally available to the public. They may also shift development and training costs to Medicare for services they market to the public.

For all these reasons this legislation is providing us an opportunity to increase our ability to protect the Medicare program from instances of fraud and abuse by establishing procedures for identifying, evaluating, and resolving organizational conflicts of interest.

II. Provisions of the Proposed Rule

This regulation is part of our overall contracting strategy, which is designed to build on the strengths of the marketplace. We intend to implement the MIP incrementally in a manner that will provide a way to test alternatives and to transition integrity activities to MIP contractors. We are committed to conducting procurements using full and open competition that will provide opportunities for a wide range of contractors to participate in the program. We will continue to encourage new and innovative approaches in the marketplace to protect the Medicare Trust Funds.

A. The Medicare Integrity Program

1. Basis, Scope, and Applicability

In accordance with section 1893 of the Act, this proposed rule would amend part 421 by adding a new subpart D entitled, ''Medicare Integrity Program Contractors''. This subpart would define the types of entities

eligible to become MIP contractors; identify the program integrity functions a MIP contractor may perform; describe procedures for awarding and renewing contracts; establish procedures for identifying, evaluating, and resolving organizational conflicts of interest; prescribe responsibilities; and set forth limitations on MIP contractor liability. The provisions of this subpart supplement the Federal acquisition regulations set forth at 48 CFR chapter 1 and the Department's acquisition regulations at 48 CFR chapter 3. Subpart D would be applicable to entities that seek to compete for or receive award of a contract under section 1893 of the Act including entities that perform functions under this subpart emanating from the processing of claims for individuals entitled to benefits as qualified railroad retirement beneficiaries. We would set forth the basis, scope, and applicability of subpart D in § 421.300.

2. Definition of Eligible Entities

As discussed earlier, under sections 1816(a) and 1842(a) of the Act, public or private entities and agencies (Medicare intermediaries and carriers) participate in the administration of the Medicare program under agreements or contracts entered into with us (on the Secretary's behalf). Basically, the carrier must be a voluntary association, corporation, partnership, or other nongovernmental entity lawfully engaged in providing or paying for health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements. In general, the intermediary must be an entity that has an agreement with us and has been nominated by a provider to determine and make Medicare Part A payments and to perform other related functions. Current regulations at §§ 421.110 and 421.202 specify the eligibility requirements current Medicare contractors must meet before entering into or renewing an agreement or contract.

In accordance with section 1893(c) of the Act, proposed § 421.302 would provide that an entity is eligible to enter into a MIP contract if, in general, it demonstrates the capability to perform MIP contractor functions; it agrees to cooperate with the Office of Inspector General (OIG), the Attorney General, and other law enforcement agencies in the investigation and deterrence of fraud and abuse of the Medicare program, including making referrals; it complies with the conflict of interest standards in 48 CFR Chapters 1 and 3 and is not excluded under the conflict of interest provisions established by this rule; and it meets other requirements that we may impose. Also, in accordance with the undesignated paragraph following section 1893(c)(4) of the Act, we would specify that Medicare carriers are deemed to be eligible to perform the activity of developing and periodically updating a list of durable medical equipment items that are subject to prior authorization.

Note that, in accordance with section 1893(d) of the Act, we may continue to contract, for the performance of MIP activities, with intermediaries and carriers that had a contract with us on August 21, 1996 (the effective date of enactment of Public Law 104–191). However, in accordance with section 1816(l) or section 1842(c)(6) of the Act (both added by Public Law 104–191), they may not duplicate activities under both an intermediary agreement or carrier contract and a MIP contract, with one excepted activity. The exception permits a carrier to develop and update a list of items of durable medical equipment that are subject to prior authorization both under the MIP contract and its contract under section 1842 of the Act.

3. Definition of MIP Contractor

We propose to define ''Medicare integrity program contractor,'' at § 400.202 (Definitions specific to Medicare), as an entity that has a contract with us under section 1893 of the Act to perform program integrity activities.

4. Services to be Procured

A MIP contractor may perform some or all of the MIP activities performed currently by intermediaries and carriers. Section 421.304 would state that the contract between HCFA and a MIP contractor specifies the functions the contractor performs. In accordance with section 1893(b) of the Act, proposed § 421.304 identifies the following as MIP activities.

a. Medical, utilization, and fraud review. Medical and utilization review includes the processes necessary to ensure both the appropriate utilization of services and that services meet the professionally recognized standards of care. These processes include review of claims, medical records, and medical necessity documentation and analysis of patterns of utilization to identify inappropriate utilization of services. This would include reviewing the activities of providers/suppliers and other individuals and entities (including health maintenance organizations, competitive medical plans, and health care prepayment plans). This function results in the identification of overpayments, prepayment denials, recommendations for changes in national coverage policy, changes in local medical review policies and payment screens, referrals for fraud and abuse, and the identification of the education needs of beneficiaries, providers, and suppliers.

Fraud review includes fraud prevention initiatives, responding to external customer complaints of alleged fraud, the development of strategies to detect potentially fraudulent activities that may result in improper Medicare payment, and the identification and development of fraud cases for referral to law enforcement. Each solicitation will specify when cases should be referred to the OIG. In general, however, identified overpayments exceeding a threshold amount set by the OIG, recurring acts of improper billing, and substantiated allegations of fraudulent activity will be promptly referred to a Regional Office of Investigation.

b. Cost report audits. Providers and managed care plans receiving Medicare payments are subject to audit for all payments applicable to services furnished to beneficiaries. The audit ensures that proper payments are made for covered services, provides verified financial information for making a final determination of allowable costs, identifies potential instances of fraud and abuse, and ensures the completion of special projects.

This functional area includes the receipt, processing, and settlement of cost reports based on reasonable costs, prospective payment, or any other basis, and the establishment or adjustment of the interim payment rate using cost report or other information.

c. Medicare secondary payer activities. The Medicare secondary payer function is a process developed as a payment safeguard to protect the Medicare program against mistaken primary payments. The focus of this process is to ensure that the Medicare program pays only to the extent required by statute. Entities under a MIP contract that includes Medicare secondary payer functions would be responsible for identifying Medicare secondary payer situations and/or pursuing recovery of mistaken payments from the appropriate entity or individual, depending on the specifics of the contract.

This functional area includes the processes performed to identify beneficiaries for whom there is coverage which is primary to Medicare. Through these processes, information may be acquired for subsequent use in

beneficiary claims adjudication, recovery, and litigation.

d. Education. This functional area includes educating beneficiaries, providers, suppliers, and other individuals regarding payment integrity and benefit quality assurance issues.

e. Developing prior authorization lists. This functional area includes developing and periodically updating a list of durable medical equipment items that, in accordance with section 1834(a)(15) of the Act, are subject to prior authorization. Section 1834(a)(15) requires prior authorization to be performed on the following items of durable medical equipment: Items identified as subject to unnecessary utilization; items supplied by suppliers that have had a substantial number of claims denied under section 1862(a)(1) of the Act as not reasonable or necessary or for whom a pattern of overutilization has been identified; or a customized item if the beneficiary or supplier has requested an advance determination. Prior authorization is a determination that an item of durable medical equipment is covered prior to when the equipment is delivered to the Medicare beneficiary.

Application of MIP—It should be noted that the MIP functions are not limited to services furnished under fee-for-service payment methodologies. MIP functions are applicable to all types of claims. They are also applicable to all types of payment systems including, but not limited to, managed care and demonstration projects.

5. Competitive Requirements

We would specify, in § 421.306(a), that MIP contracts will be awarded in accordance with 48 CFR chapters 1 and 3, 42 CFR part 421 subpart D, and all other applicable laws and regulations. Further, in accordance with section 1893(d)(2) of the Act, we would specify that the procedures set forth in these authorities will be used: (1) When entering into new contracts; (2) when entering into contracts that may result in the elimination of responsibilities of an individual intermediary or carrier; and (3) at any other time we consider appropriate.

In proposed section 421.306(b), we would establish an exception to competition which allows a successor in interest to an intermediary agreement or carrier contract to be awarded a contract for MIP functions without competition, if its predecessor performed program integrity functions under the transferred agreement or contract and the resources, including personnel, which were involved in performing those functions, were transferred to the successor.

This proposal is made in anticipation that some intermediaries and carriers may engage in transactions under which the recognition of a successor in interest by means of a novation agreement may be appropriate, and the resources involved in the intermediary's or carrier's MIP activities are transferred along with its other Medicare-related resources to the successor in interest. For example, the intermediary or carrier may undergo a corporate reorganization under which the corporation's Medicare business is transferred entirely to a new subsidiary corporation. When all of a contractor's resources or the entire portion of the resources involved in performing a contract are transferred to a third party, HCFA may recognize the third party as the successor in interest to the contract through approval of a novation agreement. See 48 CFR 42.12.

If the intermediary or carrier were performing MIP activities under its contract on August 21, 1996, the date of the enactment of the MIP legislation, the statute permits HCFA to continue to contract with the intermediary or carrier for the performance of those activities without using competitive procedures. In the context of a corporate reorganization, under which all of the resources involved in performing the contract, including those involved in performing MIP activities, are transferred to a successor in interest, HCFA may determine that breaking out the MIP activities and competing them separately would not be in the best interest of the government.

Inherent in the requirement of section 1893(d) of the Act that the Secretary establish competitive procedures to be used when entering into contracts for MIP functions is the authority to establish exceptions to those procedures. See 48 CFR 6.3. Moreover, intermediary agreements and carrier contracts have, by statute, been noncompetitively awarded under sections 1816(a) and 1842(b)(1) of the Act. Furthermore, those agreements and contracts have in recent years prior to the enactment of the MIP legislation included program integrity activities, a fact that the Congress acknowledged in section 1893(d)(2) of the Act. We believe that creating an exception to the use of competition for cases in which the same resources, including the same personnel, continue to be used by a third party as successor in interest to an intermediary agreement or carrier contract is consistent with Congress' authorization to forgo competition when the contracting entity was carrying out the MIP functions on the date of enactment of the MIP legislation. Section 421.306(b) would provide an interim solution to permit continuity in the performance of the MIP functions until such time as we are prepared to procure MIP functions on the basis of full and open competition.

We would further specify, in § 421.306(c), that an entity must meet the eligibility requirements established in proposed § 421.302 to be eligible to be awarded a MIP contract.

We would state, in § 421.308(a), that we specify an initial contract term in the MIP contract and that contracts may contain renewal clauses. Contract renewal provides a mutual benefit to both parties. Renewing a contract, when appropriate, results in continuity both for us and the contractor and is in the best interest of the Medicare program. The benefits are realized through early communication of our intention whether to renew a contract, which permits both parties to plan for any necessary changes in the event of nonrenewal. Furthermore, as a prudent administrator of the Medicare program, we must ensure that we have sufficient time to transfer the MIP functions should a reassignment of the functions be necessary (either because the contractor has given notice of its intent to nonrenew or because we have determined that reassignment is in the best interest of the Medicare program). Therefore, in § 421.308(a), we would specify that we may renew a MIP contract, as we determine appropriate, by giving the contractor notice, within timeframes specified in the contract, of our intention to do so. (The solicitation document that resulted in the contract will contain further details regarding this provision.)

Based on section 1893(d)(3) of the Act, we would specify, in paragraph (b) of § 421.308, that we may renew a MIP contract without competition if the contractor continues to meet all the requirements of proposed subpart D of part 421, the contractor meets or exceeds all performance standards and requirements in the contract, and it is in the best interest of the Government.

We would provide, at § 421.308(c), that, if we do not renew the contract, the contract will end in accordance with its terms, and the contractor does not have a right to a hearing or judicial review regarding the nonrenewal. This is consistent with our longstanding policy with regard to intermediary and carrier contracts.

6. Conflict of Interest Rules

This proposed rule would establish the process for identifying, evaluating, and resolving conflicts of interest as required by section 1893(d)(1) of the Act. The process has been designed to

ensure that the more diversified business arrangements of potential contractors do not inhibit competition between providers/suppliers or in other types of businesses related to the insurance industry or have the potential for harming Government interests.

On December 6, 1996, we held an open forum discussion with certain organizations and groups that may, or whose members may, be directly affected by contracts awarded to perform functions under the MIP. During the forum, participants discussed whether certain examples were conflicts of interest and how the conflicts, when present, could be mitigated. In addition, the conflict of interest situations were made available for public review on our Internet home page.

In general, some of the participants had concerns that a MIP contractor could not perform audit or review functions on itself, its subsidiaries, its direct competitors, or its private sector clients without the presence of a potential conflict of interest. The conflicts of interest described could make it impossible for contractor personnel to be objective in performing contract work or to provide impartial assistance or advice to the Government or could give the contractor an unfair competitive advantage.

Some of the participants recommended that the conflict of interest standards we establish restrict a MIP contractor from having an ownership interest or contractual relationship with any provider it will be auditing or reviewing. Also, the participants generally agreed that requirements dictating disclosure of a contractor's financial interests would help mitigate conflicts of interest and that each contractor's situation should be considered on a case-by-case basis.

In developing the conflict of interest requirements, we had several options. We could refuse to contract with any entity if a conflict of interest situation either exists or is perceived to exist, or we could choose not to contract with any health-care related entities. We could try to develop a list of all potential situations where a conflict of interest could possibly arise.

We rejected all of these options and adopted a ''process approach.'' While the process described below employs a greater test than generally prescribed in the Federal acquisition regulations for conflict of interest situations, we believe that the sensitive nature of the work to be performed under the contract, the need to preserve the public trust, and the history of fraud and abuse in the Medicare program merits these further requirements. The emphasis on process requires—

- Disclosure by the offeror or contractor via an Organizational Conflicts of Interest Certificate;
- The offeror or contractor to submit a plan to mitigate situations that could be considered potential conflicts of interest;
- The offeror to describe a program that it will establish, if awarded the contract, to monitor its compliance with any plans approved by us to resolve conflicts of interest; and
- The offeror to describe plans to have a compliance audit completed by an independent auditor.

Specifically, in § 421.310(b), we would state the general rule that, except as provided in § 421.310(d), we do not enter into a MIP contract with an offeror or contractor that we have determined has, or has the potential for, an unresolved organizational conflict of interest. Paragraph (d) of § 421.310 would provide that we may contract with an offeror or contractor that has an unresolved conflict if we determine that it is in the best interest of the Government to do so. We would define ''organizational conflict of interest,'' at § 421.310(a), basing our definition on the definition of that term contained in the FAR at 48 CFR 9.501(d). That definition states that 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, or a person has an unfair competitive advantage.'' To clarify how this definition would apply to the MIP contract, we would add that, for purposes of the MIP contract, the activities and relationships described include those of the offeror or contractor itself and other business related to it and those of its officers, directors (including medical directors), managers, and subcontractors.

In paragraph (c) of § 421.310, we would state that we determine that an offeror or contractor has an organizational conflict of interest, or a potential for the conflict exists, if the offeror or contractor either is, or has a present, or known future, direct or indirect financial relationship with, an entity we describe in § 421.310(c)(3), which is discussed later in this preamble. In paragraph (a) of § 421.310, we would define ''financial relationship'' as (1) a direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity that exists through equity, debt, or other means and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest, or (2) a compensation arrangement with an entity. This definition is similar to the definition at § 411.351, which is used for purposes of the provision which generally prohibits physicians from making referrals for Medicare services to entities with which the physician or a member of the physician's immediate family has a financial relationship. The definition at § 411.351 was based on section 1877(a)(2) of the Act as it read before January 1, 1995. To reflect the current reading of section 1877(a)(2), we have added, in our proposed definition, that an indirect interest can exist through multiple levels.

In paragraph (c)(2) of § 421.310, we would specify that a financial relationship may exist either through an offeror's or contractor's parent companies, subsidiaries, affiliates, subcontractors, or current clients. We would also specify that a financial relationship may exist from the activities and relationships of the officers, directors (including medical directors), or managers of the offeror or contractor and may be either direct or indirect. We would define an indirect financial relationship as an ownership or investment interest that is held in the name of another but provides benefits to the officer, director, or manager.

In § 421.310(c)(3), we would provide that an offeror or contractor has a conflict of interest, or a potential conflict of interest, if it is, or has a present or known future financial relationship with, an entity that—

- Provides, insures, or pays for health benefits, with the exception of health plans provided as the entity's employee fringe benefit;
- Conducts audits of health benefit payments or cost reports;
- Conducts statistical analysis of health benefit utilization;
- Would review or does review, under the contract, Medicare services furnished by a provider or supplier that is a direct competitor of the offeror or contractor;
- Prepared work or is under contract to prepare work that would be reviewed under the MIP contract; or
- Is affiliated, as that term is explained in 48 CFR 19.101, with a provider or supplier to be reviewed under the MIP contract. (Section 19.101 of 48 CFR states that—

* * * business concerns are affiliates of each other if, directly or indirectly, either one controls or has the power to control the other, or another concern controls or has the power to control

both. In determining whether affiliation exists, consideration is given to all appropriate factors including common ownership, common management, and contractual relationships; provided, that restraints imposed by a franchise agreement are not considered in determining whether the franchisor controls or has the power to control the franchisee, if the franchisee has the right to profit from its effort, commensurate with ownership, and bears the risk of loss of failure. Any business entity may be found to be an affiliate, whether or not it is organized for profit or located inside the United States.

Section 19.101 explains that control may exist through stock ownership, stock options, convertible debentures, voting trusts, common management, and contractual relationships.)

We would be interested in receiving comments as to how we might better identify those situations that create a conflict of interest. For example, we had originally considered including all entities that provide, insure, or pay for health benefits. We have, however, identified the situation in which an offeror or contractor provides health benefits as an employee fringe benefit as being one where the likelihood of a conflict would not exist. We would be interested in receiving comments as to whether it would be appropriate to create other exceptions.

In § 421.310(c)(4), we would specify that we may determine that an offeror or contractor has an organizational conflict of interest, or the potential for one exists, based on apparent organizational conflicts of interest or on other contracts and grants with the Federal Government. We would provide that an apparent conflict of interest exists if a prudent business person has cause to believe that the offeror or contractor would have a conflict of interest in performing the requirements of the MIP contract. We would further provide that no inappropriate action by the offeror or contractor is necessary for an apparent conflict to exist. We believe 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.

In paragraph (e) of § 421.310, we would specify that an offeror or contractor is responsible for determining whether an organizational conflict of interest exists in any of its proposed or actual subcontractors and consultants at any tier. We also would specify that the offeror or contractor is responsible for ensuring that its subcontractors and consultants have mitigated any conflicts or potential conflicts.

In paragraph (f) of § 421.310, we would state that we consider that a conflict of interest has occurred if, during the term of the contract, the contractor received any fee, compensation, gift, payment of expenses, or any other thing of value from an entity that is reviewed, audited, investigated, or contacted during the normal course of performing activities under the MIP contract. We have considered creating an exception for those compensations, fees, gifts, and other things of value that are in an amount that would not affect a contractor's impartiality or objectivity in carrying out its responsibilities under the MIP contract. We would be interested in receiving comments suggesting how we might determine an appropriate dollar amount for such an exception.

We would also specify in paragraph (f) of § 421.310 that a conflict of interest has occurred during the term of the contract if we determine that the contractor's activities are creating a conflict. In addition, we would specify that, if we determine that a conflict of interest exists, among other actions, we may, as we deem appropriate—

- Not renew the contract for an additional term;
- Modify the contract; or
- Terminate the contract.

In § 421.312(a), we would specify that offerors and MIP contractors must submit an Organizational Conflicts of Interest Certificate that contains the following information unless it has otherwise been provided in the proposal, in which case it must be referenced:

- A description of all business or contractual relationships or activities that may be viewed by a prudent business person as a conflict of interest.
- A description of the methods the offeror or contractor will apply to mitigate any situation listed in the Certificate that could be identified as a conflict of interest.
- A description of the offeror's or contractor's program to monitor its compliance and the compliance of its proposed and actual subcontractors and consultants with the conflict of interest requirements as identified in the relevant solicitation.
- A description of the offeror's or contractor's plans to contract for a compliance audit to be conducted by an independent auditor would be required for all MIP contractor procurements.
- An affirmation, using language that we may prescribe, signed by an official authorized to bind the offeror or contractor, that the offeror or contractor understands that we 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 action.
- Corporate and organizational structure.
- Financial interests in other entities, including the following:

  + Percentage of ownership in any other entity.

  + Income generated from other sources.

  + A list of current or known future contracts or arrangements, regardless of size, with any insurance organization; subcontractor of an insurance organization; or providers or suppliers furnishing services for which payment may be made under the Medicare program. This information is to include the dollar amount of the contracts or arrangements, the type of work performed, and the period of performance.
- Information regarding potential conflicts of interest and financial information regarding certain contracts for all of the offeror's or contractor's officers, directors (including medical directors), and managers who would be or are involved in the performance of the MIP contract. We may also require officers, directors (including medical directors) and managers to provide financial information regarding their ownership in other entities and their income from other sources.

We would also specify that the solicitation may require more detailed information than identified above. Our proposed provisions do not describe all of the information that may be required, or the level of detail that would be required, because we wish to have the flexibility to tailor the disclosure requirements to each specific procurement.

With regard to ownership, we invite public comments to establish the level of financial interest that could be considered a material interest in different situations. While we would not establish this level in the final rule, it may be included in solicitations for specific contract situations.

We intend to reduce the reporting and recordkeeping requirements as much as is feasible, while taking into consideration our need to have assurance that a conflict of interest does not exist in the MIP contractors.

By providing documentation of potential conflicts of interest and how the offeror plans to mitigate those conflicts in the Certificate, the offeror gives us enough information to determine on a case-by-case basis if conflicts of interest have been adequately mitigated or should preclude award of MIP contracts. The burden associated with providing the requested information is justified by the large expansion of competition the process allows.

We propose, in § 421.312(b) that the Organizational Conflicts of Interest Certificate be disclosed—

- With the offeror's proposal;
- When the HCFA Contracting Officer requests a revision in the Certificate;
- As part of a compliance audit by the independent auditor;
- Forty-five days before any change in the information submitted on the Certificate. In this case, only changed information must be submitted.

We would state, in § 421.312(c), that we evaluate organizational conflicts of interest and potential conflicts using the information provided in the Certificate.

Because potential offerors may have questions about whether information submitted in response to a solicitation, including the Organizational Conflicts of Interest Certificate, may be redisclosed under the Freedom of Information Act, we provide the following information.

To the extent that a proposal containing the Organizational Conflicts of Interest Certificate is submitted to us as a requirement of a competitive solicitation under 41 U.S.C. Chapter 4, Subchapter IV, we will withhold the proposal when requested under the Freedom of Information Act. This withholding is based upon 41 U.S.C. § 253b(m). However, there is one exception to this policy. It involves any proposal that is set forth or incorporated by reference in the contract awarded to the proposing bidder. Such a proposal may not receive categorical protection. Rather, we will withhold, under 5 U.S.C. 552(b)(4), information within the proposal (and Certificate) that is required to be submitted that constitutes trade secrets or commercial or financial information that is privileged or confidential provided the criteria established by *National Parks & Conservation Association* v. *Morton*, 498 F.2d 765 (D.C. Cir 1974), as applicable, are met. For any such proposal, we will follow pre-disclosure notification procedures set forth at 45 CFR 5.65(d). In addition, we will protect under 5 U.S.C. 552(b)(6) any information within the Certificate that is of a highly sensitive personal nature.

Any proposal containing the Organizational Conflicts of Interest Certificate submitted to us under an authority other than 41 U.S.C. Chapter 4, Subchapter IV, and any Certificate or information submitted independent of a proposal will be evaluated solely on the criteria established by *National Parks & Conservation Association* v. *Morton* and other appropriate authorities to determine if the proposal or Certificate in whole or in part contains trade secrets or commercial or financial information that is privileged or confidential and protected from disclosure under 5 U.S.C. 552(b)(4). Again, for any such proposal or Certificate, we will follow pre-disclosure notification procedures set forth at 45 CFR 5.65(d) and will also invoke 5 U.S.C. 552(b)(6) to protect information that is of a highly sensitive personal nature.

We already protect information we receive in the contracting process. However, to allay any fears potential offerors might have about disclosure, we propose to provide, at § 421.312(d), that we protect disclosed proprietary information as allowed under the Freedom of Information Act and that we require signed statements from our personnel with access to proprietary information that prohibit personal use during the procurement process and term of the contract.

In proposed § 421.314, we describe how conflicts of interest are resolved. We specify that we establish a Conflicts of Interest Review Board to resolve conflicts of interest and that we determine when the Board is convened. We would define resolution of an organizational conflict of interest as a determination that——

- The conflict has been mitigated;
- The conflict precludes award of a contract to the offeror;
- The conflict requires that we modify an existing contract;
- The conflict requires that we terminate an existing contract; or
- It is in the best interest of the Government to contract with the offeror or contractor even though the conflict exists.

Examples of methods an offeror or contractor may use to mitigate organizational conflicts of interest, including those created as a result of the financial relationships of individuals within the organization are shown below. These examples are not intended to be an exhaustive list of all the possible methods to mitigate conflicts of interest nor are we obligated to approve a mitigation method that uses one or more of these examples. An offeror's or contractor's method of mitigating conflicts of interest would be evaluated on a case-by-case basis.

- Divestiture of or reduction in the amount of the financial relationship the organization has in another organization to a level acceptable to us and appropriate for the situation.
- If shared responsibilities create the conflict, a plan, included in the Organizational Conflicts of Interest Certificate and approved by us, to separate lines of business and management or critical staff from work on the MIP contract.
- If the conflict exists because of the amount of financial dependence upon the Federal Government, negotiating a phasing out of other contracts or grants that continue in effect at the start of the MIP contract.
- If the conflict exists because of the financial relationships of individuals within the organization, divestiture of the relationships by the individual involved.
- If the conflict exists because of an individual's indirect interest, divestiture of the interest to levels acceptable to us or removal of the individual from the work under the MIP contract.

In the procurement process, we determine which proposals are in a ''competitive range.'' The competitive range is based on cost or price and other factors that are stated in the solicitation and includes all proposals that have a reasonable chance for contract award. Using the process proposed in this regulation, offerors will not be excluded from the competitive range based solely on conflicts of interest. If we determine that an offeror in the competitive range has a conflict of interest that is not adequately mitigated, we would inform the offeror of the deficiency and give it an opportunity to submit a revised Certificate. At any time during the procurement process, we may convene the Conflict of Interest Review Board to evaluate and resolve conflicts of interest.

By providing a better process for the identification, evaluation, and resolution of conflicts of interest, we not only protect Government interests but help ensure that contractors will not restrict competition in their service areas by using their position as a MIP contractor.

7. Limitation on MIP Contractor Liability and Payment of Legal Expenses

As discussed earlier, contractors who perform activities under the MIP contract will be reviewing activities of providers and suppliers that provide services to Medicare beneficiaries. Their contracts will authorize them to evaluate the performance of providers,

suppliers, individuals, and other entities that may subsequently challenge their decisions. To reduce or eliminate a MIP contractor's exposure to possible legal action from those it reviews, section 1893(e) of the Act requires that we, by regulation, limit a MIP contractor's liability for actions taken in carrying out its contract. We must establish, to the extent we find appropriate, standards and other substantive and procedural provisions that are the same as, or comparable to, those contained in section 1157 of the Act.

Section 1157 of the Act limits liability and provides for the payment of legal expenses of an Utilization and Quality Control Peer Review Organization (PRO) that contracts to carry out functions under section 1154(e) of the Act. Specifically, section 1157 provides that PROs, their employees, fiduciaries, and anyone who furnishes professional services to a PRO are protected from civil and criminal liability in performing their duties under the Act or their contract, provided these duties are performed with due care. Following the mandate of section 1893(e), this proposed rule, at § 421.316(a), would protect MIP contractors from liability in the performance of their contracts provided they carry out their contractual duties with care.

In accordance with section 1893(e), we propose to employ the same standards for the payment of legal expenses as are contained in section 1157(d) of the Act. Therefore, § 421.316(b) will provide that we will make payment to MIP contractors, their members, employees, and anyone who provides them legal counsel or services for expenses incurred in the defense of any legal action related to the performance of a MIP contract. We propose that the payment be limited to the reasonable amount of expenses incurred, as determined by us, provided funds are available and that the payment is otherwise allowable under the terms of the contract.

In drafting § 421.316(2), we considered employing a standard for the limitation of liability other than the due care standard. For example, we considered whether it would be appropriate to provide that a contractor would not be criminally or civilly liable by reason of the performance of any duty, function, or activity under its contract provided the contractor was not grossly negligent in that performance. However, section 1893(e) requires that we employ the same or comparable standards and provisions as are contained in section 1157 of the Act. We do not believe that it would be appropriate to expand the scope of immunity to a standard of gross negligence, as it would not be a comparable standard to that set forth in section 1157(b) of the Act.

We also considered indemnifying MIP contractors employing provisions similar to those contained in the current Medicare intermediary agreements and carrier contracts. Generally, intermediaries and carriers are indemnified for any liability arising from the performance of contract functions provided the intermediary's or carrier's conduct was not grossly negligent, fraudulent, or criminal. However, we may indemnify a MIP contractor only to the extent we have specific statutory authority to do so. Section 1893(e) does not provide that authority. In addition, § 421.316(a) provides for immunity from liability in connection with the performance of a MIP contract provided the contractor exercised due care. Indemnification is not necessary since the MIP contractors will have immunity from liability under § 421.316(a).

B. Intermediary and Carrier Functions

Section 1816(a) of the Act, which provides that providers may nominate an intermediary, requires only that nominated intermediaries perform the functions of determining payment amounts and making payment, and section 1842(a) of the Act requires only that carriers perform ''some or all'' of the functions cited in that section. Our requirements at §§ 421.100 and 421.200 concerning functions to be included in intermediary agreements and carrier contracts far exceed those of the statute. Therefore, on February 22, 1994, we published a proposed rule (59 FR 8446) that would distinguish between those functions that the statute requires be included in agreements with intermediaries and those functions, which although not required to be performed by intermediaries, may be included in intermediary agreements at our discretion. We also proposed that any functions included in carrier contracts would be included at our discretion. In addition, we proposed to add payment on a fee schedule basis as a new function that may be performed by carriers.

In light of the expansion of our contracting authority by section 1893 of the Act to allow us to contract with eligible entities to perform Medicare program integrity activities performed currently by intermediaries and carriers, we have decided not to finalize the February 1994 proposed rule. Instead, in this proposed rule we are setting forth a new proposal to bring those sections of the regulations that concern the functions Medicare intermediaries and carriers perform into conformity with the provisions of sections 1816(a), 1842(a), and 1893(b) of the Act.

As noted in section I.A. of this preamble, our regulations at § 421.100 specify a list of functions that must, at a minimum, be included in all intermediary agreements. Similarly, § 421.200 specifies a list of functions that must, at a minimum, be included in all carrier contracts. These requirements far exceed those of the statute.

Section 1816(a) of the Act requires only that an intermediary agreement provide for determination of the amount of payments to be made to providers and for the making of the payments. Section 1816(a) permits, but does not require, an intermediary agreement to include provisions for the intermediary to provide consultative services to providers to enable them to establish and maintain fiscal records or to otherwise qualify as providers. It also provides that, for those providers to which the intermediary makes payments, the intermediary may serve as a channel of communications between us and the providers, may make audits of the records of the providers, and may perform other functions as are necessary.

We believe that section 1816(a) mandates only that an intermediary make payment determinations and make payments and that, because of the nomination provision of section 1816(a), these functions must remain with intermediaries. We believe that section 1816(a) does not require that the other functions set forth at § 421.100 (c) through (i) be included in all intermediary agreements. Further, section 1893 of the Act permits the performance of functions related to Medicare program integrity by other entities. Thus, § 421.100 needs to be revised to be consistent with section 1893 and the implementing regulation. We also believe that mandatory inclusion of all functions in all agreements limits our ability to efficiently and effectively administer the Medicare program. For example, if an otherwise competent intermediary performs a single function poorly, it would be efficient and effective to have that function transferred to another contractor that could carry it out in a satisfactory manner. The alternative is to not renew or to terminate the agreement of that intermediary and to transfer all functions to a new contractor that may not have had an ongoing relationship with the local provider community.

Therefore, we would revise § 421.100 to specify that an agreement between us and an intermediary specifies the functions to be performed by the intermediary and that these must include determining the amount of payments to be made to providers for covered services furnished to Medicare beneficiaries and making the payments and may include any or all of the following functions:

- Any or all of the MIP functions identified in proposed § 421.304, provided that they are continuing to be performed under an agreement entered into under section 1816 of the Act that was in effect on August 21, 1996, and they do not duplicate work being performed under a MIP contract.
- Undertaking to adjust overpayments and underpayments and to recover overpayments when it has been determined that an overpayment has been made.
- Furnishing to us timely information and reports that we request in order to carry out our responsibilities in the administration of the Medicare program.
- Establishing and maintaining procedures that we approve for the review and reconsideration of payment determinations.
- Maintaining records and making available to us the records necessary for verification of payments and for other related purposes.
- Upon inquiry, assisting individuals with respect to matters pertaining to an intermediary contract.
- Serving as a channel of communication to and from us of information, instructions, and other material as necessary for the effective and efficient performance of an intermediary contract.
- Undertaking other functions as mutually agreed to by us and the intermediary.

In § 421.100(c), we would specify that, with respect to the responsibility for services to a provider-based HHA or a provider-based hospice, when different intermediaries serve the HHA or hospice and its parent provider under § 421.117, the designated regional intermediary determines the amount of payment and makes payments to the HHA or hospice. The intermediary and/or MIP contractor serving the parent provider performs fiscal functions, including audits and settlement of the Medicare cost reports and the HHA and hospice supplement worksheets.

Section 1842(a), which pertains to carrier contracts, requires that the contract provide for some or all of the functions listed in that paragraph, but does not specify any functions that must be included in a carrier contract. As in the case of intermediary agreements, our experience has been that mandatory inclusion of a long list of functions in all contracts restricts our ability to administer the carrier contracts with optimum efficiency and effectiveness. We believe that the requirements of the regulations for both intermediaries and carriers should be brought into conformity with the statutory requirements. Therefore, we would revise existing § 421.200, ''Carrier functions,'' to make it consistent with section 1893 of the Act and the implementing regulations. We would provide that a contract between HCFA and a carrier specifies the functions to be performed by the carrier, which may include the following:

- Any or all of the MIP functions described in § 421.304 if the following conditions are met: (1) The carrier is continuing those functions under a contract entered into under section 1842 of the Act that was in effect on August 21, 1996; and (2) they do not duplicate work being performed under a MIP contract, except that the function related to developing and maintaining a list of durable medical equipment may be performed under both a carrier contract and a MIP contract.
- Receiving, disbursing, and accounting for funds in making payments for services furnished to eligible individuals within the jurisdiction of the carrier.
- Determining the amount of payment for services furnished to an eligible individual.
- Undertaking to adjust incorrect payments and recover overpayments when it has been determined that an overpayment has been made.
- Furnishing to us timely information and reports that we request in order to carry out our responsibilities in the administration of the Medicare program.
- Maintaining records and making available to us the records necessary for verification of payments and for other related purposes.
- Establishing and maintaining procedures under which an individual enrolled under Part B will be granted an opportunity for a fair hearing.
- Upon inquiry, assisting individuals with matters pertaining to a carrier contract.
- Serving as a channel of communication to and from us of information, instructions, and other material as necessary for the effective and efficient performance of a carrier contract.
- Undertaking other functions as mutually agreed to by us and the carrier.

C. Technical and Editorial Changes

Because we propose to add a new subpart D to part 421 that would apply to MIP contractors, we propose to change the title of part 421 from ''Intermediaries and Carriers'' to ''Medicare Contracting''. We also propose to revise § 421.1, which sets forth the basis, scope, and applicability of part 421. We would revise this section to add section 1893 of the Act to the list of provisions upon which the part is based. We would also make editorial and other changes (such as reorganizing the contents of the section and providing headings) that improve the readability of the section without affecting its substance.

In addition, numerous sections of our regulations specifically refer to an action being taken by an intermediary or a carrier. If the action being described may now be performed by a MIP contractor that is not an intermediary or a carrier, we would revise those sections to indicate that this is the case. As an example, § 424.11, which sets forth the responsibilities of a provider, specifies, in paragraph (a)(2), that the provider must keep certification and recertification statements on file for verification by the intermediary. A MIP contractor now may also perform the verification. Therefore, we would revise § 424.11(a)(2) to specify that the provider must keep certification and recertification statements on file for verification by the intermediary or MIP contractor. Because our regulations are continuously being revised and sections redesignated, we have not identified all such sections that will have technical changes in this rule, but we will do so in the final rule. If we determine that substantive changes to our regulations are necessary, we will make those changes through separate rulemaking.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a

collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the issues for sections §§ 421.310 and 421.312 of this document, which contain information collection requirements.

Section 421.310 Conflict of Interest Identification

Section 421.310(e) requires offerors to determine if an organizational conflict of interest exists in any of its proposed or actual subcontractors at any tier and to ensure that the subcontractors have mitigated any conflict of interest or potential conflict of interest. As discussed below, the information collection requirements for § 421.312 also require an offeror to list in an Organizational Conflicts of Interest Certificate situations that could be identified as conflicts of interest and to describe methods it would apply to mitigate those situations. Based on our best estimate, we believe that the requirement will impose a burden of 80 hours on each offeror with respect to information it provides for its own organization. It is assumed that offerors will impose the same or similar disclosure requirements on their proposed or actual subcontractors as imposed by us on offerors, with the understanding that we would not expect them to require that independent auditors perform compliance audits on subcontractors. Based on this assumption, an offeror's burden with respect to its subcontractors is estimated to be one-half the burden imposed on an offeror with respect to its own organization.

We expect 15 offerors for each type of MIP contract. We estimate that the requirement of this provision will impose a burden of 40 hours per subcontractor on each offeror to identify and mitigate any organizational conflicts of interest for its subcontractors at any tier. We believe that, on average, each offeror will need to evaluate three subcontractors. The total burden referenced in § 421.310(e) with respect to an offeror's subcontractors is 1,800 burden hours.

Section 421.312 Conflict of Interest Evaluation

Section 421.312 requires offerors that wish to be eligible for the award of a contract under this subpart and MIP contractors to submit an Organizational Conflicts of Interest Certificate for pre- and post-award purposes.

Based on comments provided by the public on possible methods we could use to identify, evaluate, and resolve potential conflicts of interest, we found that only by imposing the information collection requirements referenced in this section could competition remain open to all interested parties regardless of their current lines of business and, at the same time provide us with enough information to determine on a case-by-case basis if conflicts of interest have been properly identified and adequately mitigated. Only by imposing these information collection requirements can we determine whether an offeror should be awarded a MIP contract.

Below is a summary of the proposed Organizational Conflict of Interest Certificate disclosure requirements and related burden required with the offeror's proposal. The items of information described below will be required for all MIP contractor procurements, unless the information is otherwise provided in the proposal, in which case it must be referenced. The last item identifies some information that officers, directors, and managers will be required to provide in all MIP procurements and some information that they may be required to provide in a MIP procurement.

- *A description of all business or contractual relationships or activities that a prudent business person may view as a conflict of interest.*

We have received comments from the insurance industry and affiliated sources that some situations that we may not readily identify as conflicts nonetheless appear to create conflicts of interest. If a prudent business person could believe a conflict of interest exists in a situation, the entity is required to report the situation even if we have not created a ''classification'' for the situation. We would use this information to evaluate the situation and to determine if it is adequately mitigated or requires no mitigation. In addition, we would use this information to adapt to changing environments and to modify the conflict of interest requirements.

- *A description of the methods the offeror/contractor will apply to mitigate any situations listed in the Certification that could be identified as conflicts of interest.*

We would use the description of the methods the offeror/contractor will apply to mitigate any situations listed in the Certification that could be identified as conflicts of interest to determine if conflicts would be neutralized effectively by the methods described. Generally, we consider a conflict of interest to exist when a contractor's ability to make impartial decisions or perform its work under its contract objectively has been or may be compromised. The offeror/contractor could propose to mitigate a conflict of interest by using methods such as divestiture or reduction of a conflicting financial interest, reassignment of work responsibilities to exclude individuals with conflicting interests from performing work under the contract, or separating lines of business. We would assess the effectiveness of the mitigation method using the information disclosed regarding an offeror's/contractor's organizational structure, financial interests, or other relationships as may be required in a solicitation as discussed below.

- *A description of the offeror's/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.*

We would evaluate the proposed compliance program to determine if the program would enable an offeror/contractor to effectively monitor its compliance and its subcontractors' compliance with conflict of interest requirements specific to the contract. This requirement is integrally connected with an entity's description of its method to mitigate conflicts. Once conflicts are mitigated at the inception of a contract, an entity must be vigilant to ensure that the methods are followed and that new conflicts of interest that arise during the term of the contract are identified and mitigated. We would use the compliance program to ensure we award contracts only to offerors that will follow proposed methods for mitigation of conflicts and that offerors establish an administrative mechanism for disclosure of changing situations that may require contract modifications.

- *An affirmation, using language that we may prescribe, that the offeror/contractor understands that we may consider any deception or omission in the Certificate grounds for nonconsideration in the procurement*

process, termination of the contract, or other contract action.

The affirmation places a higher degree of accountability on the entity for the accuracy of the information disclosed than would otherwise be afforded. By signing the affirmation, the offeror/contractor will be put on notice of the consequences for any false statement or omission of information regarding conflicts of interest. The person signing the affirmation will be put on notice of the offeror's/contractor's responsibility for ensuring the veracity of the information disclosed. We would consider the provision of false or deceptive information in the affirmation as possible grounds for elimination of an offeror from consideration in the procurement process or taking other appropriate contract or legal action.

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

We would use this information to ensure that the offeror has an arrangement with an independent source that will verify compliance with conflict of interest requirements.

• *Corporate and organizational structure.*

We would require this information to determine if legal entities are connected through partnerships, joint ventures, or other legal arrangements. We would assess the types of relationships, evaluate an offeror's/contractor's mitigation methods, and determine if the conflicts of interest based on an offeror's/contractor's relationships have been resolved as part of the procurement process. This information would also be used during the term of the contract to evaluate the mitigation of conflicts when structures change.

• *Financial interests in other entities, including the following:*

+ *Percentage of ownership in any other entity.*

We would use the percentage of ownership interest and the dollar value of financial interests to evaluate reported conflicts of interest and the adequacy of an offeror's/contractor's mitigation methods. Both these measures were suggested by the participants in the 1996 open forum discussion as appropriate considerations in evaluating conflicts of interest. We would perform the evaluation on a case-by-case basis.

• *Income generated from other sources.*

We would use this information to determine if the offeror/contractor could be unduly influenced by other financial relationships it may have with possible customers, competitors, or other parties interested in influencing the performance of the MIP contractor. Income can be generated in a variety of ways, for example, as fees, salaries, reimbursements, or stock options. This information would enable us to evaluate the adequacy of an offeror's/contractor's proposed mitigation methods for conflicts of interest that arise from financial dependence on other entities.

• *A list of current or known future contracts or arrangements, regardless of size, with any insurance organization; subcontractor of an insurance organization; or provider or supplier furnishing services for which payment may be made under the Medicare program. This information is to include the dollar amount of the contracts or arrangements, the type of work performed, and the period of performance.*

We would use this information to evaluate an offeror's/contractor's conflicts that are based on contractual arrangements and to assess the adequacy of its mitigation method. The offeror/contractor would be required to disclose future contracts so that we can assess whether mitigation methods address conflicts that will develop during the procurement process or during the term of the contract.

• *Information regarding potential conflicts of interest and financial information regarding certain contracts for all of the offeror's/contractor's officers, directors (including medical directors), and managers who would be or are involved in the performance of the MIP contract.*

We would evaluate this information to determine if individuals who can control the outcome of work performed under a MIP contract may be unduly influenced by their own or their close relatives' business relationships or contracts. We need the information to protect the monies disbursed for both program and administrative services and to ensure that an offeror's/contractor's mitigation methods adequately eliminate any conflicts that exist due to relationships of an offeror's/contractor's officers, directors, or managers.

Private sector participants at the December 6, 1996 open forum discussion expressed the opinion that full disclosure of all of an offeror's/contractor's relationships would ameliorate conflicts of interest. We considered that, while this might be appropriate in some MIP contractor procurements, it would be unduly burdensome and unnecessary as a blanket requirement in all MIP procurements. Instead, we identified information, described above, that we believe to be essential to the process and require this information to be disclosed in MIP procurements.

The amount of burden associated with these requirements will generally decrease as the size of the offeror/contractor decreases. Smaller offerors/contractors and those not involved in the insurance industry may have no potential conflicts of interest to report if they do not participate in other lines of business and/or if they do not participate in lines of business related to the insurance, health, and health management and consulting industries that are likely to have potential conflicts of interest.

Therefore, based on comments provided by the public and our prior experience, we expect the Certificate and supporting materials will take approximately 80 hours to prepare by each offeror/contractor for its own organization. This estimate is based on the fact that the majority of these disclosure requirements will be compiled using existing data, which an offeror/contractor uses to satisfy other business needs, and the assumption that approximately one-third of the offerors will not have any potential conflicts of interest to report. We expect 15 offerors for each MIP contract. The total burden referenced in this section is 1,200 burden hours.

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to the Office of Management and Budget (OMB) for its review of these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attn: John Burke, Attn: HCFA–7020–P, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer

V. Regulatory Impact Statement

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and,

when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. Intermediaries and carriers are not considered to be small entities.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

B. Summary of the Proposed Rule

As discussed in detail above, this rule implements section 1893 of the Act, which encourages proactive measures to combat waste, fraud, and abuse and to protect the integrity of the Medicare program. The objective of the proposed regulation is to provide a procurement procedure to supplement the requirements of the FAR and specifically address contracts to perform MIP functions identified in the law.

As part of their existing contractual duties, both intermediaries and carriers must perform certain program integrity activities or payment safeguard activities. These activities include, but are not limited to, conducting review of claims to determine whether services were reasonable and necessary, deterring and detecting Medicare fraud, auditing provider cost reports, and ensuring that Medicare pays the appropriate amount when a beneficiary has other health insurance. This rule provides that these functions, as specified below, will be performed under new MIP contracts:

- Review of provider activities such as medical review, utilization review, and fraud review.
- Audit of cost reports.
- Medicare secondary payer review and payment recovery.
- Provider and beneficiary education on payment integrity and benefit quality assurance issues.
- Developing and updating lists of durable medical equipment items that are to be subject to prior approval provisions.

C. Discussion of Impact

We expect that this rule will have a positive impact on the Medicare program, Medicare beneficiaries, providers, suppliers, and entities that have not previously contracted with us. It is possible that some providers and suppliers may experience a slight increase in administrative costs as their claims are subjected to closer review. Current intermediaries and carriers that seek award of MIP contracts may incur costs in complying with new requirements set forth in the rule, but the effect is not expected to be material. To the extent that small entities could be affected by the rule, and because the rule raises certain policy issues with respect to conflict of interest standards, we provide an impact analysis for those entities we believe will be most heavily affected by the rule.

We believe that this rule will have an impact, although not a significant one, in five general areas. The Medicare program and Health Insurance Trust Funds, Medicare beneficiaries and taxpayers, entities that have not previously contracted with us, and Medicare providers and suppliers would benefit from the rule. Current intermediaries and carriers may experience a somewhat negative impact, although the effect on these organization should be tempered by the benefits the new rule will confer.

1. The Medicare Program and Health Insurance Trust Funds

In recent years, sizable cuts in intermediaries' and carriers' budgets for program safeguards have diminished efforts to thwart improper billing practices. The Health Insurance Portability and Accountability Act provides for a direct apportionment from the Health Insurance Trust Funds for carrying out the MIP. Appropriations totaled $440 million for FY 1998 and $500 million for FY 1998. By FY 2003, appropriations are expected to grow to $720 million.

Creating a separate and dependable long-term funding source for MIP will allow us the flexibility to invest in innovative strategies to combat the fraud and abuse drain on the Trust Funds. By shifting emphasis from post-payment recoveries on incorrectly paid claims to pre-payment strategies, most claims will be paid correctly the first time.

Improper billing and health care fraud are difficult to quantify because of their hidden nature. However, a General Accounting Office (GAO) report on Medicare (GAO/HR–91–10, February 1997) suggests that by reducing unnecessary or inappropriate payments, the Federal Government would realize large savings and help slow the growth in Medicare costs. In this report, the GAO states that estimates of ''the costs of fraud and abuse ranging from 3 to 10 percent have been cited for health expenditures nationwide, so applying this range to Medicare suggests that such losses in fiscal year 1996 could have been from $6 billion to as much as $20 billion.''

The savings realized from our payment safeguard activities for FYs 1988–1996 were as follows:

Year	Total cost*	Total savings*	Return on investment
FY1988	$313.6	$3,654.1	12:1
FY1989	376.3	3,961.6	11:1
FY1990	348.7	5,234.4	15:1
FY1991	360.7	5,703.4	16:1
FY1992	350.7	5,153.2	15:1
FY1993	406.3	6,506.6	16:1
FY1994	412.4	5,412.7	13:1
FY1995	428.3	6,314.9	15:1
FY1996	441.1	6,190.4	14:1

*Dollars in millions.

In our Justification of Estimates for Appropriations Committees for fiscal year 1998, we projected the return on investment for various payment safeguard activities under MIP. Overall, we expect that every dollar expended in fiscal year 1998 to perform integrity functions will save $12 for the Medicare program. We estimate that medical review and utilization review performed under MIP will produce a return on investment of 8:1 for Part A claims and 14:1 for Part B claims. Every dollar spent on audit functions under MIP is expected to save $6 for the Medicare program. For Medicare secondary payer functions, we project a 50:1 return on investment for Part A claims and a 9:1 return for Part B claims. The overall return for Medicare secondary payer functions performed under MIP is estimated to be 26:1.

In addition to these economic advantages, the Medicare program will benefit in a qualitative way. MIP, as this proposed rule would implement it, gives us a tool to better administer the Medicare program and accomplish our mission of providing access to quality health care for Medicare beneficiaries. Under this rule, program integrity activities will be performed under specialized contracts that are subject to more stringent conflict of interest standards than were previously employed. In addition, for the first time we will be able to use competitive procedures to separately contract for the performance of integrity functions. In general, economic theory postulates that competition results in a better price for the consumer who, in this instance, is HCFA on behalf of Medicare beneficiaries and taxpayers. Competition should also encourage the use of innovative techniques to perform integrity functions that will, in turn, result in more efficient and effective safeguards for the Trust Funds.

2. Medicare Beneficiaries and Taxpayers

We expect that overall this rule would have a positive effect on Medicare beneficiaries and taxpayers. Beneficiaries pay deductibles and Part B Medicare premiums. Taxpayers, including those who are not yet eligible for Medicare, contribute part of their earnings to the Part A Trust Fund. Taxpayers and beneficiaries contribute indirectly to the Part B Trust Funds because it is funded, in part, from general tax revenues. Consistent performance of program integrity activities will ensure that less money is wasted on inappropriate treatment or unnecessary services. As a result, current and future beneficiaries will obtain more value for every Medicare dollar spent.

Medicare contractors estimate that of the 130,000 calls they receive yearly concerning potential fraud and abuse, 94,000 are from beneficiaries, many of whom call to question the propriety of claims made on their behalf. Beneficiary education monies, especially when used to provide more Medicare ''scam alerts,'' will enhance a beneficiary's attention to detail and increase savings.

Beneficiaries may experience higher denial rates due to the more stringent claims review. It is expected, however, that most of the potential increase in denials will result from a determination that the services provided were not reasonable and necessary under Medicare authorities and guidelines. There are established limitations on beneficiary liability when claims are denied on this basis; thus the impact on beneficiaries will be minimized.

3. Current Intermediaries and Carriers

Although intermediaries and carriers are not considered small entities for purposes of the RFA, we are providing the following analysis. There are currently 43 Medicare intermediaries and 27 Medicare carriers plus 4 durable medical equipment regional contractors. All but 13 of these contractors are Blue Cross/Blue Shield plans. Presently, all contractors perform payment safeguard activities, and, in FY 1996, approximately 28 percent of the total contractor budget was dedicated to program integrity.

We considered prohibiting current intermediaries and carriers from entering into MIP contracts. We also considered entering into contracts with new organizations to perform all functions while simultaneously removing all payment safeguard functions from current contractors. Neither of these options appeared viable because the effect on the Medicare program would have been unduly disruptive. We do, however, expect to reduce the number of contractors when we shift and consolidate the integrity functions to MIP contractors, but the exact number cannot be determined until we begin implementing the program. The reduction in the number of contractors performing integrity functions does not mean that local contractor presence will be eliminated. Medical directors would continue to play an important role in benefit integrity activities, and we intend to retain locally-based medical directors to continue our relationship with local physicians by using groups like Carrier Advisory Committees. Locally-based fraud investigators and auditors are also likely to be used. Review policies will be coordinated across contractors to ensure consistency, but local practice will be incorporated where appropriate.

This rule may have a negative impact on current intermediaries and carriers in some respects. Current contractors will lose a portion of their Medicare business as payment safeguard functions are transferred to MIP contractors. Although their workload will be reduced, the effect on current contractors will be gradual because we have a long-term strategy for the implementation of MIP. As discussed above, we believe that it would be too disruptive to the Medicare program to make a sudden, across-the-board change in contractors. The change will be made over time, in an incremental fashion, as MIP contracts are awarded; therefore, we cannot quantify the effect.

On the other hand, current contractors would benefit from this proposed rule because, under its provisions, they are eligible to compete for MIP contracts as long as they comply with all conflict of interest and other requirements. (Current contractors may not receive payment for performing the same program integrity activities under both a MIP contract and their existing contract.) We considered proposing rules that identified specific conflict of interest situations that would prohibit the award of a MIP contract. We also considered prohibiting a MIP contractor whose contract was completed or terminated from competing for another MIP contract for a certain period. Instead, the proposed rule would establish a process for evaluating, on a case-by-case basis, situations that may constitute conflicts of interest. It permits current contractors to position themselves to be eligible for a MIP contract by mitigating any conflicts of interest they may have in order to compete. The economic impact on intermediaries and carriers is lessened by the proposed approach when compared to the alternatives we considered.

The current contractors who are awarded MIP contracts will also benefit from the consistent funding provided by the law for program integrity activities. This stable, long-term funding mechanism will allow Medicare contractors to attract, train, and retain qualified professional staff to perform claims review and audit, to identify and refer fraud cases to law enforcement agencies and to support the ongoing development of these cases for prosecution by the Department of Justice.

There will be an economic impact on current contractors that propose to

perform MIP contracts using subcontractors. MIP contractors would be required to determine if any of their subcontractors, at any tier, have conflicts of interest and to ensure that any conflicts are mitigated. A MIP contractor would apply to its subcontractors the same conflict of interest standard to which it must adhere. It is impossible to assess the precise economic impact of this portion of the proposed rule because a MIP contractor is free to contract with any subcontractor. A MIP contractor may seek out subcontractors that are conflict free, which would reduce or eliminate the time expended monitoring conflict of interest situations.

4. New Contracting Entities

Entities that have not previously performed Medicare payment safeguard activities will experience a positive effect from this rule. Integrity functions such as audit, medical review, and fraud investigation may be consolidated in a MIP contract to allow suspect claims to be identified and investigated from all angles. Contractors may subcontract for these specific integrity functions, thus creating new markets and opportunities for small, small disadvantaged, and woman-owned businesses.

Use of full and open competition to award MIP contracts may encourage innovation and the creation of new technology. Historically, cutting edge technologies and analytical methodologies created for the Medicare program have benefitted the private insurance arena.

This proposed rule, however, could also have an adverse economic impact on newly-contracting entities. They, like existing contractors, will be required to absorb the cost of mitigating conflicts of interest and complying with conflict of interest requirements.

5. Providers and Suppliers

There could be some burden imposed on providers and suppliers that are small businesses or not-for-profit organizations by the need to deal with a new set of contractors. There are approximately 1 million health care providers and suppliers (depending on how group practices and multiple locations are counted) that bill independently. The proposed rule does not necessarily impose any action on the part of these providers and suppliers. It is possible that some of them would have to devote more effort in responding to MIP contractors' inquiries generated by more stringent claims review and that they could incur a modest increase in administrative costs. In our analysis of possible administrative costs to providers and suppliers, we assumed that a contractor would make two follow-up inquiries to a provider or supplier for each potential recovery of an incorrect payment. Assuming that the response to each inquiry would require a provider or supplier to expend 30 minutes of clerical time, at $10 per hour, and 15 minutes of professional time, at $100 per hour, we estimate that the average response to an inquiry would cost $30. The resulting added cost to providers and suppliers would be under $10 million annually.

Most Medicare contractors do not maintain toll-free lines for providers or suppliers. A provider's or supplier's telephone bill could increase if it must contact a MIP contractor that is out of its calling area. However, it is possible that a provider's or supplier's intermediary or carrier may also be its MIP contractor. We believe that the centralization of certain functions would result in more consistent policy and lessen the need for a provider or supplier to communicate with its contractor. Since we plan to phase-in the transfer of the MIP activities, we do not anticipate a significant annual impact on telephone bills.

Overall, we expect that providers and suppliers will benefit qualitatively from this proposed rule. Many providers and suppliers perceive that their reputations are tarnished by the few dishonest providers and suppliers that take advantage of the Medicare program. The media often focus on the most egregious cases of Medicare fraud and abuse, leaving the public with the perception that physicians and other health care practitioners routinely make improper claims. This rule would allow us to take a more effective and wider ranging approach to identifying, stopping, and recovering from unscrupulous providers and suppliers. As the number of dishonest providers and suppliers and improper claims diminishes, ethical providers and suppliers will benefit.

This proposed rule could be considered to have a negative impact on any provider or supplier that routinely submits questionable claims and would impact those that have been receiving inappropriate payments. Since the objective of this proposed rule is to eliminate improper payments, we will not analyze the effect the rule may have on unscrupulous providers or suppliers. We do not believe that this rule will reduce a provider's or supplier's legitimate income from Medicare. As claims are more closely and systematically reviewed, providers and suppliers may experience an increase in the number of claims denied. This slight negative impact should decrease as providers become more knowledgeable regarding what claims are appropriate.

D. Conclusion

We conclude that money would be saved and the solvency of the Trust Funds extended as a result of this proposed rule. The dynamic nature of fraud and abuse is illustrated by the fact that wrongdoers continue to find ways to evade safeguards. This supports the need for constant vigilance and increasingly sophisticated ways to protect against ''gaming'' of the system. We solicit public comments as well as data on the extent to which any of the affected entities would be significantly economically affected by this proposed rule. However, based on the above analysis, we have determined, and certify, that this proposed rule would not have a significant economic impact on a substantial number of small entities. We also have determined, and certify, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals. In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 400

Grant programs—health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV would be amended as follows:

A. Part 400

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

2. Section 400.202 is amended by adding the following definition in alphabetical order, to read as follows:

§ 400.202 Definitions specific to Medicare.

* * * * *

Medicare integrity program contractor means an entity that has a contract with

HCFA under section 1893 of the Act to perform program integrity activities.

* * * * *

B. Part 421

PART 421—MEDICARE CONTRACTING

1. The part heading is revised to read as set forth above.

2. The authority citation for part 421 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

3. Section 421.1 is revised to read as follows:

§ 421.1 Basis, applicability, and scope.

(a) *Basis.* This part is based on the indicated provisions of the following sections of the Act:

1124—Requirements for disclosure of certain information.

1816 and 1842—Use of organizations and agencies in making Medicare payments to providers and suppliers of services.

1893—Requirements for protecting the integrity of the Medicare program.

(b) *Additional basis.* Section 421.118 is also based on 42 U.S.C. 1395(b)–1(a)(1)(F), which authorizes demonstration projects involving intermediary agreements and carrier contracts.

(c) *Applicability.* The provisions of this part apply to agreements with Part A (Hospital Insurance) intermediaries, contracts with Part B (Supplementary Medical Insurance) carriers, and contracts with Medicare integrity program contractors that perform program integrity functions.

(d) *Scope.* The provisions of this part state that HCFA may perform certain functions directly or by contract. They specify criteria and standards HCFA uses in selecting intermediaries and evaluating their performance, in assigning or reassigning a provider or providers to particular intermediaries, and in designating regional or national intermediaries for certain classes of providers. The provisions provide the opportunity for a hearing for intermediaries and carriers affected by certain adverse actions. They also provide adversely affected intermediaries an opportunity for judicial review of certain hearing decisions. They also set forth requirements related to contracts with Medicare integrity program contractors.

4. Section 421.100 is revised to read as follows:

§ 421.100 Intermediary functions.

An agreement between HCFA and an intermediary specifies the functions to be performed by the intermediary.

(a) *Mandatory functions.* The contract must include the following functions:

(1) Determining the amount of payments to be made to providers for covered services furnished to Medicare beneficiaries.

(2) Making the payments.

(b) *Additional functions.* The contract may include any or all of the following functions:

(1) Any or all of the program integrity functions described in § 421.304, provided the intermediary is continuing those functions under an agreement entered into under section 1816 of the Act that was in effect on August 21, 1996, and they do not duplicate work being performed under a Medicare integrity program contract.

(2) Undertaking to adjust incorrect payments and recover overpayments when it has been determined that an overpayment has been made.

(3) Furnishing to HCFA timely information and reports that HCFA requests in order to carry out its responsibilities in the administration of the Medicare program.

(4) Establishing and maintaining procedures as approved by HCFA for the review and reconsideration of payment determinations.

(5) Maintaining records and making available to HCFA the records necessary for verification of payments and for other related purposes.

(6) Upon inquiry, assisting individuals with respect to matters pertaining to an intermediary contract.

(7) Serving as a channel of communication to and from HCFA of information, instructions, and other material as necessary for the effective and efficient performance of an intermediary agreement.

(8) Undertaking other functions as mutually agreed to by HCFA and the intermediary.

(c) *Dual intermediary responsibilities.* With respect to the responsibility for services to a provider-based HHA or a provider-based hospice, when different intermediaries serve the HHA or hospice and its parent provider under § 421.117, the designated regional intermediary determines the amount of payment and makes payments to the HHA or hospice. The intermediary and/or Medicare integrity program contractor serving the parent provider performs fiscal functions, including audits and settlement of the Medicare cost reports and the HHA and hospice supplement worksheets.

5. Section 421.200 is revised to read as follows:

§ 421.200 Carrier functions.

A contract between HCFA and a carrier specifies the functions to be performed by the carrier. The contract may include any or all of the following functions:

(a) Any or all of the program integrity functions described in § 421.304 provided—

(1) The carrier is continuing those functions under a contract entered into under section 1842 of the Act that was in effect on August 21, 1996; and

(2) The functions do not duplicate work being performed under a Medicare integrity program contract, except that the function related to developing and maintaining a list of durable medical equipment may be performed under both a carrier contract and a Medicare integrity program contract.

(b) Receiving, disbursing, and accounting for funds in making payments for services furnished to eligible individuals within the jurisdiction of the carrier.

(c) Determining the amount of payment for services furnished to an eligible individual.

(d) Undertaking to adjust incorrect payments and recover overpayments when it has been determined that an overpayment has been made.

(e) Furnishing to HCFA timely information and reports that HCFA requests in order to carry out its responsibilities in the administration of the Medicare program.

(f) Maintaining records and making available to HCFA the records necessary for verification of payments and for other related purposes.

(g) Establishing and maintaining procedures under which an individual enrolled under Part B will be granted an opportunity for a fair hearing.

(h) Upon inquiry, assisting individuals with matters pertaining to a carrier contract.

(i) Serving as a channel of communication to and from HCFA of information, instructions, and other material as necessary for the effective and efficient performance of a carrier contract.

(j) Undertaking other functions as mutually agreed to by HCFA and the carrier.

6. A new subpart D is added to part 421 to read as follows:

Subpart D—Medicare Integrity Program Contractors

Sec.

Subpart D—Medicare Integrity Program Contractors

§ 421.300 Basis, applicability, and scope.

(a) *Basis.* This subpart implements section 1893 of the Act, which requires HCFA to protect the integrity of the Medicare program by entering into contracts with eligible entities to carry out Medicare integrity program functions.

(b) *Applicability.* This subpart applies to entities that seek to compete or receive award of a contract under section 1893 of the Act including entities that perform functions under this subpart emanating from the processing of claims for individuals entitled to benefits as qualified railroad retirement beneficiaries.

(c) *Scope.* This subpart defines the types of entities eligible to become Medicare integrity program contractors; identifies the program integrity functions a Medicare integrity program contractor performs; describes procedures for awarding and renewing contracts; establishes procedures for identifying, evaluating, and resolving organizational conflicts of interest; prescribes responsibilities; and sets forth limitations on contractor liability. The provisions of this subpart are based on the acquisition regulations set forth at 48 CFR Chapters 1 and 3.

§ 421.302 Eligibility requirements for Medicare integrity program contractors.

If an entity meets the following conditions, HCFA may enter into a contract with it to perform the functions described in § 421.304:

(a) Demonstrates the ability to perform the Medicare integrity program contractor functions described in § 421.304. For purposes of developing and periodically updating a list of DME under § 421.304(e), an entity is deemed to be eligible to enter into a contract under the Medicare integrity program to perform the function if the entity is a carrier with a contract in effect under section 1842 of the Act.

(b) Agrees to cooperate with the OIG, the Attorney General, and other law enforcement agencies, as appropriate, including making referrals, in the investigation and deterrence of fraud and abuse of the Medicare program.

(c) Complies with conflict of interest provisions in 48 CFR Chapters 1 and 3 and is not excluded under the conflict of interest provision at § 421.310.

(d) Meets other requirements that HCFA establishes.

§ 421.304 Medicare integrity program contractor functions.

The contract between HCFA and a Medicare integrity program contractor specifies the functions the contractor performs. The contract may include any or all of the following functions:

(a) Conducting medical reviews, utilization reviews, and fraud reviews related to the activities of providers of services and other individuals and entities (including entities contracting with HCFA under part 417 of this chapter) furnishing services for Medicare payment. These reviews include medical, utilization, and fraud reviews.

(b) Auditing cost reports of providers of services, or other individuals or entities (including entities contracting with HCFA under part 417 of this chapter), as necessary to ensure proper Medicare payment.

(c) Determining appropriate Medicare payment to be made for services, as specified in section 1862(b) of the Act, and taking action to recover inappropriate payments.

(d) Educating providers, suppliers, beneficiaries, and other persons regarding payment integrity and benefit quality assurance issues.

(e) Developing, and periodically updating, a list of items of durable medical equipment that are frequently subject to unnecessary utilization throughout the contractor's entire service area or a portion of the area, in accordance with section 1834(a)(15)(A) of the Act.

§ 421.306 Awarding of a contract.

(a) HCFA awards Medicare integrity program contracts in accordance with acquisition regulations set forth at 48 CFR chapters 1 and 3, this subpart, and all other applicable laws and regulations. These requirements for awarding Medicare integrity program contracts are used—

(1) When entering into new contracts;

(2) When entering into contracts that may result in the elimination of responsibilities of an individual intermediary or carrier under section 1816(l) or section 1842(c) of the Act, respectively; and

(3) At any other time HCFA considers appropriate.

(b) HCFA may award an entity a Medicare integrity program contract without competition if—

(1) Through approval of a novation agreement, HCFA recognizes the entity as the successor in interest to an intermediary agreement or carrier contract under which the intermediary or carrier was performing activities described in section 1893(b) of the Act on August 21, 1996;

(2) The intermediary or carrier has transferred to the entity all of the resources, including personnel, that were involved in performance under the intermediary agreement or carrier contract and performance of Medicare integrity program activities; and

(3) The intermediary or carrier continued to perform Medicare integrity program activities until transferring the resources to the entity.

(c) An entity is eligible to be awarded a Medicare integrity program contract only if it meets the eligibility requirements established in § 421.302.

§ 421.308 Renewal of a contract.

(a) HCFA specifies an initial contract term in the Medicare integrity program contract. Contracts under this subpart may contain renewal clauses. HCFA may renew the Medicare integrity program contract, without regard to any provision of law requiring competition, as it determines to be appropriate, by giving the contractor notice, within timeframes specified in the contract, of its intent to do so.

(b) HCFA may renew a Medicare integrity program contract without competition if—

(1) The Medicare integrity program contractor continues to meet the requirements established in this subpart;

(2) The Medicare integrity program contractor meets or exceeds all of the performance requirements established in its current contract; and

(3) It is in the best interest of the Government.

(c) If HCFA does not renew a contract, the contract will end in accordance with its terms, and the contractor does not have the right to a hearing or judicial review of the nonrenewal decision.

§ 421.310 Conflict of interest identification.

(a) *Definitions.* As used in this subpart, the following definitions apply:

Financial relationship means—

(1) A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity that exists through equity, debt, or other means and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

(2) A compensation arrangement with an entity.

Organizational conflict of interest has the meaning given at 48 CFR 9.501, except that, for purposes of this subpart, the activities and relationships described include those of the offeror or contractor itself and other business

related to it and those of its officers, directors (including medical directors), managers, and subcontractors.

(b) *General.* Except as provided in paragraph (d) of this section, HCFA does not enter into a contract under this subpart with an offeror or contractor that HCFA determines has, or has the potential for, an unresolved organizational conflict of interest.

(c) *Identification of conflict.* (1) HCFA determines that an offeror or contractor has an organizational conflict of interest, or the potential for the conflict exists, if—

(i) The offeror or contractor is an entity described in paragraph (c)(3) of this section; or

(ii) The offeror or contractor has a present, or known future, direct or indirect financial relationship with an entity described in paragraph (c)(3) of this section.

(2) A financial relationship may exist either—

(i) Through an offeror's or contractor's parent companies, subsidiaries, affiliates, subcontractors, or current clients; or

(ii) From the activities and relationships of the officers, directors (including medical directors), or managers of the offeror or contractor and may be either direct or indirect. An officer, director, or manager has an indirect financial relationship if an ownership or investment interest is held in the name of another but provides benefits to the officer, director, or manager. Examples of indirect financial relationships are holdings in the name of a spouse or dependent child of the officer, director, or manager and holdings of other relatives who reside with the officer, director, or manager.

(3) For purposes of paragraphs (c)(1)(i) and (c)(1)(ii) of this section, the entity is one that—

(i) Provides, insures, or pays for health benefits, with the exception of health plans provided as the entity's employee fringe benefit;

(ii) Conducts audits of health benefit payments or cost reports;

(iii) Conducts statistical analysis of health benefit utilization;

(iv) Would review or does review, under the contract, Medicare services furnished by a provider or supplier that is a direct competitor of the offeror or contractor;

(v) Prepared work or is under contract to prepare work that would be reviewed under the Medicare program integrity contract;

(vi) Is affiliated, as that term is explained in 48 CFR 19.101, with a provider or supplier to be reviewed under the contract.

(4) HCFA may determine that an offeror or contractor has an organizational conflict of interest, or the potential for a conflict exists, based on the following:

(i) Apparent organizational conflicts of interest. An apparent organizational conflict of interest exists if a prudent business person has cause to believe that the offeror or contractor would have a conflict of interest in performing the requirements of a contract under this subpart. No inappropriate action by the offeror or contractor is necessary for an apparent organizational conflict of interest to exist.

(ii) Other contracts and grants with the Federal Government.

(d) *Exception.* HCFA may contract with an offeror or contractor that has an unresolved conflict of interest if HCFA determines that it is in the best interest of the Government to do so.

(e) *Offeror's or contractor's responsibility with regard to subcontractors.* An offeror or contractor is responsible for determining whether an organizational conflict of interest exists in any of its proposed or actual subcontractors at any tier and is responsible for ensuring that the subcontractors have mitigated any conflict of interest or potential conflict of interest.

(f) *Post-award conflicts of interest.* (1) In addition to the conflicts identified in paragraph (c) of this section, HCFA considers that a conflict of interest has occurred if during the term of the contract—

(i) The contractor receives any fee, compensation, gift, payment of expenses, or any other thing of value from any entity that is reviewed, audited, investigated, or contacted during the normal course of performing activities under the Medicare integrity program contract; or

(ii) HCFA determines that the contractor's activities are creating a conflict of interest.

(2) In the event HCFA determines that a conflict of interest exists during the term of the contract, among other actions, it may, as it deems appropriate—

(i) Not renew the contract for an additional term;

(ii) Modify the contract; or

(iii) Terminate the contract.

§ 421.312 Conflict of interest evaluation.

(a) *Disclosure.* Offerors that wish to be eligible for the award of a contract under this subpart and Medicare integrity program contractors must submit, at times specified in paragraph (b) of this section, an Organizational Conflicts of Interest Certificate. The Certificate must contain the information specified in paragraphs (a)(1) through (a)(8) of this section, unless the information has otherwise been provided in the proposal, in which case it must be referenced. Each solicitation issued for a contract under this subpart contains the requirements for disclosure for pre- and post-award purposes. The solicitation may require more detailed information than identified in this section.

(1) A description of all business or contractual relationships or activities that may be viewed by a prudent business person as a conflict of interest.

(2) A description of the methods the offeror or contractor will apply to mitigate any situations listed in the Certificate that could be identified as a conflict of interest.

(3) 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.

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

(5) 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.

(6) Corporate and organizational structure.

(7) Financial interests in other entities, including the following:

(i) Percentage of ownership in any other entity.

(ii) Income generated from other sources.

(iii) A list of current or known future contracts or arrangements, regardless of size, with any—

(A) Insurance organization or subcontractor of an insurance organization; or

(B) Providers or suppliers furnishing health services for which payment may be made under the Medicare program.

(iv) In the case of contracts or arrangements identified in accordance with paragraph (a)(7)(iii) of this section, the dollar amount of the contracts or arrangements, the type of work performed, and the period of performance.

(8) The following information for all of the offeror's or contractor's officers, directors (including medical directors),

and managers who would be or are involved with the performance of the Medicare integrity program contract:

(i) The information required under paragraphs (a)(1), (a)(7)(iii), and (a)(7)(iv) of this section.

(ii) If required by the solicitation, the information specified in paragraphs (a)(7)(i) and (a)(7)(ii) of this section.

(b) *When disclosure is made.* The Organizational Conflicts of Interest Certificate is submitted—

(1) With the offeror's proposal;

(2) When the HCFA Contracting Officer requests a revision in the Certificate;

(3) As part of a compliance audit by an independent auditor; and

(4) 45 days before any change in the information submitted in accordance with paragraph (a) or paragraph (b) of this section. Only changed information must be submitted.

(c) *Evaluation.* HCFA evaluates organizational conflicts of interest and potential conflicts, using the information provided in the Organizational Conflicts of Interest Certificate, in order to promote the effective and efficient administration of the Medicare program.

(d) *Protection of proprietary information disclosed.* (1) HCFA protects disclosed proprietary information as allowed under the Freedom of Information Act (5 U.S.C. 552).

(2) HCFA requires signed statements from HCFA personnel with access to proprietary information that prohibit personal use during the procurement process and term of the contract.

§ 421.314 Conflict of interest resolution.

(a) *Review Board.* HCFA establishes a Conflicts of Interest Review Board to resolve organizational conflicts of interest and determines when the Board is convened.

(b) *Resolution.* Resolution of an organizational conflict of interest is a determination that—

(1) The conflict has been mitigated;

(2) The conflict precludes award of a contract to the offeror;

(3) The conflict requires that HCFA modify an existing contract;

(4) The conflict requires that HCFA terminate an existing contract; or

(5) It is in the best interest of the Government to contract with the offeror or contractor even though the conflict exists.

§ 421.316 Limitation on Medicare integrity program contractor liability.

(a) None of the following will be held by reason of the performance of any duty, function, or activity required or authorized under this subpart or under a valid contract entered into under this subpart to have violated any criminal law or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in that performance:

(1) An entity having a contract with HCFA under this subpart (that is, a contractor under this subpart).

(2) A person employed by or who has a fiduciary relationship with or who furnishes professional services to a contractor under this subpart.

(b) HCFA makes payment, to a contractor under this subpart, or to a member or employee of the contractor, or to any person who furnishes legal counsel or services to the contractor, of an amount equal to the reasonable amount of the expenses incurred in connection with the defense of a suit, action, or proceeding, as determined by HCFA, if—

(1) The suit, action, or proceeding was brought against the contractor, or a member or employee of the contractor, by a third party and relates to the performance by the contractor, member, or employee of any duty, function, or activity under a contract entered into with HCFA under this subpart;

(2) The funds are available; and

(3) The expenses are otherwise allowable under the terms of the contract.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 5, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: March 16, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–7190 Filed 3–16–98; 5:00 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 4200

[WO–130–1820–00–24 1A]

RIN 1004–AC70

Grazing Administration: Alaska; Livestock

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Land Management (BLM) proposes to remove the regulations which implement the livestock grazing program on BLM lands in Alaska because they are obsolete. There are currently no livestock grazing operations under BLM's program, and we do not anticipate receiving any more applications. Due to Native and State of Alaska land selections, the amount of BLM lands suitable for livestock grazing has decreased dramatically. If applicants wish to apply to graze livestock other than reindeer, BLM may still issue special use permits.

DATES: BLM must receive your comments at the address below on or before May 19, 1998. BLM will not necessarily consider any comments received after the above date during its decision on the proposed rule.

ADDRESSES: If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to Bureau of Land Management, Administrative Record, Room 401 LS, 1849 C Street, NW, Washington, D.C. 20240. You may also comment via the Internet to WOComment@wo.blm.gov. Please submit comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include ''attn: AC70'' and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at (202) 452–5030. Finally, you may hand-deliver comments to BLM at 1620 L Street, N.W., Room 401, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Peggy Fox, Alaska State Office, Bureau of Land Management, U.S. Department of the Interior, 222 West 7th Avenue, #13, Anchorage, Alaska 99513–7599; Telephone: 907–271–3346 (Commercial or FTS).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

Written Comments

Written comments on the proposed rule should be specific, should be confined to issues pertinent to the proposed rule, and should explain the reason for any recommended change. Where possible, comments should reference the specific section or paragraph of the proposal which the commenter is addressing. BLM may not necessarily consider or include in the