Dated: May 23, 2005.

James M. Taitt,

Acting Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 05–11979 Filed 6–16–05; 8:45 am]

BILLING CODE 4310–05–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7924–4]

National Oil and Hazardous Substance Pollution Contingency Plan National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete the Metropolitan Mirror and Glass (MM&G) Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region 3 is issuing a notice of intent to delete MM&G Superfund Site (Site) located in Frackville, Schuylkill County, Commonwealth of Pennsylvania, from the National Priorities List (NPL) and requests public comments on this notice of intent. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is found at appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP), have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

In the ''Rules and Regulations'' section of today's **Federal Register**, EPA is publishing a direct final notice of deletion of MM&G Superfund Site without prior notice of intent to delete because EPA views this as a noncontroversial revision and anticipate no adverse comment. EPA has explained its reasons for this deletion in the preamble to the direct final notice of deletion. If no adverse comment(s) are received on this notice of intent to delete or the direct final notice of deletion, EPA will not take further action on this notice of intent to delete. If adverse comment(s) are received, EPA will withdraw the direct final notice of deletion and it will not take effect. EPA will, as appropriate, address all public comments in a subsequent final deletion notice based on this notice of intent to delete. EPA will not institute a second comment period on this notice of intent to delete. Any parties interested in commenting must do so at this time. For additional information, see the direct final notice of deletion which is located in the Rules section of this **Federal Register**.

DATES: Comments concerning this Site must be received by July 18, 2005.

ADDRESSES: Written comments should be addressed to: David Polish, Community Involvement Coordinator, U.S. EPA (3HS43), 1650 Arch Street, Philadelphia, PA 19103–2029, *polish.david@epa.gov*, (215) 814–3327 or (800) 553–2509.

FOR FURTHER INFORMATION CONTACT: Eugene Dennis, Remedial Project Manager, U.S. EPA (3HS21), 1650 Arch Street, Philadelphia, PA 19103–2029, (215) 814–3202 or (800) 553–2509.

SUPPLEMENTARY INFORMATION: For additional information, see the Direct Final Notice of Deletion which is located in the Rules section of this **Federal Register**.

Information Repositories: Repositories have been established to provide detailed information concerning this decision at the following address: U.S. EPA Region 3 Regional Center for Environmental Information, 1650 Arch Street, Philadelphia, Pennsylvania, 19103, (215) 814–5254 or (800) 553–2509, Monday through Friday 8 a.m. to 4:30 p.m.; West Mahanoy Township Building, 190 Pennsylvania Avenue, Shenandoah, Pennsylvania 17976, (570) 462–2958.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O 12777, 56 FR 54757, 3 CFR, 1991 Comp., p.351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p193.

Dated: May 31, 2005.

Richard J. Kampf,

Acting Regional Administrator, Region 3.

[FR Doc. 05–11828 Filed 6–16–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 400 and 421

[CMS–6030–P2]

RIN 0938–AN72

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish the Medicare Integrity Program (MIP) and implement program integrity activities that are funded from the Federal Hospital Insurance Trust Fund. 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.

This proposed rule would bring certain sections of the Medicare regulations concerning fiscal intermediaries and carriers into conformity with the Social Security Act (the Act). The rule would distinguish between those functions that the statute requires to be included in agreements with fiscal intermediaries and those that may be included in the agreements. It would also provide that some or all of the functions may be included in carrier contracts. Currently all these functions are mandatory for carrier contracts.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. e.d.t on August 16, 2005.

ADDRESSES: In commenting, please refer to file code CMS–6030–P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments*, (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services,

Department of Health and Human Services, Attention: CMS–6030–P2, P.O. Box 8014, Baltimore, MD 21244–8014.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number 1–800–743–3951 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

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

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code [CMS–6030–P2] and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

[If you choose to comment on issues in this section, please include the caption ''Background'' at the beginning of your comments.]

A. Current Medicare Contracting Environment

Since the inception of the Medicare program, the Medicare contracting authorities have been in place and largely unchanged until the last few years. At the inception of the Medicare program, 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), the Congress provided that public agencies or private organizations may participate in the administration of the Medicare program under agreements or contracts entered into with CMS.

These Medicare contractors are known as fiscal intermediaries (section 1816(a) of the Act) and carriers (section 1842(a) of the Act). With certain exceptions, fiscal 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 § 400.202. That is, a provider is a hospital, rural care primary hospital, skilled nursing facility (SNF), home health agency (HHA), 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 (NPP), laboratories, and durable medical equipment (DME) 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 organization 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 organization.'' No entity may be considered for a carrier contract unless it can demonstrate that it meets this definition of carrier.

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

Section 1816(a) of the Act authorizes us to enter into agreements with public agencies or private organizations (fiscal intermediaries) for the purpose of administering Part A of the Medicare program. 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 a fiscal intermediary if the entity was first ''nominated'' by a group or association of providers to make Medicare payments to it. Effective October 1, 2005, section 911 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) eliminates the requirement that fiscal intermediaries be nominated, and establishes the requirement that Medicare contracts awarded to Medicare Administrative Contractors (MACs) be competitively bid.

Section 421.100 requires that the agreement between us and a fiscal intermediary specify the functions the fiscal intermediary must perform. In addition to requiring any items

specified by us in the agreement that are unique to that fiscal intermediary, our regulations require that all fiscal 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 fiscal intermediaries furnish information and reports, perform certain functions for provider-based HHAs 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 requires that the contract between CMS and a Part B carrier specify the functions the carrier must perform. In addition to requiring any items specified by CMS in the contract that are unique to that carrier, we 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 this context that Medicare fiscal intermediary and carrier contracts are significantly different from standard Federal Government contracts.

Specifically, the Medicare fiscal 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. The 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 fiscal 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 fiscal intermediary agreements in certain circumstances, and, similarly, § 421.205 provides for termination of carrier contracts.

Each year, the Congress appropriates funds to support Medicare contractor activities. These funds are distributed to the contractors based on annual budget and performance negotiations, which allocate funds by program activity to each of the current Medicare contractors. Historically, approximately one-half of the funds were for payment for the processing of claims; an additional one-quarter of the funds were for program integrity 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 potential 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 was allocated for beneficiary and provider or supplier services and for various productivity investments.

B. Discussion About Medicare Administrative Contractors (MACs)

The MMA was enacted on December 8, 2003. Section 911 of the MMA adds new section 1874A to the Act, establishing the Medicare Fee-for-Service (FFS) Contracting Reform (MCR) initiative that will be implemented over the next several years. Under this provision, effective October 1, 2005, we have the authority to replace the current Medicare fiscal intermediary and carrier contracts with new MACs using competitive procedures.

Between 2005 and 2011, we will conduct full and open competitions to replace the current contracts with MACs. These MACs will handle many of the same basic functions that are now performed by fiscal intermediaries and carriers. Additionally, MACs may be charged with performing functions under the Medicare Integrity Program under section 1893 of the Act. The statute does not preclude the current fiscal intermediaries and carriers from competing for the MAC contracts.

Among other provisions, section 1874A of the Act establishes eligibility requirements for the MACs, describes the functions these new contractors may perform (which may include functions of section 1893 of the Act so long as these responsibilities do not duplicate activities that are being carried out under a Medicare Integrity Program contract), and specifies various requirements for the structure, terms and conditions of these new MAC contracts. In particular, section 1874A of the Act specifies that the Federal Acquisition Regulation (FAR) will apply to the MAC contracts, except to the extent inconsistent with a specific requirement of section 1874A of the Act. Unlike the contracting authority of section 1893 of the Act, the new authority of section 1874A of the Act does not mandate that the Secretary publish either a proposed or final regulation prior to entering into MAC contracts. Instead, the Congress when enacting the authority of section 1874A of the Act, placed a clear reliance on the existing well-defined regulatory framework of the FAR.

We considered whether we should propose regulations for the MAC authority in conjunction with this proposed rule to implement the authority of section 1893 of the Act. Since we are still analyzing whether any of the specific requirements of section 1874A of the Act need elaboration in the regulations, we are not prepared to do so at this time. As section 1874A of the Act places reliance on the FAR for MAC contracts and since section 1874A of the Act does not impose any requirement to issue additional rules in order to initiate procurements under the MAC authority, we do not believe such rules are required to initiate the implementation of section 1874A of the Act. We will, however, continue to analyze issues posed by the new contracting authority and the transition to that framework, and will propose rules for the authority of new section 1874A of the Act if and when we identify issues that need to be addressed through rulemaking.

However, because the history and structure of the Medicare program dictate that claims processing, customer service, and program integrity functions are highly interdependent, and since sections 1816, 1842, 1893 and 1874A of the Act are part of the same legislative development relating to Medicare administration, we will from time-to-time discuss the section 1874A of the Act authority and its potential impact on fiscal intermediaries, carriers, and the MIP contractors in this preamble. Further, this proposed rule was modified from our earlier proposal on this topic to make clear that section 1874A of the Act authorizes MAC contractors to perform functions of section 1893 of the Act. We also make clear that we may impose certain MIP requirements (for example, those proposed for § 421.302(a)) on the MACs when we elect to include functions of section 1893 of the Act in their contracts. Finally, it is our intention that the proposed rule changes at § 421.100 and § 421.200 discussed below would remain in effect only until all the Medicare fiscal intermediary and carrier contracts are replaced by MAC contracts in accordance with the MMA.

The MMA establishes a phase-in process for the transition of the current contractors to MACs. We are currently in the process of developing the Statement of Work (SOW) and

performance requirements for MACs, and further regulatory and administrative guidance will be published as these details are developed. More information about our plans to implement Medicare contracting reform, including our Report to the Congress on this subject, can be obtained by accessing the Internet at *http://www.cms.hhs.gov/medicarereform/contractingreform/*.

C. The Medicare Integrity Program

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191) was enacted on August 21, 1996. Section 202 of HIPAA added new section 1893 to the Act establishing the Medicare Integrity Program (MIP). This program is funded from the Medicare Hospital Insurance Trust Fund for program integrity activities. Specifically, section 1893 of the Act expands our contracting authority to allow us to contract with eligible entities to perform Medicare program integrity activities. These activities include: Medical, potential 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 DME 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:

- Procedures for identifying, evaluating, and resolving organizational conflicts of interest that are consistent with rules generally applicable to Federal acquisition and procurement.
- Competitive procedures for entering into new contracts under section 1893 of the Act and for entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier, and other procedures we deem appropriate.
- A process for renewing contracts entered into under section 1893 of the Act.

Section 1893(d) of the Act also specifies the process for contracting with eligible entities to perform program integrity activities. 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.

The Congress established section 1893 of the Act to strengthen our ability to deter potential 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 were 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 potential 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 potential fraud and abuse. The funding mechanism will help us shift emphasis from post-payment recoveries on potentially 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 generally in use in 1996, section 1893 of the Act greatly expands our contracting authority relative to the contracting authority of original sections 1816 and 1842 of the Act. 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 of the Act allows us to attract a variety of offerors with potentially new and different skill sets and permits those offerors to propose innovative approaches to implement MIP to deter potential fraud and abuse. By using competitive procedures, as established in the FAR and supplemented by the Department of Health and Human Services Acquisition Regulation (HHSAR), our ability to manage the MIP activities is greatly enhanced, and we can seek to obtain the best value for our contracted services.

Third, section 1893 of the Act requires us to address potential conflicts of interest among prospective MIP contractors before entering into any contracting arrangements with them. Section 1893 of the Act instructs the Secretary to establish procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to FAR contracts.

D. Experience With MIP Contractors

The MIP authority, established by HIPAA, gave CMS specific contracting authority, consistent with the FAR, to enter into contracts with entities to promote the integrity of the Medicare program.

On March 20, 1998, we issued a proposed rule to implement provisions of section 1893 of the Act to which we received comments (63 FR 13590). We reviewed and considered all the comments received concerning the MIP regulation. Comments received addressed a variety of issues, such as conflict of interest issues, coordination among Medicare contractors, contractor functions, and eligibility requirements. Overall, we found that few changes were needed to the regulatory text. Due to time constraints, however, a final rule was never published. Notwithstanding, section 1893 of the Act granted us the authority to contract with eligible entities to perform program integrity activities prior to publication of the final rule.

Section 902 of the MMA mandated that final rules relating to the Medicare program based on a previous publication of a proposed regulation or an interim final regulation be published within three years except under exceptional circumstances. Given that it has been greater than three years since the publication of the initial proposed MIP regulations, we are reissuing these regulations in proposed form at this time.

The publication of the 1998 proposed rule (63 FR 13590) enabled us to contract with entities to perform Medicare program integrity functions to promote the integrity of the Medicare program prior to the publication of a final rule.

Since the publication of the 1998 proposed rule and in accordance with this MIP authority, we currently maintain the following MIP contracts: 12 Indefinite Delivery-Indefinite Quantity (IDIQ) contracts for the Program Safeguard Contractor (PSC) effort; one Coordination of Benefits (COB) contract, and 8 IDIQ contracts for the Medicare Managed Care (MMC) Program Integrity Contractors effort. (IDIQ contracts are explained in detail in FAR 48 CFR subpart 16.5.) After being awarded an IDIQ contract, organizations can competitively bid on task orders released by CMS to specifically address program integrity issues within the scope of the IDIQ contract. These MIP contractors are discussed below.

1. Program Safeguard Contractors (PSCs)

Since 1999, we have awarded more than 40 individual task orders under the PSC IDIQ contract, including 17 Benefit Integrity (BI) Model PSCs. These BI PSCs are tasked with performing fraud and abuse detection and prevention activities for their respective jurisdictions. Specific activities include fraud case development, local and national data analysis to identify potentially fraudulent billing schemes or patterns, law enforcement support, medical review for a BI purpose, and identification and development of appropriate administrative actions. Four of the 17 BI PSCs have additional medical review functions. The remaining task orders issued under the PSC IDIQ contract have focused on specific program vulnerabilities and problem areas (for example, Comprehensive Error Rate Testing (CERT), Correct Coding Initiative (CCI), and Data Assessment & Verification (DAVe)). More information on PSCs can be accessed on the Internet at *http://www.cms.hhs.gov/PROVIDERS/PSC/pscwebp2.asp.*

Overall, we have seen success in the implementation of the PSC program. Since 2002, 12 of the 17 BI Model PSCs were awarded and transitioned. Typically, a 3 to 6 month period was allowed for the PSCs to transition the BI workload from the Fiscal Intermediary and Carrier that had previously been performing this workload.

2. Coordination of Benefits Contractor (COB)

In November 1999, we awarded one COB contract to consolidate activities that support the collection, management, and reporting of other health insurance coverage for Medicare beneficiaries. The purposes of the COB program are to identify the health benefits available to a Medicare beneficiary and to coordinate the payment process to prevent mistaken payment of Medicare benefits. In January 2001, the COB contractor assumed all Medicare Secondary Payer (MSP) claims investigations. Implementing this single-source development approach greatly reduced the amount of duplicate MSP investigations. It also offered a centralized, one-stop customer service approach for all MSP-related inquiries, including those seeking general MSP information, except for those related to specific claims or recoveries that serve to protect the Medicare Trust Funds.

3. Medicare Managed Care Program Integrity Contractors (MMC–PICs)

MMC–PICs supplement our regional office integrity responsibilities related to Medicare Advantage (MA), formerly known as Medicare+Choice (M+C). Similar to the PSC, MMC–PIC was designed specifically to identify, stop, and prevent fraud, waste, and abuse.

Services performed under MMC–PIC include—

- Complete monthly analysis of plan discrepancies and report to MA Organizations;
- Review and analyze State regulatory practices;
- Evaluate marketing operations;
- Audit financial and medical records including claims, payments, and benefit packages;
- Evaluate enrollment and encounter data;
- Collect information and review matters that may contain evidence of fraud, waste, and abuse and make referrals to the appropriate government authority;
- Compliance testing of internal controls of Health Care Prepayment Plan (HCPP) contracting organizations;
- Complete all Retroactive Payment Adjustments and Retroactive Enrollments or Disenrollments submitted by MA Organizations;
- Complete final reconciliation of payment for non-renewals of MA contracts; and,
- Make reconsideration determinations with plans that request decisions regarding payments.

II. Provisions of the Proposed Rule

[If you choose to comment on issues in this section, please include the caption ''Provisions of the Proposed Rule'' at the beginning of your comments.]

This regulation is part of our overall contracting strategy, which is designed to build on the strengths of the marketplace. 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.

As discussed earlier in the background section, the implementation of section 1874A of the Act is also a major element of our contracting strategy. We are not including extensive rules relating to that authority in this proposal, for the reasons discussed earlier, but interested parties can gain information about our plans for implementing section 1874A of the Act by accessing the Internet at *http://www.cms.hhs.gov/medicarereform/contractingreform.* In addition, the public can also send us informal questions about the Medicare administrative contractor (MAC) implementation through this site; any official comments on this proposed rule should be submitted in accordance with the instructions contained in the ''Addresses'' section of this preamble.

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 will:

- Define the types of entities eligible to become MIP contractors. We also clarify that, in accordance with section 1874A of the Act, a MAC may perform MIP functions under certain conditions;
- Identify 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 consistent with the FAR;
- Prescribe responsibilities; and,
- Set forth limitations on MIP contractor liability.

Subpart D will apply 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 (§ 421.302)

In accordance with section 1893(c) of the Act, proposed § 421.302(a) would provide that an entity is eligible to enter into a MIP contract if it:

- Demonstrates the capability to perform MIP contractor functions;
- Agrees to cooperate with the Office of Inspector General (OIG), the Department of Justice (DOJ), and other law enforcement agencies in the investigation and deterrence of potential fraud and abuse in the Medicare program, including making referrals;
- 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;
- Maintains an appropriate written code of conduct and compliance

policies that include, without limitation, an enforced policy on employee conflicts of interest;

• Meets financial and business integrity requirements to reflect adequate solvency and satisfactory legal history; and,

• 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 DME items that are subject to prior authorization.

It is not possible to identify in this rule each and every possible contractor eligibility requirement that may appear in a future solicitation. In order to permit us maximum flexibility to tailor our contractor eligibility requirements to specific solicitations while satisfying the intent of section 1893 of the Act, any contractor eligibility requirements in addition to those specified in proposed § 421.302(a)(1) through (a)(4) will be contained in the applicable solicitation.

At § 421.302(b)(1), we propose to make clear that a MAC under section 1874A of the Act may perform any or all of the MIP functions as are listed and described in § 421.304. However, in performing such functions, the MAC may not duplicate work being performed under a MIP contract. We believe this proposed provision is consistent with sections 1874A(a)(4)(G) and 1874A(a)(5) of the Act, as added by the MMA.

At § 421.302(b)(2), we also make clear our discretion to require a MAC performing any of the MIP functions under § 421.304 to abide by the eligibility requirements applicable to MIP contracts, that is, the four elements listed at § 421.302(a). The first requirement at § 421.302(a) relating to demonstrated capability and the third requirement relating to addressing conflicts of interest are consistent with provisions in the authorizing statute for MAC contracts (section 1874A(a)(2)of the Act). While the second requirement, which pertains to cooperation with the OIG and other forms of law enforcement, is not reiterated in section 1874A of the Act, we believe this requirement is not inconsistent with section 1874A of the Act or the FAR. This requirement is, in fact, compatible with our general practices, multiple statutes and regulations governing HHS operations and contracts, and finally also with provisions within title XI of the Act. Once again, the fourth requirement makes clear our authority to impose additional reasonable requirements through contract and it makes sense to apply this element to MAC contractors. Our specific approach to all these issues, of course, will be made clear in any solicitation for MAC contracts.

Note that, in accordance with section 1893(d) of the Act, we may continue to contract, for the performance of MIP activities, with fiscal intermediaries and carriers that had a contract with us on August 21, 1996 (the effective date of enactment of Pub. L. 104–191). However, in accordance with sections 1816(l) or 1842(c)(6) of the Act (both added by Pub. L. 104–191), and section 1874A(a)(5)(A) of the Act (added by the MMA), these contractors as well as MACs may not duplicate activities under a fiscal intermediary agreement or carrier contract and a MIP contract, with one excepted activity. The exception permits a carrier or a MAC to develop and update a list of items of DME that are subject to prior authorization both under the MIP contract and its contract under section 1842 of the Act. This discretion to continue the performance of MIP activities through the fiscal intermediary and carrier contracts until they are phased out in accordance to section 911(d) of the MMA, is provided for in proposed changes to § 421.100 and § 421.200 discussed later in this preamble.

3. Definition of MIP Contractor (§ 400.202)

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 exclusively one or more of the program integrity activities specified in that section. The inclusion of the word ''exclusively'' in this definition is intended to conform with section 1874A(a)(5)(B) of the Act as added by the MMA.

4. Services to be Procured (§ 421.304)

A MIP contractor may perform some or all of the MIP activities listed in § 421.304. Section 421.304 would state that the contract between CMS 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 potential 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 or suppliers and other individuals and entities (including health maintenance organizations, competitive medical plans, health care prepayment plans, and MA plans). This function results in the identification of overpayments, prepayment denials, recommendations for changes in national coverage policy, changes in local coverage determinations (LCD) policies and payment screens, referrals for potential fraud and abuse, and the identification of the education needs of beneficiaries, providers, and suppliers.

Potential 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 potential fraud cases for referral to law enforcement. Each solicitation will specify when cases should be referred to the OIG or other law enforcement agency. In general, however, identified overpayments, recurring acts of improper billing, and substantiated allegations of potentially fraudulent activity will be promptly referred to a Regional OIG.

(b) Cost report audits. Providers and managed care plans receiving Medicare payments are subject to audits 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 recommended settlement terms for 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 making 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 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 DME items that, in accordance with section 1834(a)(15) of the Act, are subject to prior authorization. Prior authorization is a determination that an item of DME is covered prior to when the equipment is delivered to the Medicare beneficiary. Section 1834(a)(15) of the Act requires prior authorization to be performed on the following items of DME:

- 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.

We note that the MIP functions are not limited to services furnished under fee-for-service payment methodologies. MIP functions apply to all types of claims. They also apply to all types of payment systems including, but not limited to, managed care and demonstration projects. MIP functions will also apply to payments made under the Medicare Part D prescription drug benefit that will be implemented on January 1, 2006.

5. Competitive Requirements (§ 421.306)

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. Furthermore, in accordance with section 1893(d)(2) of the Act, we would specify that the procedures set forth in these authorities will be used: (a) When entering into new contracts; (b) when entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier; and (c) at any other time we consider appropriate.

In proposed § 421.306(b), we will establish an exception to competition that allows a successor in interest to a fiscal 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 provision will remain in effect until all fiscal intermediary agreements and carrier contracts are transitioned to MACs in accordance with section 911(d) of the MMA.

This proposal is made in anticipation that some fiscal intermediaries and carriers, prior to the competition of their contracts in accordance with the MMA, 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 fiscal intermediary's or carrier's MIP activities are transferred along with its other Medicare-related resources to the successor in interest. For example, the fiscal 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, we 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 fiscal intermediary or carrier was performing program integrity activities under its contract on August 21, 1996, the date of the enactment of the MIP legislation, the statute permits us to continue to contract with the fiscal intermediary or carrier for the performance of those activities without using competitive procedures (but only through and, no later than, September 30, 2011). 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, we may determine that breaking out the MIP activities and competing them separately (prior to the MAC contract competitions) 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, the statute states that fiscal intermediary agreements and carrier contracts will be noncompetitively awarded under sections 1816(a) and 1842(b)(1) of the Act. Furthermore, those agreements and contracts have, in recent years prior and subsequent 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. 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 a fiscal intermediary agreement or carrier contract is consistent with the Congress' authorization to forego competition when the contracting entity was carrying out the MIP functions on the date of enactment of the MIP legislation. Section 421.306(b) permits continuity in the performance of the MIP functions until such time as we determine a need to procure MIP functions on the basis of full and open competition.

The exception to competition will operate only where a fiscal intermediary or carrier that performed program integrity functions under an agreement or a contract in place on August 21, 1996, transfers its functions by means of a valid novation agreement in accordance with the requirements of the FAR. This exception is intended to be applied only until we are prepared to award MIP contracts on the basis of FAR competitive procedures, or until we compete the full fiscal intermediary and carrier workloads (both MIP and non-MIP functions) in accordance with the MMA. The exception is not intended, and will not be used, to circumvent the competitive process when we make competitive awards of MIP and MAC contracts. This provision is intended to provide us with flexibility in handling Medicare functions in the face of *bona fide* changes in corporate structure that often have little, if anything, to do with the Medicare program.

We 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.

6. Renewal of MIP Contracts (§ 421.308)

Proposed § 421.308(a) specifies that an initial contract term will be defined 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 if a reassignment of the functions becomes necessary (either because the contractor has given notice of its intent to non-renew 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 results in the contract will contain further details regarding this provision.)

The renewal clause referred to in this section is not an ''option'' as defined in the FAR at 48 CFR 2.101. Section 1893 of the Act allows for the renewal of MIP contracts without regard to any provision of the law requiring competition if the contractor has met or exceeded performance requirements. As stated in FAR 48 CFR 2.101, '' 'Option' means a unilateral right in a contract by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the contract, or may elect to extend the term of the contract.''

As described in the FAR, 48 CFR subpart 17.2, an option is different than a renewal clause in several respects. The length of time of an option is established in a contract. In contrast, the length of a renewal period in a MIP contract may not be defined. Furthermore, an option must be exercised during the life of the contract. A MIP renewal clause can be invoked only after the exhaustion of the initial contract period of performance, including any option provisions. Finally, an option allows us to extend the term of a contract only up to 60 months, the maximum term allowed by the FAR (excluding GSA awards). A MIP contract renewal clause allows the term of a MIP contract to surpass that limit, as long as the contractor meets the conditions in the regulation and the contract (including performance standards established in its contract) and we have a continuing need for the supplies or services under contract.

Based on section 1893(d)(3) of the Act, we would specify, in § 421.308(b), 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 the 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 non-renewal. This is consistent with our longstanding policy for fiscal intermediary and carrier contracts.

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

When soliciting for MIP contracts, we will adhere to the requirements of the FAR organizational conflict of interest guidance, found at 48 CFR subpart 9.5. Given 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, we will maintain the rebuttable presumption that each prospective contract involves a significant potential organizational conflict of interest. In light of this presumption, we will apply the general rules in FAR 905.5 and such requirements as may be applicable to an individual procurement.

Prior to awarding a MIP contract, our contracting officer will fashion an organizational conflict of interest clause specific to the contractor for inclusion in the contract. In general, we will 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.

In § 421.310(a), we will specify that an offeror for MIP contracts is, and MIP contractors are, subject to the conflict of interest standards and requirements of the FAR organizational conflict of interest guidance, found at 48 CFR subpart 9.5, and the requirements and standards as are contained in each individual contract awarded to perform functions found at section 1893 of the Act.

In § 421.310(b), we state that we consider that a conflict of interest has occurred if, during the term of the contract, the contractor or its employee, agent or subcontractor has received, solicited, or arranged to receive any fee, compensation, gift, payment of expenses, offer of employment, 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 MIP contract. We incorporate the definition of ''gift'' from 5 CFR 2635.203(b) of the Standards of Ethical Conduct for Employees of the Executive Branch, which excludes from the definition items such as greeting cards, soft drinks, and coffee.

We also specify in § 421.310(b), if we determine that the contractor's activities are creating a conflict, then a conflict of interest has occurred during the term of the contract. 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 for default.

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.

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.

Because potential offerors may have questions about whether information submitted in response to a solicitation, including information regarding potential conflicts of interest, may be redisclosed under the Freedom of Information Act (FOIA), we provide the following information.

To the extent that a proposal containing information 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 FOIA. 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 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).

Any proposal containing the information submitted to us under an authority other than 41 U.S.C. Chapter 4, Subchapter IV, and any 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 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, 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. It should be noted that the protection of proposals under FOIA does not preclude CMS from releasing contractor proposals when necessitated by law, such as in the case of a lawful subpoena.

We already protect information we receive in the contracting process. However, to allay any fears potential offerors might have about disclosure, at § 421.312(d) we propose to provide, that we protect disclosed proprietary information as allowed under the FOIA 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 § 421.312, we describe how conflicts of interest are resolved. We specify that we may establish a Conflicts of Interest Review Board to assist the contracting officer in resolving conflicts of interest and we determine when or if 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 for default; or,
- It is in the best interest of the Government to contract with the offeror or contractor even though the conflict exists.

The following are 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. 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, subject to our approval, 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 the most highly rated proposals that have a reasonable chance for contract award unless the range is further reduced for purposes of efficiency in accordance with FAR 15.306. 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 mitigation plan. At any time during the procurement process, we may convene the Conflict of Interest Review Board to evaluate and assist the contracting officer in resolving 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 hinder competition in their service areas by misusing their position as a MIP contractor.

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

Contractors which 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 a Quality Improvement Organization (QIO) (formerly Peer Review Organization (PRO)) that contracts to carry out functions under section 1154(e) of the Act. Specifically, section 1157 of the Act provides that QIOs, their employees, fiduciaries, and anyone who furnishes professional services to a QIO, 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) of the Act, 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) of the Act, 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(a), 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) of the Act 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 fiscal intermediary agreements and carrier contracts. Generally, fiscal intermediaries and carriers are indemnified for any liability arising from the performance of contract functions provided the fiscal 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) of the Act does not provide that authority. Note however, that section 1874A of the Act as added by the MMA would provide us with some discretion to indemnify MAC contractors. In addition, proposed § 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 a fiscal intermediary, requires only that nominated fiscal 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. Section 911 of the MMA eliminates the requirement that fiscal intermediaries be nominated, and effective October 1, 2005, establishes the requirement that Medicare contracts awarded to MACs be competitively bid by September 30, 2011.

Our existing requirements at § 421.100 and § 421.200 concerning functions to be included in fiscal 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 fiscal intermediaries and those functions, which although not required to be performed by fiscal intermediaries, may be included in fiscal 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.

The February 1994 proposed rule was never finalized, but its content was re-proposed in our initial 1998 proposed rule for the MIP program (63 FR 13590). This second proposed rule sets forth a new proposal to bring those sections of the regulations that concern the functions Medicare fiscal intermediaries and carriers perform into conformity with the provisions of sections 1816(a), 1842(a), and 1893(b) of the Act, for so long as the fiscal intermediary and carrier contracts exist until they are all replaced by MAC contracts.

As noted in section I.A. of this preamble, our current regulations at § 421.100 specify a list of functions that must, at a minimum, be included in all fiscal 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.

Until October 1, 2005, section 1816(a) of the Act, in its present form, requires only that a fiscal intermediary agreement provide for determination of the amount of payments to be made to providers and for the making of the payments. Pending the effective date of changes made by the MMA, section 1816(a) permits, but does not require, a fiscal intermediary agreement to include provisions for the fiscal 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 fiscal intermediary makes payments, the fiscal 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.

Section 1816(a) of the Act, in its present form until October 1, 2005, mandates only that a fiscal intermediary make payment determinations and make payments and, because of the nomination provision of section 1816(a) of the Act, these functions must remain with fiscal intermediaries. We believe that, pending the effective date of changes made by the MMA, section 1816(a) of the Act does not require that the other functions set forth at § 421.100(c) through (i) be included in all fiscal intermediary agreements. Furthermore, section 1893 of the Act permits the performance of functions related to Medicare program integrity by other entities. Thus, § 421.100 would be revised to be consistent with section 1893 of the Act and the implementing regulation. The 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 fiscal 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 fiscal intermediary and to transfer all functions to a new contractor, which may not have had an ongoing relationship with the local provider community.

Therefore, we will revise § 421.100 to state that an agreement between CMS and a fiscal intermediary specifies the functions to be performed by the fiscal 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 is 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 with other related purposes.

• Upon inquiry, assisting individuals with matters pertaining to a fiscal 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 a fiscal intermediary contract.

• Undertaking other functions as mutually agreed to by us and the fiscal intermediary.

In § 421.100(c), we specify that, for the responsibility for services to a provider-based HHA or a provider-based hospice, when different fiscal intermediaries serve the HHA or hospice and its parent provider under § 421.117, the designated regional fiscal intermediary determines the amount of payment and makes payments to the HHA or hospice. The fiscal intermediary 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.

Pending the effective date of changes made by the MMA, section 1842(a) of the Act, which pertains to carrier contracts, requires that the contracts 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 fiscal 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 fiscal 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 state that a contract between CMS 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 DME 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, and because we may eventually propose regulations pertaining to MAC contracts, 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 a fiscal intermediary or a carrier. If the action being described may now be performed by a MIP contractor that is not a fiscal intermediary or a carrier, we would revise those sections to indicate that this is the case. For 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 fiscal intermediary. A MIP contractor now may also perform the verification. Therefore, we will revise § 424.11(a)(2) to specify that the provider must keep certification and recertification statements on file for verification by the fiscal intermediary or MIP contractor. Because our regulations are continuously being revised and sections redesignated, we have not identified all sections that will have technical changes in this proposed rule, but we may 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

This document does not impose new information collection and recordkeeping requirements subject to the Paperwork Reduction Act of 1995 (PRA). Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the PRA of 1995.

V. Regulatory Impact Statement

A. Introduction

[If you chose to comment on issues in this section, please include the caption ''Regulatory Impact Statement'' at the beginning of your comments.]

We have examined the impacts of this proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 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. Fiscal

intermediaries and carriers are not considered to be small entities.

Section 1102(b) of the 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

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. On March 20, 1998, we issued a proposed rule to implement provisions of section 1893 of the Act (63 FR 13590). Section 1893 of the Act grants us the authority to contract with eligible entities to perform program integrity activities prior to a final rule being published. Since the publication of the 1998 proposed rule, this authority has allowed us to enter into contracts, consistent with FAR, with new specialty contractors to promote the integrity of the Medicare program, despite a final rule never being published.

Section 902 of the MMA mandates that final rules based on a previous publication of a proposed regulation or an interim final regulation must be published within three years except under exceptional circumstances. Given that it has been greater than three years since the publication of the initial proposed Medicare Integrity Program regulations, we are publishing this new proposed rule in order to maintain our authority to enter into contracts with contractors to promote the integrity of the Medicare program. However, our experience in contracting with entities to perform MIP functions allows us to discuss some of the successes we have had with MIP.

The objective of this proposed regulation is to maintain our authority to contract with entities to perform program integrity functions, and to provide a procurement procedure to supplement the requirements of the FAR and specifically address contracts to perform MIP functions identified in the law.

According to the previously published proposed rule and mirrored in this current proposed rule, the following functions, as specified below, may be performed under MIP contracts:

- Review of provider activities such as medical review, utilization review, and potential 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 DME items that are to be subject to prior approval provisions.

C. Discussion of Impact

Our MIP experience since 1999 suggests that this rule will continue to have a positive impact on the Medicare program, Medicare beneficiaries, providers, suppliers, and entities that have not previously contracted with us. Existing MIP contractors that seek renewal of MIP contracts should not expect any additional costs in complying with the requirements set forth in the rule, as these requirements are similar yet more streamlined than those set forth in the 1998 proposed rule and are currently applied by MIP contractors. To the extent that small entities could be affected by the rule, and because the rule raises certain policy issues for conflict of interest standards, we provide an impact analysis for those entities that 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: (1) The Medicare program and Health Insurance Trust Fund; (2) Medicare beneficiaries and taxpayers; (3) current fiscal intermediaries and carriers; (4) entities that have not previously contracted with us; and (5) Medicare providers and suppliers.

1. The Medicare Program and Health Insurance Trust Fund

HIPAA provides for a direct apportionment from the Health Insurance Trust Fund for program integrity activities to thwart improper billing practices. Appropriations totaled $700 million for 2002, and $720 million for FY 2003 and all subsequent years.

A separate and dependable long-term funding source for MIP allows us the flexibility to invest in innovative strategies to combat the fraud and abuse drain of the Medicare 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, estimates suggest that the percentage of improper Medicare fee for service payments as compared to total fee for service payments have declined since the implementation of MIP contractors:

Year	Improper payment (in billions)	Percentage of FFS total (percent)	Total FFS payments (in billions)
1998	$12.6	7.1	$176.1
1999	13.5	7.97	169.5
2000	11.9	6.8	173.6
2001	12.1	6.3	191.8
2002	13.3	6.3	212.7
2003	11.6	5.8	200
2004	19.9	9.3	[1] 213.5

[1] Since 1996, HHS has annually determined the rate of improper payments for fee-for-service claims paid by Medicare contractors. The survey measures claims found to be medically unnecessary, inadequately documented, or improperly coded. From 1996 until 2002, the survey was conducted by the OIG based on a survey of some 6,000 claims. In 2003, CMS launched an expanded effort, reviewing approximately 128,000 Medicare claims to learn more precisely where errors are being made. The 2003 figures used in the above table reflect the adjusted error rate figures. The unadjusted figures, calculated using CMS' expanded effort, were $19.6 billion for improper payment and an error rate of 9.8. The numbers reported for 2004 are unadjusted and reflect CMS'' findings since employing its expanded effort.

We should note that the positive error rate trend also relates to other initiatives including fiscal intermediary and carrier education efforts, partnering with the American Medical Association (AMA), and anti-fraud and abuse efforts such as Operation Restore Trust.

In 2004, we announced new steps to measure error rates in Medicare payments more accurately and comprehensively at the contractor level,

and to further reduce improper payments through targeted error improvement initiatives. Under the new measurement process for the Medicare error rate, the net national rate for fiscal year 2004 was 9.3 percent. This error rate is not comparable to the rates determined by the previous method used by CMS. We hope to reduce the error rate by more than half to 4.7 percent in four years, by building on recent reforms in payment oversight and new authorities in the Medicare law.

In addition to economic advantages, MIP funding and contracting improvements will allow us to better serve Medicare beneficiaries in a qualitative way. MIP gives us a tool to better administer the Medicare program and accomplish our mission of providing access to quality health care for Medicare beneficiaries. We will continue to use competitive procedures to contract separately for the performance of integrity functions. In general, economic theory postulates that competition results in a better price for the consumer which, in this instance, is CMS 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

MIP contracts have had, and we expect will continue to have, an overall 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 Fund 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 evidence, MIP funds have contributed to a reduction in the total percentage of improper payments made for fee-for-service (FFS) claims paid in 2003 to 5.8 [2] percent of all FFS claims, down from 7.1 percent of FFS claims in 1998.[3] As a result, current and future beneficiaries will obtain more value for every Medicare dollar spent.

3. Current Fiscal Intermediaries and Carriers

Although fiscal intermediaries and carriers are not considered small entities for purposes of the RFA, and effective October 1, 2005, we have the authority to replace the current Medicare fiscal intermediary and carrier contracts with new MAC contracts, we are providing the following analysis.

There are currently 25 Medicare fiscal intermediaries and 18 Medicare carriers plus 4 DME regional contractors which are also carriers. Presently, all these contractors perform general program integrity activities addressed in this proposed rule apart from, but not duplicative of, MIP contractors. In FY 2004, approximately 29 percent of the total contractor budget was dedicated to program integrity.

Current fiscal intermediaries and carriers are not prohibited from entering into MIP contracts when we compete contracts for section 1893 of the Act activities. Medical directors continue to play an important role in medical review activities, and locally-based medical directors improve our relationship with local physicians by using groups like Carrier Advisory Committees. Locally-based fraud investigators and auditors are being used as necessary. Upon the publication of this proposed regulation, we anticipate that review policies will continue to be coordinated across contractors to ensure consistency, while local practice will continue to be incorporated where appropriate.

This rule may have had a negative impact on current fiscal intermediaries and carriers in some respects. Many current fiscal intermediaries and carriers may have lost a portion of their Medicare business since 1998 as fraud review functions were transferred to MIP contractors. These contractors may have some additional functions transferred to MIP contractors in the next few years. Nevertheless, the effects of section 911 of the MMA will be more significant on the current fiscal intermediary and carrier.

However, current contractors have benefited from the MIP program and will benefit from this proposed rule. Under the provisions of this proposal, 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 but not renewed 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 at the time of contracting, situations that may constitute conflicts of interest in accordance with the FAR, subpart 9.5. 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 fiscal intermediaries and carriers is lessened by the proposed approach when compared to the alternatives we considered.

The current contractors that are awarded MIP contracts, or that continue to perform MIP functions under their fiscal intermediary or carrier contracts, will also benefit from more consistent funding provided by the law for program integrity activities. This more stable, long-term funding mechanism enables Medicare contractors to attract, train, and retain qualified professional staff to assist these contractors to fulfill their program integrity functions.

There will be an economic impact on current contractors that propose to perform MIP contracts using subcontractors. 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. However, our requirements rely heavily on FAR subpart 9.5, which normally apply to both prime contractors and subcontractors. Thus, we do not believe this provision imposes any additional negative burden on current fiscal intermediaries or carriers.

4. New Contracting Entities

Entities that have not previously performed Medicare program integrity activities will experience a positive

[2] This 2003 figure reflects the adjusted error rate figures. The unadjusted figures, calculated using CMS' expanded effort, were $19.6 billion for improper payment and an error rate of 9.8%. See note 1 for more detail.

[3] From 1996 until 2002, the HHS OIG used a sample size of about 6,000 claims to conduct the process used to measure Medicare payment error rates. The measured error rate declined from 13.8 percent in 1996 to 6.3 percent in 2002. In fiscal year 2003, and as part of the agency's enhanced efforts to improve payment accuracy, CMS began calculating the Medicare FFS error rate and estimate of improper claim payments using a new methodology approved by the OIG. Under the new measurement process for the Medicare error rate, the net national rate for fiscal year 2004 was 9.3 percent.

effect from this rule. Integrity functions such as audit, medical review, and potential 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.

Since the publication of the 1998 proposed rule and in accordance to this MIP authority, we have awarded 12 Indefinite Delivery-Indefinite Quantity (IDIQ) contracts for the Program Safeguard Contractor (PSC) effort, one Coordination of Benefits (COB) contract, and 8 IDIQ contracts for the Medicare Managed Care Program Integrity Contractors (MMC–PICs) effort. With the forthcoming implementation of the Part D prescription drug benefit included in the MMA, there will be further opportunities for new entities to compete for MIP contracts to perform program oversight activities for this new benefit.

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 benefited the private insurance arena.

5. Providers and Suppliers

Because MIP contractors have been in place since 1998, we anticipate no additional 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 1.1 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.

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.

D. Conclusion

Since the publication of the 1998 proposed rule, we have awarded MIP contracts to contractors in order to perform program integrity activities and there has been a decrease in the percentage of improper claims paid. In anticipation of our continued authority to award contracts to entities to continue these activities, we have announced initiatives to measure error rates in Medicare payments more accurately and comprehensively, and to further reduce improper payments.

We conclude that our continued authority would save the Medicare program additional money and extend the solvency of the Trust Funds 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.

For reasons set forth in the preamble in this proposed regulation, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapter IV as follows:

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 CMS under section 1893 of the Act to perform exclusively one or more of the program integrity activities specified in that section.

* * * * *

PART 421—MEDICARE CONTRACTING

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

4. 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).

5. Section 421.1 is revised to read as follows:

§ 421.1 Basis, applicability, and scope.

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

Section 1124—Requirements for disclosure of certain information.

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

Section 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 fiscal intermediary agreements and carrier contracts.

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

(d) *Scope.* The scope of this part is as follows:

(1) Specifies that CMS may perform certain functions directly or by contract.

(2) Specifies criteria and standards CMS uses in selecting fiscal intermediaries and evaluating their performance, in assigning or reassigning

a provider or providers to particular fiscal intermediaries, and in designating regional or national fiscal intermediaries for certain classes of providers.

(3) Provides the opportunity for a hearing for fiscal intermediaries and carriers affected by certain adverse actions.

(4) Provides adversely affected fiscal intermediaries an opportunity for judicial review of certain hearing decisions.

(5) Sets forth requirements related to contracts with Medicare integrity program contractors.

6. Section 421.100 is revised to read as follows:

§ 421.100 Intermediary functions.

An agreement between CMS 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 is determined that an overpayment was made.

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

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

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

(6) Upon inquiry, assisting individuals for matters pertaining to an intermediary agreement.

(7) Serving as a channel of communication to and from CMS 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 CMS and the intermediary.

(c) *Dual intermediary responsibilities.* For 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 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.

7. Section 421.200 is revised to read as follows:

§ 421.200 Carrier functions.

A contract between CMS 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 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.

(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 DME 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 is determined that an overpayment was made.

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

(f) Maintaining records and making available to CMS 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 is granted an opportunity for a fair hearing so long as these functions are not being performed by a Qualified Independent Contractor under section 1869 of the Act.

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

(i) Serving as a channel of communication to and from CMS 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 CMS and the carrier.

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

Subpart D—Medicare Integrity Program Contractors

Sec.

421.300 Basis, applicability, and scope.
421.302 Eligibility requirements for Medicare integrity program contractors.
421.304 Medicare integrity program contractor functions.
421.306 Awarding of a contract.
421.308 Renewal of a contract.
421.310 Conflict of interest requirements.
421.312 Conflict of interest resolution.
421.316 Limitation on Medicare integrity program contractor liability.

Subpart D—Medicare Integrity Program Contractors

§ 421.300 Basis, applicability, and scope.

(a) *Basis.* This subpart implements section 1893 of the Act, which requires CMS to protect the integrity of the Medicare program by entering into contracts with eligible entities to carry out Medicare integrity program functions. The provisions of this subpart are based on section 1893 of the Act (and, where applicable, section 1874A of the Act) and the acquisition regulations set forth at 48 CFR Chapters 1 and 3.

(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.* The scope of this subpart follows:

(1) Defines the types of entities eligible to become Medicare integrity program contractors.

(2) Identifies the program integrity functions a Medicare integrity program contractor performs.

(3) Describes procedures for awarding and renewing contracts.

(4) Establishes procedures for identifying, evaluating, and resolving organizational conflicts of interest.

(5) Prescribes responsibilities.

(6) Sets forth limitations on contractor liability.

§ 421.302 Eligibility requirements for Medicare integrity program contractors.

(a) CMS may enter into a contract with an entity to perform the functions described in § 421.304 if the entity meets the following conditions:

(1) 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.

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

(3) 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.

(4) Maintains an appropriate written code of conduct and compliance policies that include, without limitation, an enforced policy on employee conflicts of interest.

(5) Meets financial and business integrity requirements to reflect adequate solvency and satisfactory legal history.

(6) Meets other requirements that CMS establishes.

(b) A MAC as described in section 1874A of the Act may perform any or all of the functions described in § 421.304, except that the functions may not duplicate work being performed under a Medicare integrity program contract.

(c) If a MAC performs any or all functions described in § 421.304, CMS may require the MAC to comply with any or all of the requirements of paragraph (a) of this section as a condition of its contract.

§ 421.304 Medicare integrity program contractor functions.

The contract between CMS 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 reviews of potential fraud related to the activities of providers of services and other individuals and entities (including entities contracting with CMS under parts 417 and 422 of this chapter) furnishing services for which Medicare payment may be made either directly or indirectly.

(b) Auditing cost reports of providers of services, or other individuals or entities (including entities contracting with CMS under parts 417 and 422 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 DME 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) CMS awards and administers Medicare integrity program contracts in accordance with acquisition regulations set forth at 48 CFR chapters 1 and 3, this subpart, all other applicable laws, and all applicable regulations. These requirements for awarding Medicare integrity program contracts are used as follows:

(1) When entering into new contracts.

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

(3) At any other time CMS considers appropriate.

(b) CMS may award an entity a Medicare integrity program contract without competition if all of the following conditions apply:

(1) Through approval of a novation agreement in accordance with the requirements of the Federal Acquisition Regulation (FAR), CMS recognizes the entity as the successor in interest to a fiscal intermediary agreement or carrier contract under which the fiscal intermediary or carrier was performing activities described in section 1893(b) of the Act on August 21, 1996.

(2) The fiscal 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, 48 CFR chapters 1 and 3, and other applicable laws and regulations.

§ 421.308 Renewal of a contract.

(a) CMS specifies an initial contract term in the Medicare integrity program contract. Contracts under this subpart may contain renewal clauses. CMS may, but is not required to, 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) CMS may renew a Medicare integrity program contract without competition if all of the following conditions are met:

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

(2) The Medicare integrity program contractor meets or exceeds the performance requirements established in its current contract.

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

(c) If CMS does not renew a contract, the contract ends in accordance with its terms.

§ 421.310 Conflict of interest requirements.

(a) Offerors for MIP contracts and MIP contractors are subject to the following:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under 48 CFR subpart 9.5.

(2) The standards and requirements as are contained in each individual contract awarded to perform section 1893 of the Act functions.

(b) *Post-award conflicts of interest.* (1) CMS considers that a conflict of interest has developed if, during the term of the contract, if either of the following occurs:

(i) The contractor or its employee, agent, or subcontractor receives, solicits, or arranges to receive any fee, compensation, gift (as defined at 5 CFR 2635.203(b)), payment of expenses, offer of employment, 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.

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

(2) In the event CMS 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.

(iii) Terminate the contract for default.

§ 421.312 Conflict of interest resolution.

(a) *Review Board*. CMS may establish a Conflicts of Interest Review Board to assist the contracting officer in resolving organizational conflicts of interest and determine when the Board is convened.

(b) *Resolution*. Resolution of an organizational conflict of interest is a determination by the contracting officer that:

(1) The conflict is mitigated.

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

(3) The conflict requires that CMS modify an existing contract.

(4) The conflict requires that CMS terminate an existing contract for default.

(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) A MIP contractor, a person or an entity employed by, or having a fiduciary relationship with, or who furnishes professional services to a MIP contractor is not in violation of any criminal law or civilly liable under any law of the United States or of any State (or political subdivision thereof) 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, provided due care was exercised in that performance and the contractor has a contract with CMS under this subpart.

(b) CMS will pay a contractor, a person or an entity described in paragraph (a) of this section, or anyone who furnishes legal counsel or services to a contractor or person, a sum equal to the reasonable amount of the expenses, as determined by CMS, incurred in connection with the defense of a suit, action, or proceeding, if:

(1) The suit, action, or proceeding was brought against the contractor, such person or entity by a third party and relates to the contractor's, person's or entity's performance of any duty, function, or activity under a contract entered into with CMS 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 20, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: May 20, 2005.

Michael O. Leavitt,

Secretary.

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