DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services (CMS)

42 CFR Parts 400 and 421

[CMS–6030–F]

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: Final rule.

SUMMARY: This final rule establishes the Medicare Integrity Program (MIP) and implements program integrity activities that are funded from the Federal Hospital Insurance Trust Fund. This final rule sets forth the definitions related to 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 final rule brings certain sections of the Medicare regulations concerning fiscal intermediaries (FIs) and carriers into conformity with the Social Security Act (the Act). The rule distinguishes between those functions that the statute requires to be included in agreements with FIs and those that may be included in the agreements. It also provides that some or all of the functions may be included in carrier contracts.

DATES: *Effective Dates:* These regulations are effective on October 23, 2007.

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SUPPLEMENTARY INFORMATION:

I. Background

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 enacting 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), as those sections existed prior to the October 1, 2005 effective date of amendments made by section 911(b) and (c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA), the Congress provided that public agencies or private organizations may participate administering the Medicare program under agreements or contracts entered into with CMS.

These Medicare contractors (which are, for the purposes of this preamble, contractors that received awards under sections 1816 and 1842 of the Act prior to October 1, 2005) are known as fiscal intermediaries (FIs) and carriers. With certain exceptions, FIs 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. ''Provider'' means a hospital, a critical access hospital (CAH), a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare; or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services; or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services. ''Supplier'' is defined as a physician or other practitioner, or an entity other than a provider that furnishes health care services under Medicare.)

The former section 1842(a) of the Act authorized 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. The former section 1842(f) of the Act provided 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 was eligible for consideration for a carrier contract unless it could demonstrate that it met this definition of carrier.

Section 1842(b) of the Act provided 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, remained in effect for carrier contracts.

The former section 1816(a) of the Act authorized us to enter into agreements with public agencies or private organizations (that is, FIs) 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. Section 1816(a) gave us the authority to enter into an agreement with an entity to serve as a FI 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 MMA eliminated the requirement that FIs 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 CMS and a FI specify the functions the FI must perform. In addition to requiring any items specified by CMS in the agreement that are unique to that FI, our regulations require that all FIs 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 FIs 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, utilization patterns, and Part B redeterminations. 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 FI and carrier contracts are significantly different from standard Federal government contracts.

The Medicare FI 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 then-existing 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 FIs 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 terminating FI agreements in certain circumstances, and, similarly, § 421.205 provides for terminating carrier contracts.

Each year, the Congress appropriates funds to support Medicare contractor activities. In addition, the Medicare Integrity Program (MIP) authorized by the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA) provides funding for program integrity efforts. These funds are distributed to the contractors based on annual budget and performance negotiations, where funds are provided by program activity to each of the current Medicare contractors. Historically, approximately 33 percent of these funds were for payment for the processing of claims; an additional 25 percent of the funds were for program integrity activities. These include 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 or settling 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 operational functions.

B. Discussion About Medicare Administrative Contractors (MACs)

Section 911 of the MMA added 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 FI and carrier contractors with new MACs using competitive procedures.

In 2005, we began the process to conduct full and open competitions to replace the current contracts with MACs. (This process is required to be completed by 2011.) These MACs will handle many of the same basic functions that are now performed by FIs and carriers. Additionally, MACs may be charged with performing functions under the MIP under section 1893 of the Act. The statute does not preclude the current FIs 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 MIP contract); and specifies various requirements for the structure, terms, and conditions of these new MAC contracts. In particular, section 1874A(a)(6) of the Act specifies that the Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) 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 section 1874A of the Act, directed CMS in section 1874A(a)(6) of the Act to utilize the existing well-defined regulatory framework of the FAR.

As one element of our implementation of section 1874A of the Act, we published the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates final rule (71 FR 68228 through 68230) which made certain changes to 42 CFR 421 Subparts A and B, and established a new Subpart E, to make clear how Medicare providers and suppliers will be assigned to FIs, carriers, and MACs during the implementation period for section 1874A.

The first of the full and open MAC competitions was for the DME claims workloads. We decided to start the Medicare contractor reform initiative with the DME MAC contracts because the workload of the then-existing four durable medical equipment regional carriers (DMERCs) was stable and the risk of any significant program disruption to the provider and beneficiary communities would have been minimal. We awarded the contracts for the four specialty MACs that will handle administration of Medicare claims for DME during 2006, and we anticipate that the last of these workloads will be fully implemented by the summer of 2007.

During the initial implementation phase (2005 through 2011), we plan to compete and award contracts for 15 Part A and Part B MACs servicing the majority of all types of providers (both Part A and Part B). We designed the new MAC jurisdictions to balance the allocation of workloads, promote competition, account for the integration of claims processing activities, and mitigate the risk to the Medicare program during the transition to the new contractors. The new jurisdictions reasonably balance the number of FFS beneficiaries and providers. These jurisdictions will be substantially more alike in size than the existing FI and carrier jurisdictions, and they will promote much greater efficiency in processing Medicare's billion claims a year. On July 31, 2006, we announced that we had awarded the first of the Part A/B MAC contracts (Jurisdiction 3).

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

Section 202 of HIPAA added new section 1893 to the Act establishing the MIP. This program is funded from the Medicare Hospital Insurance Trust Fund to perform program integrity activities with respect to all parts of the Medicare program. Specifically, section 1893 of the Act expanded 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;

educating 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 performing specific Medicare program integrity activities, which 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 eliminating responsibilities of an individual FI 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 any relationship 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 stable funding source allows us the flexibility to invest in innovative strategies to combat potential fraud and abuse. The funding mechanism has helped us shift our emphasis from postpayment 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. The flexibility made possible by 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 us specific contracting authority, consistent with the FAR, to enter into contracts with entities to promote the integrity of the Medicare program.

In the March 20, 1998 **Federal Register** (63 FR 13590), we published a proposed rule that would implement provisions of section 1893 of the Act. We reviewed and considered all the timely comments received concerning the proposed MIP regulatory provisions. 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. 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 publishing the final rule.

Section 1871(a), added by 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 3 years except under exceptional circumstances. Given that it had been greater than 3 years since the publication of the initial proposed MIP regulations, we issued a second proposed rule in the **Federal Register** on June 17, 2005 (70 FR 35204 through 35220).

In the March 20, 1998 proposed rule (63 FR 13590), we outlined our authority to contract with entities to perform Medicare program integrity functions to promote the integrity of the Medicare program prior to publishing a final rule. 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; 1 Coordination of Benefits (COB) contract, 8 IDIQ contracts for the Medicare Managed Care (MMC) Program Integrity Contractors effort, 8 IDIQ contracts for the Medicare Drug Integrity Contractor (MEDIC) effort, and other contracts. (IDIQ contracts are explained in detail in FAR 48 CFR subpart 16.5.) After being awarded an IDIQ contract, organizations are given a fair opportunity to be considered for award of task orders released by CMS to specifically address program integrity issues within the scope of the IDIQ contract. These MIP contractors, which are discussed in the following section, must comply with the CMS Business Partners Systems Security Manual (BPSSM) and its operational appendices (A, B, C, and D); the CMS Policy for IT Security; and the CMS Information Security ''Virtual Handbook.'' CMS' Core Security Requirements, as defined in the CMS BPSSM, include, but are not limited to, security standards adopted under the Health Insurance Reform regulations published under the HIPAA and Title X, section 1002 of the Homeland Security Act of 2002, the Federal Information Security Management Act of 2002 (FISMA) (Pub. L. 107–296). The CMS requirements are applicable to MIP contracts and to all subcontracts to MIP contractors. The BPSSM can be found at *http://www.cms.hhs.gov/informationsecurity/.* The security requirements include the following:

- Contractor appointment of a dedicated systems security officer.
- Contractor certification for compliance with CMS Systems Security Requirements.
- Contractor administration of a systems security program.
- Contractor correction of any security deficiencies, conditions, weaknesses, findings, or gaps identified by all audits, reviews, evaluations, tests, and assessments.

• Contractor compliance with CMS' security certification and accreditation.

CMS security requirements are fully defined at *http://www.cms.hhs.gov/informationsecurity/* and will be described in detail in the MIP-related statement of work and task orders.

1. Program Safeguard Contractors (PSCs)

Since 1999, we have awarded more than 65 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 identifying and developing 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)).

Overall, we have been successful in implementing the PSC program. Since 2002, 12 of the 17 BI Model PSC contracts were awarded and transitioned. Typically, a 3 to 6 month period was allowed for the PSCs to transition the BI workload from the FI 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 the 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 most MSP-related inquiries, including those seeking general MSP information.

Another task that the COB contractor is responsible for is coordinating benefits with entities (including insurers and other benefit programs) that pay after Medicare. These entities sign a standard COB agreement for this purpose. Under a signed COB agreement, the COB contractor collects information about beneficiaries who have supplemental insurance. This information is used under Parts A and B of Medicare to cross Medicare processed claims data over to insurers or benefit programs for calculating their supplemental or tertiary payments, as applicable. This coordination of benefits is consolidated at the COB contractor. The COB contractor also has a role under Part D to collect supplemental payer information. This information is then shared and used by pharmacies to send secondary claims to supplemental payers.

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, the MMC–PIC was designed specifically to identify, stop, and prevent fraud, waste, and abuse.

Services performed by a 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

In the June 17, 2005 **Federal Register** (70 FR 35204), we published a proposed rule as part of our overall contracting strategy, which is designed to build on the strengths of the marketplace. We will continue to encourage new and innovative approaches in the marketplace to protect the Medicare Trust Funds.

As discussed in the section I.B. of this preamble, implementing 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 final rule, 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 MAC implementation through this site.

A. The Medicare Integrity Program

1. Basis, Scope, and Applicability

In accordance with section 1893 of the Act, we proposed to amend part 421 by adding a new subpart D entitled, ''Medicare Integrity Program Contractors.'' This subpart would—

• Define the types of entities eligible to become MIP contractors. 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 would 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, we proposed to add § 421.302(a) to 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 investigating and deterring 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 proposed to 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.

In the June 17, 2005 proposed rule (70 FR 35204), we stated that it is not possible to identify each and every possible contractor eligibility requirement that may appear in a future solicitation. Therefore, we proposed that 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 § 421.302(a)(1) through (a)(4) would be contained in the applicable solicitation.

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

At proposed § 421.302(b), we also clarified 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) related to demonstrated capability and the third requirement related to addressing conflicts of interest were consistent with provisions in the authorizing statute for MAC contracts (section 1874A(a)(2)of the Act). While the second requirement, which pertained to cooperation with the OIG and other forms of law enforcement, was not stated in section 1874A of the Act, we believed that 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 with provisions within Title XI of the Act. The fourth requirement clarified our authority to impose additional reasonable requirements through contract, and therefore, it made sense to apply this element to MAC contractors. Our specific approach to all these issues would be clarified in any solicitation for MAC contracts.

In accordance with section 1893(d) of the Act, we may continue to contract, for the performance of MIP activities, with FIs and carriers that had a contract with us on August 21, 1996 (the effective date of enactment of HIPAA). However, in accordance with sections 1816(l) or 1842(c)(6) of the Act (both added by HIPAA and both now repealed by the MMA), and section 1874A(a)(5)(A) of the Act (added by the MMA), these contractors and MACs (which may also perform MIP activities) may not duplicate activities under a FI 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 FI and carrier contracts until they are phased out in accordance to section 911(d) of the MMA was provided for in proposed changes to § 421.100 and § 421.200.

3. Definition of MIP Contractor (§ 400.202)

We proposed 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 identified 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 identifying 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 identifying the education needs of beneficiaries, providers, and suppliers.

Potential fraud review includes fraud prevention initiatives, responding to external customer complaints of alleged fraud, developing strategies to detect potentially fraudulent activities that may result in improper Medicare payment, and identifying and developing potential fraud cases to refer to law enforcement.

(b) *Cost Report Audits.* Providers and managed care plans receiving Medicare payments are subject to audits for all payments. The audits help ensure that proper payments are made in accordance with Medicare payment policy, verify financial information for making a final determination of allowable costs, identify potential instances of fraud and abuse, and ensure the completion of special projects. This functional area includes the receipt, processing, and settlement of cost reports based on reasonable costs, prospective payment, or any other basis; and the establishment or adjustment of the interim payment rate using cost report or other information.

(c) *Medicare Secondary Payer Activities.* The Medicare secondary payer function is a process developed as a payment safeguard to protect the Medicare program against making mistaken primary payments. The focus of this process is to ensure that the Medicare program pays only to the extent required by statute. Contractors performing Medicare secondary payer functions would be responsible for identifying Medicare secondary payer situations and pursuing the 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 were not limited to services furnished under FFS 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 also apply to payments made under the Medicare Part D prescription drug benefit that was implemented on January 1, 2006.

5. Competitive Requirements (§ 421.306)

We specified, in § 421.306(a), that MIP contracts would 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 specified that the procedures set forth in these authorities would be used: (1) When entering into new contracts; (2) when entering into contracts that may result in the elimination of responsibilities of an individual FI or carrier; and (3) at any other time we consider appropriate.

In § 421.306(b), we proposed to establish an exception to competition that allows a successor in interest to a FI 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 would remain in effect until all FI agreements and carrier contracts were transitioned to MACs in accordance with section 1874A of the Act.

The proposal was made in anticipation that some FIs 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 FI's or carrier's MIP activities were transferred along with its other Medicare-related resources to the successor in interest. For example, the FI 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 as specified in the FAR at 48 CFR 42.1200.

If the FI or carrier was performing program integrity activities under its contract on August 21, 1996, the date of the enactment of the MIP legislation, section 1893(d) of the Act permits us to continue to contract with the FI 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 was the authority to establish exceptions to those procedures. (See 48 CFR 6.3) Moreover, the statute stated that FI agreements and carrier contracts would 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 FI 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 the time 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 FI 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 FI and carrier workloads (both MIP and non-MIP functions) in accordance with section 1874A(b) of the Act. 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.

In § 421.306(c), we further specified 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) specified 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 can be 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 and resources to transfer the MIP functions if a reassignment of the functions becomes necessary (either because the contractor has given notice of its intent to nonrenew or because we have determined that reassignment is in the best interest of the Medicare program). Therefore, in § 421.308(a), we proposed to 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 would 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 subpart 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 the FAR at 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 go into effect only after exhausting 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 specified, 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.

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

7. Conflict of Interest Rules

The proposed rule established 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.

Given the sensitive nature of the work to be performed under the MIP contract(s), the need to preserve the public trust, and the history of fraud and abuse in the Medicare program, our contracting officers may include an organizational conflict of interest provision in the solicitation and subsequent contract award document, which may be tailored to each procurement. The contract provision will be consistent with the guidelines found at FAR 9.5, Organizational and consultant conflicts of interest, as well as address specific concerns for identifying, mitigating and resolving actual, apparent or perceived conflict(s) of interest. In general, the contracting officer will not enter into a MIP contract with an offeror that has been determined to have, or has the potential for, an unresolved organizational conflict of interest.

In § 421.310(a), we specified that an offeror for MIP contracts is, and MIP contractors are, subject to the organizational 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 stated 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 incorporated 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 specified in § 421.310(b) that 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 specified that, if we determine that a conflict of interest exists, we may, as we deem appropriate—

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

We also specified that the solicitation may require more detailed information than identified above. Our proposed provisions did 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 intended to minimize the reporting and recordkeeping requirements as much as is feasible, while taking into consideration our need to have assurance that MIP contractors do not have, and will not develop during the time of performance, a conflict of interest.

Because potential offerors may have questions about whether information submitted in response to a solicitation, including information regarding potential conflicts of interest, may be disclosed under a request submitted under the Freedom of Information Act (FOIA), we provided 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, and a FOIA request is made for a copy of that proposal, we will withhold the proposal to the extent authorized by law. This withholding is based upon 41 U.S.C. 253b(m). However, there is one exception to this requirement that involves any proposal that is set forth or incorporated by reference in the contract awarded to an offeror or bidder. In such cases, the FOIA does not offer presumptive categorical protection. Rather, we would withhold, under 5 U.S.C. 552(b)(4), information within the proposal 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. In such cases, we will follow the predisclosure 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 proposals such as this, we will follow the predisclosure 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 would cause a clearly unwarranted invasion of personal privacy if disclosed. 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 of commercial information, at § 421.312(d) we proposed protection of disclosed submitted proprietary information as allowed under the FOIA and to require signed statements from our personnel with access to proprietary information that prohibit unauthorized use during the procurement process and term of the contract.

In § 421.312, we described our proposal to resolve conflicts of interest. We specified that we may establish a Conflicts of Interest Review Board to assist the contracting officer in resolving conflicts of interest and determine when or if the Board is convened. We would define resolution of an organizational conflict of interest as a determination of the following:

- The conflict was 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.
- 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 will 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 unless the range is further reduced for purposes of efficiency in accordance with FAR 15.306. Using the process in the proposed regulation, offerors would not be excluded from the competitive range based solely on conflicts of interest. If we determined 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 Conflicts 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 also 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 that perform activities under the MIP contract would be reviewing activities of providers and suppliers that provide services to Medicare beneficiaries. Their contracts would 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 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, as specified in § 421.316(a), we proposed to protect MIP contractors from liability in the performance of their contracts provided they carry out their contractual duties with due care.

In accordance with section 1893(e) of the Act, we proposed 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) would provide that we 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 proposed 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 FI agreements and carrier contracts. However, we may indemnify a MIP contractor only to the extent we have specific statutory authority to do so, and 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, we proposed at § 421.316(a) to provide 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 would have immunity from liability as specified in § 421.316(a).

B. Intermediary and Carrier Functions

The former section 1816(a) of the Act, which provided that providers could nominate a FI, required only that nominated FIs perform the functions of determining payment amounts and making payment, and the former section 1842(a) of the Act required only that carriers perform some or all of the functions cited in that section. Section 911 of the MMA eliminated the requirement that FIs be nominated, and effective October 1, 2005, established 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 FI agreements and carrier contracts far exceeded those of the statute. Therefore, in the February 22, 1994 **Federal Register** (59 FR 8446), we published a proposed rule that would distinguish between those functions that the statute previously required to be included in agreements with FIs and those functions that, while not required to be performed by FIs, could have been included in FI agreements at our discretion. We also proposed that any functions included in carrier contracts may 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 22, 1994 proposed rule was never finalized, but its content was reproposed in our initial March 20, 1998 proposed rule for the MIP program (63 FR 13590). The second proposed rule, published on June 17, 2005, set forth a new proposal to bring those sections of the regulations that concern the functions Medicare FIs 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 FI 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 FI 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 required only that a FI 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) permitted, but did not require, a FI agreement to include provisions for the FI to provide consultative services to providers to enable them to establish and maintain fiscal records or to otherwise qualify as providers. It also provided that, for those providers to which the FI makes payments, the FI may serve as a channel of communications between us and the providers, may audit the records of the providers, and may perform other functions as were necessary.

Until October 1, 2005, section 1816(a) of the Act mandated only that a FI make payment determinations and make payments and, because of the nomination provision of section 1816(a) of the Act, these functions must remain with FIs. We believed that, pending the effective date of changes made by the MMA, section 1816(a) of the Act would not require that the other functions set forth at § 421.100(c) through (i) be included in all FI agreements. Furthermore, section 1893 of the Act permits the performance of functions related to Medicare program integrity by other entities. Thus, we proposed to revise § 421.100 to be consistent with section 1893 of the Act and the implementing regulations. 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 FI 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 FI and to transfer all functions to a new contractor, which may not have had an ongoing relationship with the local provider community.

Therefore, we proposed to revise § 421.100 to state that an agreement between CMS and a FI specifies the functions to be performed by the FI 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 an overpayment determination has been made.
- Furnishing to us timely information and reports that we request in order to carry out our responsibilities in administering the Medicare program.
- Establishing and maintaining procedures that we approve for the redetermination 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 FI 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 FI contract.
- Undertaking other functions as mutually agreed to by us and the FI.

In § 421.100(c), we specified that, for the responsibility for services to a provider-based HHA or a provider-based hospice, when different FIs serve the HHA or hospice and its parent provider, the designated regional FI determines the amount of payment and makes payments to the HHA or hospice. The FI 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 FI 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 FIs and carriers should be brought into conformity with the former statutory requirements for so long as the FI and carrier contracts exist until they are all replaced by MAC contracts. Therefore, we proposed to revise existing § 421.200, ''Carrier functions,'' to make it consistent with section 1893 of the Act and the implementing regulations. We stated 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) it does 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 an overpayment determination has been made.
- Furnishing to us timely information and reports that we request in order to carry out our responsibilities in administering 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 redetermination.
- 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

A new subpart D was added and reserved to part 421 by the Revisions to Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates final rule published in the November 24, 2006 **Federal Register** (71 FR 67960). The new subpart D will apply to MIP contractors. In addition, because we have published regulations that pertain to MAC contracts in the November 24, 2006 final rule, the title of part 421 was revised from ''Intermediaries and Carriers'' to read ''Medicare Contracting.''

Furthermore, in the June 17, 2005 proposed rule, we proposed to revise § 421.1, which sets forth the basis, scope, and applicability of part 421. We proposed to revise this section to add section 1893 of the Act to the list of provisions upon which the part is based. We also proposed to 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 FI or a carrier. (As previously noted in this preamble, FIs and carriers refer to contractors that received awards under sections 1816 and 1842 of the Act prior to October 1, 2005.) If the action being described may now be performed by a MIP contractor that is not a FI or a carrier, we proposed to 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 FI. A MIP contractor now may also perform the verification. Therefore, we proposed to revise § 424.11(a)(2) to specify that the provider must keep certification and recertification statements on file for verification by the FI or MIP contractor. Because our regulations are continuously being revised and sections redesignated, we did not identify all sections that would have technical changes in the June 17, 2005 proposed rule. If we determine that substantive changes to our regulations are necessary, we will make those changes through separate rulemaking.

III. Analysis and Responses to Public Comments

We received three timely public comments on the June 17, 2005 proposed rule (70 FR 35204 through 35220). The following is a summary of the issues raised by those comments and our responses.

Comment: Several commenters stated that due care is not the appropriate standard for MIP functions and recommended that we hold MIP contractors to a higher standard of care because the potential for abuse by MIP contractors is significant. One commenter maintained that contractors will conduct their activities in strict compliance with MIP principles if immunity is not readily available. Another commenter specifically advocated adopting a gross negligence or reckless disregard standard, stating that section 1893 of the Act gives CMS the authority to deviate from the due care standard ''to the extent the Secretary finds appropriate.'' This commenter asserted that MIP contractors should receive the same protection that intermediaries and carriers receive through their agreements and contracts (that is, immunity as long as they are not grossly negligent). The commenter explained that the nature of the functions that MIP contractors perform (for example, fraud investigations, cost report audits, and recovering overpayments) expose them to substantially greater risk of liability than Quality Improvement Organizations (QIOs), and QIOs enjoy immunity from criminal or civil liability in performance of their duties if they act with due care.

Response: As we explained in the June 17, 2005 proposed rule, we believe that the due care standard specified in § 421.316(a) is the only standard consistent with the statutory mandate of the Act. Section 1893(e) of the Act requires us to limit a contractor's liability by employing the same or comparable standards that are set forth in section 1157 of the Act. Section 1157 of the Act limits a contractor's liability under a due care standard. We believe that applying this standard to MIP contractors strikes a reasonable balance between the concerns of the contractors and those subject to the contractors' review. We believe MIP contractors operate with due care to avoid liability, and those being reviewed have the assurance that they have legal recourse if a contractor acts negligently.

Comment: One commenter stated that, to the extent that a MAC, carrier, or fiscal intermediary enters into a contract to perform MIP functions, they should

be afforded the same immunity and indemnification that exists under their MAC, carrier, or fiscal intermediary contract. In addition, the commenter urged us to add language to § 421.316(b) to clarify the continued applicability of the immunity/indemnification standards in FI and carrier contracts, as well as any standards ultimately included in MAC contracts to MIP functions.

Response: Generally, FIs and carriers are indemnified for any liability arising from the performance of contract functions provided that the FI's and the carrier's conduct was not grossly negligent, fraudulent, or criminal. However, we do not believe we have statutory authority under section 1893(e) of the Act to indemnify MIP contractors based on this same standard. As we explained in the June 17, 2005 proposed rule, section 1893(e) of the Act requires us to limit a contractor's liability by employing the same or comparable standards that are set forth in section 1157 of the Act. Section 1157 of the Act limits a contractor's liability under a due care standard. In addition, § 421.316(a) provides MIP contractors immunity from liability in connection with the performance of a MIP contract as long as the contractors exercise due care. Therefore, indemnification is not necessary since the MIP contractors will have immunity from liability as specified in § 421.316(a). Note, however, that section 1874A(d)(4) of the Act, as added by the MMA, provides that we have some discretion to indemnify MAC contractors that perform MIP functions under section 1874A(a)(4)(G) of the Act and other functions, as long as their conduct was not grossly negligent, fraudulent, or criminal in nature. Indemnification may include payment of judgments, settlements, awards, and costs (including reasonable legal expenses) as specified in section 1874A(d)(4) of the Act.

Comment: Section § 421.316(b) limits payment of expenses incurred by MIP contractors and others in defense of a legal action related to the performance of a MIP to reasonable expenses, as determined by CMS. In addition, section 421.316(b)(2) limits reimbursement to ''funds available'' in order to comply with the Anti-Deficiency Act, which applies to all government expenditures. A commenter objected to what it describes as a ''discretionary reasonableness standard'' and the ''funds available'' condition. The commenter stated that both provisions have the potential to substantially undermine the intent of the Social Security Act, which seeks to reimburse MIP contractors for their legal expenses. The commenter also called the ''funds available'' provision unprecedented, noting that neither current FI or carrier contracts nor the MMA provisions that pertain to MAC contractors impose this condition.

Response: Under § 421.316(b), we proposed to pay expenses incurred by MIP contractors and others in defense of a legal action related to the performance of a MIP as long as certain conditions are satisfied. However, we believe that this payment should be limited to reasonable expenses, as determined by us. For clarity, in making the determination of what is a ''reasonable'' cost, § 421.316(b), we adopt the description contained in the FAR at 48 CFR 31.201–3. In terms of reimbursement for legal expenses, we note that § 421.316 is more generous than FAR 31.205–47, which addresses costs related to legal and other proceedings. Under the FAR, at 48 CFR 31.205–47, for example, reimbursement is limited to 80 percent of the costs allowed. This limitation does not apply under the final rule.

As previously noted, section 421.316(b)(2) limits reimbursement to ''funds available'' in order to comply with the Anti-Deficiency Act. The Anti-Deficiency Act applies to all government expenditures and provides, among other things, that a government agency ''may not authorize an expenditure or obligation exceeding an amount available in an appropriation or fund'' as specified in 31 U.S.C. 1341. A contractor that incurs legal fees that may be reimbursable under § 421.316(b) would be expected to notify its contracting officer, under general FAR requirements, if it anticipates a cost overrun due to legal fees and expenses. Then, if the resources are available, the funding for the contract could be adjusted. We do not believe it is appropriate or necessary for CMS, in this final rule, to obligate itself to seek additional funds or to limit its actions if funds are not available for reimbursement.

Comment: A commenter noted that the preamble to the proposed rule stated that a transfer of resources, including personnel, must occur to qualify for the successor-in-interest exception. The commenter asked that we clarify whether a potential successor-in-interest may, assuming all other requirements of § 421.306(b) are met, qualify for the exception if the predecessor does not technically transfer personnel to the successor-in-interest but instead provides such personnel through an administrative services agreement.

Response: We would determine whether a particular contractor qualifies for the exception on a case-by-case basis.

Comment: A commenter asserted that medical and utilization reviews should be conducted only by physicians with the same State licensure, from the same geographic area, and within the same specialty as the physician who provided the service under review.

Response: Statements of Work for MIP contractors contain guidelines that address activities such as medical review and utilization. However, we decline to require by regulation medical or utilization review to be performed by physicians with the same State licensure, from the same geographic area, and within the same specialty as the physician who provided the service under review because we have found that nurse clinicians have the appropriate clinical experience to make objective clinical decisions. However, we recognize the value that a provider meeting these requirements may offer, and our contractors utilize (as they deem appropriate) physician consultants on a case-by-case basis to provide this specialized knowledge.

Comment: One commenter recommended that we revise § 421.312(b)(5) to state that it is in the best interest of the government to contract with the offeror or contractor even though the conflict exists (and the conflict has been mitigated to the extent possible).

Response: We appreciate the commenter's recommendation. We believe that our contracting officer must have the flexibility to enter into a contract with an offeror or contractor even if a conflict of interest exists without the additional requirement of mitigating the conflict to the extent possible. This flexibility ensures that the officer has the ability to enter into these types of contracts when doing so is in the best interest of the government. We are committed to minimizing and, where possible, eliminating all potential conflict of interests as outlined in § 421.312.

Comment: A commenter urged that, if CMS convenes a Conflicts of Interest Review Board as specified in § 421.321(a), the board's membership should include practicing physicians who regularly treat Medicare beneficiaries. According to the commenter, the board should also include representatives from the type of entity that is experiencing the conflict, CMS representatives, and other provider representatives as appropriate.

Response: The Conflicts of Interest Review Board is an internal process for CMS, which is convened only when CMS deems necessary. To maintain the

integrity of the procurement process and the confidentiality of proprietary information submitted in proposals, opening the procurement process to the public is not a viable option.

Comment: One commenter expressed concerned about a MIP contractor auditing a hospital's cost reports and a FI, a different contractor, processing the hospital's claims. Specifically, the commenter questioned whether the two contractors could effectively communicate with each other. The commenter expressed concern about access to updated claims information in cases where one contractor audited cost reports and another contractor processed claims, and urged CMS to discuss this issue with specific providers to ensure that existing roadblocks are cleared before any potential expansion of separate contractors across the country.

Response: We understand the comments related to the coordination of activities between PSCs and the claims processing contractors, especially as they relate to audit activities. We are concerned about the interaction between PSCs and other CMS contractors. We continually promote positive interaction and effective communication between all our various contractors. If significant issues arise, we will intervene to address these issues.

IV. Provisions of the Final Rule

This final rule accomplishes two primary goals. First, it implements, with certain exceptions indicated below, the provisions of the June 17, 2005 proposed rule as issued. Second, it describes two new MIP contracts that were awarded between the publication of the March 20, 1998 proposed rule and before the publication of this final rule.

A. Implementation, With Certain Exceptions, of the Provisions of the June 17, 2005 Proposed Rule

With the exception of the following, we are implementing the provisions of the June 17, 2005 proposed rule as issued.

In § 421.1, Basis, Applicability, and Scope, we are revising this section to omit the language in proposed paragraph (b) that states that ''§ 421.118 is also based on 42 U.S.C. 1395(b)–1(a)(1)(F), which authorizes demonstration projects involving FI agreements and carrier contracts.'' This language was omitted because § 421.118 was removed from the CFR by the Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates final rule (71 FR 67960).

In § 421.1(a), we are revising the description of sections 1816 and 1842 of the Act. The previous description (''Use of organizations and agencies in making Medicare payments to providers and suppliers of services'') was replaced with the following description: ''Provisions relating to the administration of Parts A and B.''

In § 421.1(b), we are revising this section to clarify that FIs and carriers refer to contractors that received awards under sections 1816 and 1842 of the Act prior to October 1, 2005 to distinguish these contractors from MACs. Therefore, § 421.1(b) is revised to read, ''The provisions of this part apply to agreements with Part A (Hospital Insurance) FIs that received awards under sections 1816 and 1842 of the Act prior to October 1, 2005, contracts with Part B (Supplementary Medical Insurance) carriers that received awards under sections 1816 and 1842 of the Act prior to October 1, 2005, and contracts with Medicare integrity program contractors that perform program integrity functions.''

In § 421.1(c)(2), we are revising this paragraph to omit language indicating that CMS specifies criteria and standards to select FIs and designate regional or national FIs for certain classes of providers. We no longer perform these functions. In addition, language was added to clarify that CMS specifies criteria and standards to evaluate the performance of successor-in-interest entities to FIs. Therefore, § 421.1(c)(2) is revised to read, ''Specifies criteria and standards CMS uses in evaluating the performance of fiscal intermediaries' successor entities and in assigning or reassigning a provider or providers to particular fiscal intermediaries.''

In § 421.302(a)(4), Definition of Eligible Entities, we are revising this section to replace the phrase ''without limitation'' with ''but are not limited to.'' This change was made to clarify that an appropriate written code of conduct and compliance policies consist of more than an enforced policy on employee conflicts of interest. Therefore, § 421.304(a)(4) is revised to read, ''Maintains an appropriate written code of conduct and compliance policies that include, but are not limited to, an enforced policy on employee conflicts of interest.''

In § 421.302, Definition of Eligible Entities, we are revising this section to omit the requirement in proposed paragraph (a)(5) that states that an entity is eligible to enter into a MIP contract if it ''meets financial and business integrity requirements to reflect adequate solvency and satisfactory legal history'' because we believe that this requirement may create an ambiguity with the 48 FAR at 9.103.

In § 421.304, Medicare integrity program contractor functions, we list the activities that a MIP contractor may perform. Section 421.304 states that the contract between CMS and a MIP contractor specifies the functions the contractor performs. Specifically in the area of medical and utilization review, we include the processes necessary to ensure both the appropriate utilization of services and that services meet the professionally recognized standards of care. We state that these processes include review of claims, medical records, and medical necessity documentation and analysis of patterns of utilization to identify inappropriate utilization of services. We proposed that 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). We are adding Part D Prescription Drug Plans to the list of entities.

We are revising § 421.304(b) to include reconciling and issuing cost report payments for providers and suppliers. Therefore, § 421.304(b) is revised to read, ''Auditing, settling, and determining cost report payments for providers of services, or other individuals or entities (including entities contracting with CMS under parts 417 and 422 of this chapter), as necessary to help ensure proper Medicare payment.''

In § 421.304(c), we are revising this paragraph to specify that we will recover mistaken and conditional payments. Therefore, § 421.304(c) is revised to read, ''Determining whether a payment is authorized under title XVIII, as specified in section 1862(b) of the Act, and recovering mistaken and conditional payments under section 1862(b) of the Act.''

In § 421.306(b), we are revising this paragraph to clarify that CMS may award an entity a Medicare integrity program contract by transfer—as opposed to ''without competition''—if certain conditions apply. The phrase ''without competition'' implies there is new work not contemplated in the original contact award. However, work transferred by novation was competed at some prior date, and a successor-in-interest would take on that work. Therefore, § 421.306(b) is revised to read, ''CMS may award an entity a Medicare integrity program contract by transfer if all of the following conditions apply * * *.''

In § 421.308(b), we are revising this paragraph to omit the phrase ''without competition'' because that term implies there is new work not contemplated in the original contact award. Therefore, § 421.308(b) is revised to read, ''CMS may renew a Medicare integrity program contract if all of the following conditions apply are met * * *.''

In § 421.310, we are revising the section to omit § 421.310(b)(1) in its entirety because, in § 421.310, we state that conflict of interest standards and requirements are contained in each contract awarded to perform section 1893 of the Act functions. To eliminate redundancy and possible ambiguities when read with the contract, we believe it is necessary to remove this section of the regulation as similar language is contained in the contract. In addition, we eliminated § 421.310(b)(1) because conflict of interest standards and requirements could vary among MIP contracts (for example, PSC and COB) and differ from those that are stated in this regulation. Finally, we removed § 421.310(b)(2)addressing the resolution of conflicts of interest in its entirety. For clarity, the language in this provision was slightly revised and moved to § 421.312(b)(2) for organizational purposes.

In § 421.312(a), we are revising the paragraph to clarify that CMS determines when to convene a Conflicts of Interest Review Board. Therefore, § 421.312(a)is revised to read, ''CMS may establish and convene a Conflicts of Interest Review Board to assist the contracting officer in resolving organizational conflicts of interest.''

In § 421.312(b), we are revising the section to separately identify resolution of pre-award and post-award conflicts to increase clarity and for organizational purposes. For resolution of post-award conflicts, we added language that clarifies that we could continue a contract even though a conflict of interest exists. Note that we did not state in § 421.312(b)(2)(iv) that the waiver of a conflict of interest must be in accordance with 48 CFR subpart 9.503 in the resolution of post-award conflicts of interest because that subpart applies only to pre-award conflicts.

In § 421.312(b)(2)(iii), which was proposed as § 421.312(b)(4) in the June 17, 2005 proposed rule before § 421.312(b) was reorganized in this final rule, we are revising this section to clarify that a contracting officer may resolve an organizational conflict of interest by not renewing an existing contract. In addition, this section is revised to omit the phrase ''for default.'' Under the FAR, a contract may be terminated for default, and it may be terminated for the convenience of the government. Therefore, § 421.312(b)(2)(iii) is revised to read, ''The conflict requires that CMS terminate or not renew an existing contract * * *.''

B. Description of Two New MIP Contractors

As explained in the preamble to this final rule, since the March 20, 1998 proposed rule was published, we had the authority to contract with entities to perform Medicare program integrity functions to promote the integrity of the Medicare program before publishing a final rule. We also noted in the preamble to this final rule that, in accordance with this MIP authority, we maintain various MIP contracts, which include, but are not limited to, the following: 12 IDIQ contracts for the PSC effort; 1 COB contract, 8 IDIQ contracts for the MMC Program Integrity Contractors effort, 8 IDIQ contracts for the MEDIC effort, and other contracts.

Between publishing the March 20, 1998 proposed rule and before publishing this final rule, we awarded two other types of MIP contracts: Workers' Compensation Review Contractors (WCRC) and Medicare Secondary Payer Recovery Contractors (MSPRC). Although these MIP contracts were not specifically identified in the March 20, 1998 proposed rule or the June 17, 2005 proposed rule, the preamble to both respective proposed rules did not provide an exhaustive list of MIP contracts; instead, it provided examples of MIP contracts and indicated that there were ''other [MIP] contracts.''

As MIP contractors, the WCRC and the MSPRC must satisfy the same requirements (for example, eligibility requirements under section 421.302) that other MIP contractors must satisfy. Their duties are briefly described as follows:

- *Workers' Compensation Review Contractor.* In September 2003, we awarded a contract to the WCRC to review and evaluate proposed Workers' Compensation Medicare Set-aside Arrangements (WCMSAs) in workers' compensation (WC) cases to help ensure that Medicare's interests are properly considered when determining the future case-related medical needs of the claimant. The purpose of the contract is to procure an independent entity with qualified medical staff to determine WCMSA amounts for future medical expenses related to the WC injury to protect Medicare's interest. This function confirms the adequacy of WCMSAs and, as a result, prevents the Medicare program from incurring costs that should be paid by a WC carrier. This initiative creates a streamlined process for review of WCMSAs and reduces the time associated with such reviews and evaluations, ultimately enhancing the level of customer service to the WC industry. More information about the WCRC can be obtained by accessing the Internet at *http://www.cms.hhs.gov/WorkersCompAgencyServices/06_wcmsasreviewprocess.asp.*
- *Medicare Secondary Payer Recovery Contractor.* In August 2006, we consolidated all of the functions related to recovering MSP Group Health Plan (GHP) and ''non-GHP'' (Workers' Compensation (WC), no-fault, and liability) debts from the Medicare claims processing contractors into one MSP Recovery Contractor (MSPRC). The MSPRC was implemented in October 2006. The MSPRC only took over cases where the debtors are employers, insurers/Third Party Administrators, WC carriers, no-fault insurers, liability insurers, or beneficiaries. Cases where debtors are providers, physicians, or suppliers remained at the FFS contractors. Furthermore, those contractors using the Healthcare Integrated General Ledger Accounting System (HIGLAS) kept cases already on that system to see through to completion. Using one contractor to perform MSP recoveries is achieving administrative and operational efficiencies, standardizing the recovery process, maximizing recoveries, and enhancing customer service. The MSPRC is already introducing innovations into the process, including establishing a virtual case system to replace paper files and using a dedicated call center with a toll-free number for more expedient customer service. More information about the MSPRC can be obtained by accessing the Internet at *http://www.cms.hhs.gov/MSPRGenInfo/.*

V. Collection of Information Requirements

This document does not impose new information collection and recordkeeping requirements subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 35). Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the PRA of 1995.

VI. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the

Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Although Table 1 shows a significant decline in improper Medicare FFS payments based on the implementation of MIP contractors and other initiatives, such as FI and carrier education efforts, the decline is a function of our efforts to prevent and recoup improper payments, which represent savings to the Medicare program. As a result, we have determined that this final rule is not a major rule, and that it would not have economically significant effects.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year. By the North American Industrial Classification (NAIC) Codes which are set by the Department of Commerce and the Business Size Standard of each of the NAIC codes which are set by the Small Business Administration, FIs and carriers (which are for the purposes of this final rule contractors that received awards under sections 1816 and 1842 of the Act prior to October 1, 2005) are not small businesses based on the NAIC code used for this type of work.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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 604 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 100 beds. We have determined, and certify, that this final rule would not have a significant economic impact on a substantial number of small entities. We also have determined, and certify, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. We have determined that this final rule would not cause the private sector or State, local, or tribal governments in the aggregate to expend $120 million or more in any given year.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Under section I of Executive Order 13132, '' '[p]olicies that have federalism implications' refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' We have determined, and certify, that this final rule would not impose substantial direct requirement costs on State and local governments, preempt State law, or otherwise have Federalism implications.

B. 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 FIs and carriers; (4) entities that have not previously contracted with us; and (5) Medicare providers and suppliers. These five general areas are examined below.

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 fiscal year (FY) 2003 and all subsequent years. The Deficit Reduction Act of 2005 (DRA) increased unrestricted general MIP funding by $100 million for FY 2006 only and provided another $12 million in MIP funds in FY 2006 for the Medicare-Medicaid (Medi-Medi) Data Match Project, bringing total MIP funding in FY 2006 to $832 million. For FY 2007, general MIP funding returns to $720 million, while the DRA provides $24 million in MIP funds for the Medi-Medi Data Match Project, for a MIP total of $744 million.

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 FFS payments as compared to total FFS payments has declined since the implementation of MIP contractors as shown in Table 1.

TABLE 1*

Year	Improper payment (in billions)	Percentage of FFS total	Total FFS payment (in billions)
1998	$14.9 billion	8.4	$177.0 billion
1999	14.5	8.6	168.9.
2000	16.4	9.4	174.6.
2001	16.8	8.8	191.3.
2002	17.1	8.0	212.8.
2003**	12.7	6.4	199.1.
2004	21.7	10.1	213.5.
2005	12.1	5.2	234.1.
2006	10.8	4.4	246.8.

*The Improper Payments Information Act of 2002 (Pub. L. 107–300) mandates that federal agencies use gross figures when reporting improper payment amounts and rates. A gross figure is calculated by adding underpayments to overpayments. All amounts and rates in this table have been converted to gross figures.

**Since 1996, HHS has annually determined the rate of improper payments for FFS 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. Because this was a new initiative, there was a high non-response rate. The 2003 figures used in the above table reflect the adjusted error rate figures, which account for this high non-response rate. If this adjustment had not been made, the improper payment would have been $21.5 billion and the national error rate would have been 10.8 percent. The numbers reported for 2004 are unadjusted and reflect CMS' findings since employing its expanded effort.

As we referred to previously, the positive error rate trend also relates to other initiatives, including FI and carrier education efforts, partnering with the provider community, and our anti-fraud and abuse efforts.

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 gross national rate for FY 2004 was 10.1 percent and decreased to 5.2 percent in 2005.

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 under the FAR 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 reducing the total percentage of improper payments made for FFS claims paid in 2006 to 4.4 percent of all FFS claims, down from 8.4 percent of FFS claims in 1998. As a result, current and future beneficiaries will obtain more value for every Medicare dollar spent. In addition, under the Medicare Secondary Payer program in FY 2005, CMS achieved $5.8 billion dollars in pre-payment and post payment savings.

3. Current Fiscal Intermediaries and Carriers

Although FIs 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 FI and carrier contracts with new MAC contracts, we are providing the following analysis.

There are currently 18 Medicare FIs, 15 Medicare carriers, 1 DME regional contractor (which is also a carrier), and 1 Medicare A/B MAC. Presently, these contractors perform general program integrity activities addressed in this final 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 FIs, carriers, and MACs are not prohibited from entering into MIP contracts when we compete contracts for (MIP) activities under section 1893 of the Act. (However, these contractors would have to meet conflict of interests requirements in the MIP contracts and the FAR.)

We believe that this rule will have a minimum impact in several areas. 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 publishing this final 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 FIs and carriers in some respects. Many current FIs and carriers may have lost a portion of their Medicare business since 1998 as fraud review and other functions were transferred to MIP contractors.

However, current contractors have benefited from the MIP program and will benefit from this final rule. Under the provisions of this rule, 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 final 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 FIs and carriers is lessened by this 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 FI 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 help them 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 final rule because a MIP contractor is generally 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 FIs or carriers.

4. New Contracting Entities

Entities that have not previously performed Medicare program integrity activities will experience a positive 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. This final rule may create new markets and opportunities for small, small disadvantaged, and woman-owned businesses.

Since publishing 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, 8 IDIQ contracts for the Medicare Managed Care Program Integrity Contractors (MMC-PICs) effort, 8 IDIQ contracts for the MEDIC effort, and other miscellaneous contracts. With the addition of the Medicare Part D prescription drug benefit included in the MMA, there will be further opportunities for entities to compete for MIP contracts to perform additional program oversight activities.

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 final 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 final 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.

C. Conclusion

Since publishing the March 20, 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 would extend the solvency of the Trust Funds as a result of this final 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'' the system. We solicited public comments as well as data on the extent to which any of the affected entities would be significantly economically affected by this final rule.

In accordance with the provisions of Executive Order 12866, this proposed notice 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, the Centers for Medicare & Medicaid Services amends 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 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).

■ 4. 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—Provisions relating to the administration of Parts A and B.

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

(b) *Applicability.* The provisions of this part apply to agreements with Part A (Hospital Insurance) fiscal intermediaries that received awards under sections 1816 or 1842 of the Act prior to October 1, 2005, contracts with Part B (Supplementary Medical Insurance) carriers that received awards under sections 1816 or 1842 of the Act prior to October 1, 2005, and contracts with Medicare integrity program contractors that perform program integrity functions.

(c) *Scope.* The scope of this part—

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

(2) Specifies criteria and standards CMS uses in evaluating the performance of fiscal intermediaries' successor entities and in assigning or reassigning a provider or providers to particular fiscal intermediaries.

(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.

■ 5. 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 redetermination 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.* Regarding the responsibility for service to provider-based HHAs and provider-based hospices, where the HHA or the hospice and its parent provider will be served by different intermediaries, the designated regional intermediary will process bills, make coverage determinations, and make payments to the HHAs and the hospices. The intermediary or Medicare integrity program contractor serving the parent provider will perform all fiscal functions, including audits and settlement of the Medicare cost reports and the HHA and hospice supplement worksheets.

■ 6. 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 redetermination.

(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.

■ 7. 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, but are not limited to, an enforced policy on employee conflicts of interest.

(5) 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, settling and determining cost report payments for providers of services, or other individuals or entities (including entities contracting with CMS under parts 417 and 422 of this chapter), as necessary to help ensure proper Medicare payment.

(c) Determining whether a payment is authorized under title XVIII, as specified in section 1862(b) of the Act, and recovering mistaken and conditional payments under section 1862(b) of the Act.

(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 by transfer 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 specified in § 421.302; 48 CFR Chapters 1 and 3; and other applicable laws and regulations.

§ 421.308 Renewal of a contract.

(a) *General.* (1) CMS specifies an initial contract term in the Medicare integrity program contract.

(2) Contracts under this subpart may contain renewal clauses.

(3) 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) *Conditions for renewal of contract.* CMS may renew a Medicare integrity program contract 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) *Nonrenewal of a contract.* If CMS does not renew a contract, the contract ends in accordance with its terms.

§ 421.310 Conflict of interest requirements.

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

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

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

§ 421.312 Conflict of interest resolution.

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

(b) *Resolution*—(1) *Pre-award conflicts.* Resolution of an organizational conflict of interest is a determination by the contracting officer that one of the following has occurred:

(i) The conflict is mitigated.

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

(iii) It is in the best interest of the government to award a contract to the offeror (in accordance with 48 CFR subpart 9.503) even though a conflict of interest exists.

(2) *Post-award conflicts.* Resolution of an organizational conflict of interest is a determination by the contracting officer that one of the following has occurred:

(i) The conflict is mitigated.

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

(iii) The conflict requires that CMS terminate or not renew an existing contract.

(iv) It is in the best interest of the government to continue the contract even though a conflict of interest 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 pays 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 the following conditions are met:

(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.

(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: January 29, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May, 11 2007.

Michael O. Leavitt,

Secretary.

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