

## § 421.300

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may waive the requirement in paragraph (e)(1) of this section as part of that determination.

(2) If adjusting Medicare payments fails to recover an advance payment, CMS may authorize the use of any other recoupment method available (for example, lump sum repayment or an extended repayment schedule) including, upon written notice from the carrier to the supplier, converting any unpaid balances of advance payments to overpayments. Overpayments are recovered in accordance with part 401, subpart F of this chapter concerning claims collection and compromise and part 405, subpart C of this chapter concerning recovery of overpayments.

(h) *Prompt payment interest.* An advance payment is a “payment” under section 1842(c)(2)(C) of the Act for purposes of meeting the time limit for the payment of clean claims, to the extent of the advance payment.

(i) *Notice, review, and appeal rights.* (1) The decision to advance payments and the determination of the amount of any advance payment are committed to CMS’s discretion and are not subject to review or appeal.

(2) The carrier must notify the supplier receiving an advance payment about the amounts advanced and recouped and how any Medicare payment amounts have been adjusted.

(3) The supplier may request an administrative review from the carrier if it believes the carrier’s reconciliation of the amounts advanced and recouped is incorrectly computed. If a review is requested, the carrier must provide a written explanation of the adjustments.

(4) The review and explanation described in paragraph (i)(3) of this section is separate from a supplier’s right to appeal the amount and computation of benefits paid on the claim, as provided at part 405, subpart H of this chapter. The carrier’s reconciliation of amounts advanced and recouped is not an initial determination as defined at § 405.803 of this chapter, and any written explanation of a reconciliation is not subject to further administrative review.

(j) *Advanced payments in exceptional circumstances.* CMS may approve, in writing to the contractor, the making

of advance payments during the period of a Public Health Emergency, as defined in § 400.200 of this chapter, or during the period under a Presidential Disaster Declaration, under the following exceptional conditions:

(1) The contractor is unable to process the claim timely, or is at risk of being untimely in processing the claim; or

(2) When the supplier has experienced a temporary delay in preparing and submitting bills to the contractor beyond its normal billing cycle.

[61 FR 49275, Sept. 19, 1996, as amended at 85 FR 19289, Apr. 6, 2020]

### Subpart D—Medicare Integrity Program Contractors

SOURCE: 72 FR 48886, Aug. 24, 2007, unless otherwise noted.

#### § 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.

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(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.

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## § 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.

### Subpart E—Medicare Administrative Contractors (MACs)

SOURCE: 71 FR 68229, Nov. 24, 2006, unless otherwise noted.

#### § 421.400 Statutory basis and scope.

(a) *Statutory basis.* This subpart implements section 1874A of the Act, which provides for the transition of the claims processing functions and operations for both Medicare Part A and Part B intermediaries and carriers to Medicare Administrative Contractors (MACs). The transition will occur between October 1, 2005, and October 1, 2011. MACs will be fully operational in distinct, nonoverlapping geographic jurisdictions by October 1, 2011.

(b) *Scope.* This subpart specifies the requirements under which providers and suppliers will be assigned to MACs.

#### § 421.401 Definitions.

For purposes of this subpart—

*Appropriate MAC* means a MAC that has a contract under section 1874A of

the Act to perform a particular Medicare administrative function in relation to:

(1) A particular individual entitled to benefits under Part A or enrolled under Part B, or both;

(2) A specific provider of services or supplier; or

(3) A class of providers of services or suppliers.

*Medicare Administrative Contractor (MAC)* means an agency, organization, or other person with a contract under section 1874A of the Act.

#### § 421.404 Assignment of providers and suppliers to MACs.

(a) *Definitions.* As used in this section—

*Chain provider* means a group of two or more providers under common ownership or control.

*Common control* exists when an individual, a group of individuals, or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of the group of suppliers or eligible providers.

*Common ownership* exists when an individual, a group of individuals, or an organization possesses significant equity in the group of suppliers or eligible providers.

*Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)* means the types of services specified in § 421.210(b).

*Eligible provider* means a hospital, skilled nursing facility, or critical access hospital that meets the definition of a provider under § 400.202 of this chapter.

*Home office* means the entity that provides centralized management and administrative services to the individual providers or suppliers under common ownership and common control, such as centralized accounting, purchasing, personnel services, management direction and control, and other similar services.

*Ineligible provider* means a provider under § 400.202 of this chapter that is not an eligible provider.

*Medicare benefit category* means a category of covered benefits under Part A or Part B of the Medicare program (for example, inpatient hospital services,