

(vii) Any other factors that appear to be relevant.

(2) *Evaluation time limit.* CMS concludes the evaluation process in a reasonable amount of time, not to exceed 2 years from the receipt date, taking into consideration the complexity of the suggestion, the number of possible implementation strategies, and CMS's current workload.

(g) *Basis for reward payment*—(1) *General rule.* If CMS determines that it is appropriate to make a reward payment for a suggestion adopted in whole or in part, that results in improved efficiency and monetary savings to the Medicare program, the payment is based on—

(i) The actual first-year net savings to the Medicare program, or

(ii) The average annual net savings to the Medicare program expected to be realized over a period of not more than 3 years if—

(A) An improvement is expected to yield monetary savings for more than 1 year and implementation involves substantial costs; or

(B) Monetary savings are negligible in the first year but are expected to substantially increase in subsequent years.

(2) *Reward payment amount.* CMS determines the amount of a reward payment using the following formula:

(i) Net savings from \$1,000 to \$10,000—10 percent of the savings, with a minimum award amount of \$100;

(ii) Net savings of \$10,001 to \$100,000—\$1,000 for the first \$10,000 of savings, plus 3 percent of the net savings over \$10,000;

(iii) Net savings of more than \$100,000—\$3,700 for the first \$100,000 of savings, plus 0.5 percent of savings over \$100,000, with a maximum award amount of \$25,000.

(h) *Adoption of suggestion and issuance of reward payment*—(1) *Adoption.* Upon completing its evaluation, CMS decides whether to adopt a suggestion. If CMS receives the same or an overlapping suggestion from two or more unrelated parties, CMS will consider a reward only for the suggestion CMS received first, if the suggestion or overlapping part of the suggestion are identical, and CMS has adopted that part. If the suggestions are not identical, CMS will

consider rewarding the suggestion received first, if it is feasible and CMS is able to adopt and implement the suggestion. If the first suggestion cannot be implemented, CMS may consider rewarding the suggestion received next, even if it is similar, provided CMS can adopt and implement the suggestion.

(2) *Issuance of reward payment.* After the reward payment amount is determined, as described in paragraph (g) of this section, CMS mails payment to the suggester (or to the legal representatives referenced in paragraph (k) of this section) only after the suggestion has been in operation for 1 year.

(i) *Group suggestions.* When CMS deems that a reward payment is appropriate for a suggestion submitted by a group of individuals, CMS pays an equal share of the reward to each of the individuals identified in the group. If an organization such as a corporation, partnership, or professional association submits a suggestion, CMS makes a single reward payment to that organization.

(j) *Change in name or address.* It is the suggester's responsibility to notify CMS of any change of address or other relevant information. If the suggester fails to update CMS on any change in this information, and the reward payment mailed to the suggester is returned to CMS, the suggester must claim the reward payment by contacting CMS within 1 year from the date CMS first mailed the reward payment to the suggester. CMS does not pay interest on rewards that, for any reason, are delayed or are not immediately claimed.

(k) *Incapacitated or deceased suggester.* If the suggester is incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the suggester or the suggester's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to CMS showing his or her authority to claim the reward. The claim must be filed within 1 year from the date on which CMS first attempted to pay the reward to the individual who submitted the suggestion.

(1) *Maintenance of records*—(1) CMS retains records related to the administration of the suggestion program in accordance with 36 CFR part 1228 (the regulations for the National Archives and Records Administration).

(2) CMS does not disclose information submitted under the suggestion program, except as required by law.

[64 FR 66401, Nov. 26, 1999]

PART 421—MEDICARE CONTRACTING

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AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 45 FR 42179, June 23, 1980, unless otherwise noted.

Subpart A—Scope, Definitions, and General Provisions

§ 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.

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(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.

[72 FR 48886, Aug. 24, 2007]

§ 421.3 Definitions.

As used in this part—

Intermediary means an entity that has a contract with CMS (under statutory provisions in effect prior to October 1, 2005) to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis (or under the prospective payment system for hospitals) and to perform other related functions. For purposes of applying the performance criteria in § 421.120 and the performance standards in § 421.122 and any adverse action resulting from that application, the term “intermediary” also means a Blue Cross plan that has entered into a sub-contract approved by CMS with the Blue Cross and Blue Shield Association to perform intermediary functions.

[71 FR 68228, Nov. 24, 2006]

§ 421.5 General provisions.

(a) *Competitive bidding not required for carriers.* CMS may enter into contracts with carriers, or with intermediaries to act as carriers in certain circumstances, without regard to section 3709 of the U.S. Revised Statutes or any other provision of law that requires competitive bidding.

(b) *Indemnification of intermediaries and carriers.* Intermediaries and carriers act on behalf of CMS in carrying out certain administrative responsibilities that the law imposes. Accordingly, their agreements and contracts contain clauses providing for indemnification with respect to actions

taken on behalf of CMS and CMS is the real party of interest in any litigation involving the administration of the program.

(c) *Use of intermediaries to perform carrier functions.* CMS may contract with an intermediary to perform carrier functions with respect to services for which Part B payment is made to a provider.

(d) *Nonrenewal of agreement or contract.* Notwithstanding any of the provisions of this part, CMS has the authority not to renew an agreement or contract when its term expires.

(e) *Intermediary availability in an area.* For more effective and efficient administration of the program, CMS retains the right to expand or diminish the geographical area in which an intermediary is available to serve providers.

(f) *Provision for automatic renewal.* Agreements and contracts under this part may contain automatic renewal clauses for continuation from term to term unless either party gives notice, within timeframes specified in the agreement or contract, of its intention not to renew.

[45 FR 42179, June 23, 1980, as amended at 54 FR 4026, Jan. 27, 1989]

Subpart B—Intermediaries

§ 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 re-determination 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.

[72 FR 48886, Aug. 24, 2007]

§ 421.103 Payment to providers.

Providers are assigned to intermediaries in accordance with § 421.104. As the Medicare Administrative Contractors (MACs) are implemented, providers are reassigned from intermediaries to MACs in accordance with § 412.404 of this chapter.

[71 FR 68228, Nov. 24, 2006]

§ 421.104 Assignment of providers of services to intermediaries during transition to Medicare Administrative Contractors (MACs).

(a) Beginning October 1, 2005, CMS assigns providers of services and other entities that may bill Part A benefits to intermediaries in a manner that will best support the transition to Medicare Administrative Contractors (MACs) under section 1874A of the Act in accordance with subpart E of this part.

(b) These providers of services and other entities must continue to bill the intermediary that they were billing prior to October 1, 2005, until one of the following events occurs:

(1) The intermediary's agreement with CMS ends, and the provider or entity is directed by CMS to bill another CMS contractor.

(2) The provider or entity is assigned to a MAC that has begun to administer claims within the geographic locale of the provider or entity.

(3) CMS directs the provider or entity to begin billing another CMS contractor in order to support the implementation of MACs under section 1874A of the Act and subpart E of this part.

(c) New providers of services and new entities will be assigned to the intermediary serving their geographic locale if no MAC has begun to administer Medicare claims in the locale. These providers or entities must continue to bill the intermediary until one of the events in paragraph (b) of this section occurs.

(d) Providers or entities will only be granted exceptions to the provisions of paragraphs (b) or (c) of this section if CMS deems the exception to be in the compelling interest of the Medicare program.

(e) CMS will notify the provider or entity, the outgoing intermediary, and the newly assigned intermediary of assignment or reassignment decisions.

[71 FR 68228, Nov. 24, 2006]

§ 421.110 Requirements for approval of an agreement.

Before entering into or renewing an intermediary agreement, CMS will—

(a) Determine that to do so is consistent with the effective and efficient administration of the Medicare program;

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(b) Review the performance of the intermediary as measured by the criteria (§ 421.120) and standards (§ 421.122); and

(c) Determine that the intermediary or prospective intermediary—

(1) Is willing and able to assist providers in the application of safeguards against unnecessary utilization of services;

(2) Meets all solvency and financial responsibility requirements imposed by the statutes and regulatory authorities of the State or States in which it, or any subcontractor performing some or all of its functions, would serve;

(3) Has the overall resources and experience to administer its responsibilities under the Medicare program and has an existing operational, statistical, and recordkeeping capacity to carry out the additional program responsibilities it proposes to assume. CMS will presume that an intermediary or prospective intermediary meets this requirement if it has at least 5 years experience in paying for or reimbursing the cost of health services;

(4) Will serve a sufficient number of providers to permit a finding of effective and efficient administration. Under this criterion no intermediary or prospective intermediary shall be found to be not efficient or effective solely on the grounds that it serves only providers located in a single State;

(5) Has acted in good faith to achieve effective cooperation with the providers it will service and with the physicians and medical societies in the area;

(6) Has established a record of integrity and satisfactory service to the public; and

(7) Has an affirmative equal employment opportunity program that complies with the fair employment provisions of the Civil Rights Act of 1964 and Executive Order 11246, as amended.

§ 421.112 Considerations relating to the effective and efficient administration of the program.

(a) In order to accomplish the most effective and efficient administration of the Medicare program, the Secretary may make determinations with respect to the termination of an intermediary

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agreement, and CMS may make determinations with respect to renewal of an intermediary agreement under § 421.110.

(b) When taking the actions specified in paragraph (a) of this section, the Secretary or CMS will consider the performance of the individual intermediary in its Medicare operations using the factors contained in the performance criteria specified in § 421.120 and the performance standards specified in § 421.122.

(c) In addition, when taking the actions listed in paragraph (a) of this section, the Secretary or CMS may consider factors relating to—

(1) Consistency in the administration of program policy;

(2) Development of intermediary expertise in difficult areas of program administration;

(3) Individual capacity of available intermediaries to serve providers as it is affected by such considerations as—

(i) Program emphasis on the number or type of providers to be served; or

(ii) Changes in data processing technology;

(4) Overdependence of the program on the capacity of an intermediary to an extent that services could be interrupted;

(5) Economy in the delivery of intermediary services;

(6) Timeliness in the delivery of intermediary services;

(7) Duplication in the availability of intermediaries;

(8) Conflict of interest between an intermediary and provider; and

(9) Any additional pertinent factors.

[45 FR 42179, June 23, 1980, as amended at 59 FR 682, Jan. 6, 1994; 71 FR 68229, Nov. 24, 2006]

§ 421.114 Assignment and reassignment of providers by CMS.

CMS may assign or reassign any provider to any intermediary if it determines that the assignment or reassignment will be in the best interests of the Medicare program.

[71 FR 68229, Nov. 24, 2006]

§ 421.120 Performance criteria.

(a) *Application of performance criteria.* As part of the intermediary evaluations authorized by section 1816(f) of

the Act, CMS periodically assesses the performance of intermediaries in their Medicare operations using performance criteria. The criteria measure and evaluate intermediary performance of functional responsibilities such as—

(1) Correct coverage and payment determinations;

(2) Responsiveness to beneficiary concerns; and

(3) Proper management of administrative funds.

(b) *Basis for criteria.* CMS will base the performance criteria on—

(1) Nationwide intermediary experience;

(2) Changes in intermediary operations due to fiscal constraints; and

(3) HFCA's objectives in achieving better performance.

(c) *Publication of criteria.* The development and revision of criteria for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, CMS will publish the performance criteria as a notice in the FEDERAL REGISTER.

[48 FR 7178, Feb. 18, 1983]

§ 421.122 Performance standards.

(a) *Development of standards.* In addition to the performance criteria (§ 421.120), CMS develops detailed performance standards for use in evaluating intermediary performance which may be based on historical performance, application of acceptable statistical measures of variation to nationwide intermediary experience during a base period, or changing program emphases or requirements. These standards are also developed considering intermediary experience and evaluate the specific requirements of each functional responsibility or criterion.

(b) *Factors beyond intermediary's control.* To identify measurable factors that significantly affect an intermediary's performance, but that are not within the intermediary's control, CMS will—

(1) Study the performance of intermediaries during the base period, and

(2) Consider the noncontrollable factors in developing performance standards.

(c) *Publication of standards.* The development and revision of standards for

evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance standards as part of the FEDERAL REGISTER notice describing the performance criteria issued under § 421.120(c). CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase “before the beginning of each evaluation period” as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the intermediaries for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§ 421.124 Intermediary's failure to perform efficiently and effectively.

(a) Failure by an intermediary to meet, or to demonstrate the capacity to meet, the criteria or standards specified in §§ 421.120 and 421.122 may be grounds for adverse action by the Secretary or by CMS, such as reassignment of providers, offer of a short-term agreement, termination of a contract, or non-renewal of a contract. If an intermediary meets all criteria and standards in its overall performance, but does not meet them with respect to a specific provider or class of providers, CMS may reassign that provider or class of providers to another intermediary in accordance with § 421.114.

(b) In addition, notwithstanding whether an intermediary meets the criteria and standards, if the cost incurred by the intermediary to meet its contractual requirements exceeds the amount which CMS finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated intermediary, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§ 421.126 Termination of agreements.

(a) *Termination by intermediary.* An intermediary may terminate its agreement at any time by—

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(1) Giving written notice of its intention to CMS and to the providers it services at least 180 days before its intended termination date; and

(2) Giving public notice of its intention by publishing a statement of the effective date of termination at least 60 days before that date. Publication must be in a newspaper of general circulation in each community served by the intermediary.

(b) *Termination by the Secretary, and right of appeal.* (1) The Secretary may terminate an agreement if—

(i) The intermediary fails to comply with the requirements of this subpart;

(ii) The intermediary fails to meet the criteria or standards specified in §§ 421.120 and 421.122; or

(iii) CMS has reassigned, under § 421.114 or § 421.116, all of the providers assigned to the intermediary.

(2) If the Secretary decides to terminate an agreement, he or she will offer the intermediary an opportunity for a hearing, in accordance with § 421.128.

(3) If the intermediary does not request a hearing, or if the hearing decision affirms the Secretary's decision, the Secretary will provide reasonable notice of the effective date of termination to—

(i) The intermediary;

(ii) The providers served by the intermediary; and

(iii) The general public.

(4) The providers served by the intermediary will be given the opportunity to nominate another intermediary, in accordance with § 421.104.

§ 421.128 Intermediary's opportunity for hearing and right to judicial review.

(a) *Basis for appeal.* An intermediary adversely affected by any of the following actions shall be granted an opportunity for a hearing:

(1) Assignment or reassignment of providers to another intermediary.

(2) Designation of a national or regional intermediary to serve a class of providers.

(3) Termination of the agreement.

(b) *Request for hearing.* The intermediary shall file the request with CMS within 20 days from the date on the notice of intended action.

(c) *Hearing procedures.* The hearing officer shall be a representative of the Secretary and not otherwise a party to the initial administrative decision. The intermediary may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings at the hearing will be made and transcribed.

(d) *Judicial review.* An adverse hearing decision concerning action under paragraph (a)(1) or (a)(2) of this section is subject to judicial review in accordance with 5 U.S.C. chapter 7.

(e) As specified in § 421.118, contracts awarded under the experimental authority of CMS are not subject to the provisions of this section.

(f) *Exception.* An intermediary adversely affected by the designation of a regional intermediary or an alternative regional intermediary for HHAs, or an intermediary for hospices, under § 421.117 of this subpart is not entitled to a hearing or judicial review concerning adverse effects caused by the designation of an intermediary.

[45 FR 42179, June 23, 1980, as amended at 47 FR 38540, Sept. 1, 1982; 49 FR 3660, Jan. 30, 1984; 53 FR 17945, May 19, 1988]

Subpart C—Carriers

§ 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.

[72 FR 48886, Aug. 24, 2007]

§ 421.201 Performance criteria and standards.

(a) *Application of performance criteria and standards.* As part of the carrier evaluations mandated by section 1842(b)(2) of the Act, CMS periodically assesses the performance of carriers in their Medicare operations using performance criteria and standards.

(1) The criteria measure and evaluate carrier performance of functional responsibilities such as—

(i) Accurate and timely payment determinations;

(ii) Responsiveness to beneficiary, physician, and supplier concerns; and

(iii) Proper management of administrative funds.

(2) The standards evaluate the specific requirements of each functional responsibility or criterion.

(b) *Basis for criteria and standards.* CMS bases the performance criteria and standards on—

(1) Nationwide carrier experience;

(2) Changes in carrier operations due to fiscal constraints; and

(3) CMS's objectives in achieving better performance.

(c) *Publication of criteria and standards.* Before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance criteria and standards as a notice in the FEDERAL REGISTER. CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase “before the beginning of each evaluation period” as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the carriers for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

§ 421.202 Requirements and conditions.

Before entering into or renewing a carrier contract, CMS determines that the carrier—

(a) Has the capacity to perform its contractual responsibilities effectively and efficiently;

(b) Has the financial responsibility and legal authority necessary to carry out its responsibilities; and

(c) Will be able to meet any other requirements CMS considers pertinent, and, if designated a regional DMEPOS carrier, any special requirements for regional carriers under § 421.210 of this subpart.

[45 FR 42179, June 23, 1980, as amended at 57 FR 27307, June 18, 1992]

§ 421.203 Carrier's failure to perform efficiently and effectively.

(a) Failure by a carrier to meet, or demonstrate the capacity to meet, the criteria and standards specified in § 421.201 may be grounds for adverse action by the Secretary, such as contract termination or non-renewal.

(b) Notwithstanding whether or not a carrier meets the criteria and standards specified in § 421.201, if the cost incurred by the carrier to meet its contractual requirements exceeds the amount that CMS finds to be reasonable and adequate to meet the cost

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which must be incurred by an efficiently and economically operated carrier, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

§ 421.205 Termination by the Secretary.

(a) *Cause for termination.* The Secretary may terminate a contract with a carrier at any time if he or she determines that the carrier has failed substantially to carry out any material terms of the contract or has performed its function in a manner inconsistent with the effective and efficient administration of the Medicare Part B program.

(b) *Notice and opportunity for hearing.* Upon notification of the Secretary's intent to terminate the contract, the carrier may request a hearing within 20 days after the date on the notice of intent to terminate.

(c) *Hearing procedures.* The hearing procedures will be those specified in § 421.128(c).

§ 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.

(a) *Basis.* This section is based on sections 1834(a)(12) and 1834(h) of the Act, which authorize the Secretary to designate one carrier for one or more entire regions to process claims for durable medical equipment, prosthetic devices, prosthetics, orthotics, and other supplies (DMEPOS). This authority has been delegated to CMS.

(b) *Types of claims.* Claims for the following, except for items incident to a physician's professional service as defined in § 410.26, incident to a physician's service in a rural health clinic as defined in § 405.2413, or bundled into payment to a provider, ambulatory surgical center, or other facility, are processed by the designated carrier for its designated region and not by other carriers—

(1) Durable medical equipment (and related supplies) as defined in section 1861(n) of the Act;

(2) Prosthetic devices (and related supplies) as described in section 1861(s)(8) of the Act, (including intra-ocular lenses and parenteral and en-

teral nutrients, supplies, and equipment, when furnished under the prosthetic device benefit);

(3) Orthotics and prosthetics (and related supplies) as described in section 1861(s)(9);

(4) Home dialysis supplies and equipment as described in section 1861(s)(2)(F);

(5) Surgical dressings and other devices as described in section 1861(s)(5);

(6) Immunosuppressive drugs as described in section 1861(s)(2)(J); and

(7) Other items or services which are designated by CMS.

(c) *Region designation.* (1) The boundaries of the initial four regions for processing claims described in paragraph (b) of this section contain the following States and territories:

(i) Region A: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, and Delaware.

(ii) Region B: Maryland, the District of Columbia, Virginia, West Virginia, Ohio, Michigan, Indiana, Illinois, Wisconsin, and Minnesota.

(iii) Region C: North Carolina, South Carolina, Kentucky, Tennessee, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Arkansas, Oklahoma, New Mexico, Colorado, Puerto Rico, and the Virgin Islands.

(iv) Region D: Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands, California, Nevada, Arizona, Washington, Oregon, Montana, Idaho, Utah, Wyoming, North Dakota, South Dakota, Nebraska, Kansas, Iowa, and Missouri.

(2) CMS has the option to modify the number and boundaries of the regions established in paragraph (c)(1) of this section based on appropriate criteria and considerations, including the effect of the change on beneficiaries and DMEPOS suppliers. To announce changes, CMS publishes a notice in the FEDERAL REGISTER that delineates the regional boundary or boundaries changed, the States and territories affected, and supporting criteria or considerations.

(d) *Criteria for designating regional carriers.* CMS designates regional carriers

to achieve a greater degree of effectiveness and efficiency in the administration of the Medicare program. In making this designation, CMS will award regional carrier contracts in accordance with applicable law and will consider some or all of the following criteria—

- (1) Timeliness of claim processing;
- (2) Cost per claim;
- (3) Claim processing quality;
- (4) Experience in claim processing, and in establishing local medical review policy; and
- (5) Other criteria that CMS believes to be pertinent.

(e) *Carrier designation.* (1) Each carrier designated a regional carrier must process claims for items listed in paragraph (b) of this section for beneficiaries whose permanent residence is within that carrier's region as designated under paragraph (c) of this section. When processing the claims, the carrier must use the payment rates applicable for the State of residence of the beneficiary, including a qualified Railroad Retirement beneficiary. A beneficiary's permanent residence is the address at which he or she intends to spend 6 months or more of the calendar year.

(2) CMS notifies affected Medicare beneficiaries and suppliers when it designates a regional carrier (in accordance with paragraph (d) of this section) to process DMEPOS claims (as defined in paragraph (b) of this section) for all Medicare beneficiaries residing in their respective regions (as designated under paragraph (c) of this section).

(3) CMS may contract for the performance of National Supplier Clearinghouse functions through a contract amendment to one of the DME regional carrier contracts or through a contract amendment to any Medicare carrier contract under § 421.200.

(4) CMS periodically recompetes the contracts for the DME regional carriers. CMS also periodically recompetes the National Supplier Clearinghouse function.

(f) *Collecting information of ownership.* Carriers designated as regional claims processors must obtain from each supplier of items listed in paragraph (b) of this section information concerning ownership and control as required by

section 1124A of the Act and part 420 of this chapter, and certifications that supplier standards are met as required by part 424 of this chapter.

[57 FR 27307, June 18, 1992, as amended at 58 FR 60796, Nov. 18, 1993; 70 FR 9239, Feb. 25, 2005]

§ 421.212 Railroad Retirement Board contracts.

In accordance with this subpart C, the Railroad Retirement Board contracts with DMEPOS regional carriers designated by CMS, as set forth in § 421.210(e)(2), for processing claims for Medicare-eligible Railroad Retirement beneficiaries, for the same contract period as the contracts entered into between CMS and the DMEPOS regional carriers.

[58 FR 60797, Nov. 18, 1993]

§ 421.214 Advance payments to suppliers furnishing items or services under Part B.

(a) *Scope and applicability.* This section provides for the following:

(1) Sets forth requirements and procedures for the issuance and recovery of advance payments to suppliers of Part B services and the rights and responsibilities of suppliers under the payment and recovery process.

(2) Does not limit CMS's right to recover unadjusted advance payment balances.

(3) Does not affect suppliers' appeal rights under part 405, subpart H of this chapter relating to substantive determinations on suppliers' claims.

(4) Does not apply to claims for Part B services furnished by suppliers that have in effect provider agreements under section 1866 of the Act and part 489 of this chapter, and are paid by intermediaries.

(b) *Definition.* As used in this section, *advance payment* means a conditional partial payment made by the contractor in response to a claim that it is unable to process within established time limits except as provided in paragraph (j) of this section.

(c) *When advance payments may be made.* Unless otherwise qualified under paragraph (j) of this section, an advance payment may be made if all of the following conditions are met:

(1) The carrier is unable to process the claim timely.

(2) CMS determines that the prompt payment interest provision specified in section 1842(c) of the Act is insufficient to make a claimant whole.

(3) CMS approves, in writing to the carrier, the making of an advance payment by the carrier.

(d) *When advance payments are not made.* Advance payments are not made to any supplier that meets any of the following conditions:

(1) Is delinquent in repaying a Medicare overpayment.

(2) Has been advised of being under active medical review or program integrity investigation.

(3) Has not submitted any claims.

(4) Has not accepted claims' assignments within the most recent 180-day period preceding the system malfunction.

(5) Is in bankruptcy.

(e) *Requirements for suppliers.* (1) Except as provided for in paragraph (g)(1) of this section, a supplier must request, in writing to the carrier, an advance payment for Part B services it furnished.

(2) A supplier must accept an advance payment as a conditional payment subject to adjustment, recoupment, or both, based on an eventual determination of the actual amount due on the claim and subject to the provisions of this section.

(f) *Requirements for carriers.* (1) A carrier must notify a supplier as soon as it is determined that payment will not be made in a timely manner, and an advance payment option is to be offered to the supplier.

(i) Unless otherwise qualified under paragraph (j) of this section, a contractor must calculate an advance payment for a particular claim at no more than 80 percent of the anticipated payment for that claim based upon the historical assigned claims payment data as defined in paragraph (f)(1)(ii) of this section for claims paid to the supplier. For suppliers qualifying and approved for advance payments under paragraph (j) of this section, a contractor may calculate an advance payment for a particular claim at up to 100 percent of the anticipated payment for that claim based upon the historical assigned

claims payment data as defined in paragraph (f)(1)(ii) of this section for claims paid to the supplier.

(ii) "Historical data" are defined as a representative 90-day assigned claims payment trend within the most recent 180-day experience before the system malfunction.

(iii) Based on this amount and the number of claims pending for the supplier, the carrier must determine and issue advance payments.

(iv) If historical data are not available or if backlogged claims cannot be identified, the carrier must determine and issue advance payments based on some other methodology approved by CMS.

(v) Advance payments can be made no more frequently than once every 2 weeks to a supplier.

(2) Generally, a supplier will not receive advance payments for more assigned claims than were paid, on a daily average, for the 90-day period before the system malfunction.

(3) A carrier must recover an advance payment by applying it against the amount due on the claim on which the advance was made. If the advance payment exceeds the Medicare payment amount, the carrier must apply the unadjusted balance of the advance payment against future Medicare payments due the supplier.

(4) In accordance with CMS instructions, a carrier must maintain a financial system of data in accordance with the Statement of Federal Financial Accounting Standards for tracking each advance payment and its recoupment.

(g) *Requirements for CMS.* (1) In accordance with the provisions of this section, CMS may determine that circumstances warrant the issuance of advance payments to all affected suppliers furnishing Part B services. CMS 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:

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(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

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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.

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§ 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, post-hospital extended care services, and physicians' services).

Provider has the same meaning as specified under § 400.202 of this chapter.

Qualified chain provider means a chain provider comprised of—

(1) 10 or more eligible providers collectively totaling 500 or more certified beds; or

(2) 5 or more eligible providers collectively totaling 300 or more certified beds, with eligible providers in 3 or more contiguous States.

Supplier has the same meaning as specified in § 400.202 of this chapter.