relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 9, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 05–3684 Filed 2–24–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 421

[CMS–1219–F]

RIN 0938–AL76

Medicare Program; Durable Medical Equipment Regional Carrier Service Areas and Related Matters

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

ACTION: Final rule.

SUMMARY: This final rule provides a mechanism for us to expeditiously make changes to the durable medical equipment regional carrier (DMERC) service area boundaries without notice and comment rulemaking. Through this mechanism, we can change the geographical boundaries served by the regional contractors that process durable medical equipment claims through issuance of a **Federal Register** notice and make other minor changes in the contract administration of the DMERCs. The mechanism provides a method for increasing or decreasing the number of DMERCs, changing the boundaries of DMERCs based on criteria other than the boundaries of the Common Working File sectors, and awarding new contractors to perform statistical analysis or maintain the national supplier clearinghouse. We will publish these changes and their justifications in a **Federal Register** notice, rather than through notice and comment rulemaking.

Although we may change the number and configuration of regional carriers, we are not altering the criteria and factors that we use in awarding contracts.

Through this final rule, we are improving the contracting process so that we can swiftly meet the challenges of the changing healthcare industry and address the changing needs of beneficiaries, suppliers, and the Medicare program.

DATES: Effective Date: These regulations are effective on March 28, 2005.

FOR FURTHER INFORMATION CONTACT: Pat Williams, (410) 786–6139.

SUPPLEMENTARY INFORMATION: This **Federal Register** document is available from the **Federal Register** online database through *GPO access*, a service of the U.S. Government Printing Office. The Web site address is *http://www.gpoaccess.gov/fr/index.html*.

I. Background

A. Legislative Overview of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Claims Administration Covering 1966 Through 1992

Medicare has covered medically necessary items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under Part B since the inception of the Medicare program in 1966. In the original authorizing legislation for the Medicare program, coverage was provided under sections 1832 and 1861(s) of the Social Security Act (the Act) (Pub. L. 89–97). Since that time, the coverage and payment rules for DMEPOS, which may now be found in sections 1832, 1834, and 1861 of the Act and their implementing regulations, have changed significantly.

From 1986 to 1992, the number of complaints about fraud and abuse in the DMEPOS benefit began to increase markedly, and a variety of government investigations identified specific weaknesses in the program. We sought solutions to known claims processing problems, including the increasing level of fraud and abuse in billing. Subsequently, the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) (Pub. L. 100–203), enacted on December 22, 1987, authorized the Secretary to designate, by regulation, regional carriers to process DMEPOS claims. (See sections 1834(a)(12) and 1834(h)(3) of the Act.)

Before 1993, Medicare Part B claims for DMEPOS items and services were assigned to each of the more than 30 local Medicare carriers and represented, on average, only 5 percent of each carrier's overall workload. After further review, we concluded that this was not the most effective structure for administering DMEPOS claims under the Medicare program. It was difficult for carriers to devote significant administrative review resources to this small percentage of claims.

In addition, DMEPOS claims were generally complex and time-consuming to process. The protocol for suppliers to obtain a Medicare billing number was ill-defined and required little identifying information or compliance with any particular business or operational standards.

Furthermore, carriers' medical review policies varied significantly and contributed to inconsistent claims processing decisions. Finally, certain DMEPOS suppliers who engaged in unethical practices were able to exploit our local Medicare carriers by electing to submit claims to carriers that provided more generous coverage, paid more than other carriers, or both. As documented in program audits and congressional hearings, fraudulent suppliers manipulated our then existing ''point of sale'' claims jurisdiction rule; these suppliers could simply locate their business offices where conditions were most favorable. The collective impact of these issues resulted in significant abuse of the Medicare program by a subset of the DMEPOS supplier community, without any measurable improvement in patient care and outcomes.

B. Agency and Congressional Efforts To Reform DMEPOS Claims Administration, 1987 Through 1994

To address the problem of fraud and abuse in the supplier community, we initiated an effort to reform the administration of the DMEPOS benefit category using several strategies. On November 6, 1991, we published a proposed rule (56 FR 56612) setting forth a new framework for DMEPOS claims processing. In that rule, we proposed to limit the number of carriers handling DMEPOS claims by establishing regional carriers who would be expert processors of DMEPOS claims. That rule also proposed to change the requirement for assigning DMEPOS claims to carriers (that is, the DMEPOS claim jurisdiction rule) from a ''point of sale'' framework to a framework based on ''beneficiary residence.'' In addition, the rule proposed to establish supplier business standards and information disclosure requirements. We expected that these changes, taken together, would make Medicare's DMEPOS claim administration apparatus less susceptible to supplier manipulation.

On June 18, 1992, we published a final rule with comment period (57 FR 27290) to implement this revised statutory authority. Additional changes were made by the final rule published on November 18, 1993 (58 FR 60789). This final rule:

- Established four regional carriers (known as DME Regional Carriers or DMERCS) to standardize the coverage and payment of DMEPOS.
- Designated the States and territories to be served by each DMERC.
- Consolidated and focused efforts to curb fraud and abuse.
- Controlled the enrollment of all DMEPOS suppliers through a National Supplier Clearinghouse (NSC) (a contractor that reviews and approves supplier applications for Medicare program billing numbers).
- Introduced the concept of a Statistical Analysis DME Regional Carrier (SADMERC) to review supplier billing patterns.
- Established minimum business standards for all suppliers wishing to enroll in the Medicare Program.
- Required that regional carriers administer DMEPOS claims based on the location (State) of the beneficiary's primary residence. The regulations for DMERC contracts, in accordance with these authorities are set forth at § 405.874, § 421.210, § 421.212, and § 424.57.

On October 31, 1994, the Congress enacted the Social Security Amendments of 1994 (Pub. L. 103–432). Among other matters, this statute established section 1834(j)(1) of the Act, which incorporated and augmented the supplier business and operational standards established in the final rule of June 18, 1992.

C. Provisions of the Existing DMERC Regulations

As noted above, there are several regulatory provisions pertaining to the operation of the DMERCs and related functions.

- Section 405.874 establishes a process by which the NSC makes determinations on whether to issue a Medicare billing number to a supplier applicant and specifies an administrative appeals process if we make an adverse determination.
- Section 421.212 specifies that the Railroad Retirement Board will use the CMS-contracted DMERCs to make DMEPOS claim determinations for Medicare-eligible railroad retirees.
- Section 424.57 provides special payment rules for DMEPOS suppliers and requirements for the issuance of DMEPOS supplier billing numbers, including a series of business and operational standards that DMEPOS suppliers must meet in order to qualify for Medicare billing privileges.

Section 421.210, which we are amending in this regulation, could be viewed as the cornerstone regulation for the DMERC carrier structure.

On June 18, 1992 (57 FR 27290), we published and implemented the existing regulations at § 421.210 under the authority of sections 1842, 1834(a), and 1834(h) of the Act. The existing regulation at § 421.210 augments and expands on the underlying statutory provisions and provides for the following:

Paragraph (a) identifies the statutory basis for the rule and indicates that the purpose of the rule is to designate one or more carriers ''by specific regions'' to process DMEPOS claims.

Paragraph (b) identifies the types of claims for DMEPOS items and services that are processed by the DMEPOS carrier.

Paragraph (c) defines four specific regions for the processing of DMEPOS claims by naming the States and territories to be included in each region. This section also states that the DMERC regions coincide with the ''sector'' boundaries of our Common Working File System.

Paragraph (d) specifies criteria that we use in designating entities to serve as regional carriers for DMEPOS claims.

Paragraph (e)(1) requires that the DMERCs process DMEPOS claims only for beneficiaries whose permanent residence falls within their designated regional areas (as established by paragraph (c) of this section). Paragraph (e)(1) also specifies that, in processing DMEPOS claims, the DMERCs apply the payment rates applicable to the State of residence of the beneficiary. In addition, the rule makes clear that the ''beneficiary residence'' jurisdiction rule applies to qualified Railroad Retirement beneficiaries and defines ''permanent residence'' for the purpose of the rule.

Paragraph (e)(2) identifies by name the initial DMERCs; paragraph (e)(3) identifies by name the initial NSC and SADMERC; paragraph (e)(4) commits us to periodically re-compete the four DME regional carrier contracts.

Paragraph (f) requires the DMERCs to collect ownership and control information, as well as supplier standard certifications, from each DMEPOS supplier that they service.

We discuss several changes to paragraphs (a), (c), (d), and (e) of § 421.210 in section II of this preamble, ''Provisions of the Proposed Regulations''.

D. Establishment and Operation of the DMERCs, 1993 Through 2003

We issued a Request for Proposal in May 1992 for the four regional DMERC contracts. We also solicited offers for two DMEPOS-related national contracts, the above-mentioned NSC and the SADMERC. In December 1992, the contracts, designed around Common Working File sectors, were awarded as follows:

Region A: Travelers Insurance Company for 10 States in the Northeast.[1]

Region B: AdminaStar Federal for 9 States in the Midwest and the District of Columbia.

Region C: Palmetto Government Benefits Administrators (GBA) for 14 States and 2 territories in the South.

Region D: CIGNA for 17 States and 3 territories in the West.

NSC: Palmetto GBA.

SADMERC: Palmetto GBA.

Initially, the DMERC and SADMERC contracts were 2-year contracts with two 1-year renewal options. The NSC was given two 1-year contracts and two 1-year renewal options. The contracts were modeled, to a significant extent, after requirements in the Federal Acquisition Regulations (FAR).

[1] The contract was initially awarded to Travelers Insurance Company and the regulations use this name. Through a series of corporate transactions, United Healthcare became the successor-in-interest to Travelers and served as the DMERC until September 2000, when HealthNow was awarded the DMERC contract for Region A.

One of the biggest challenges and accomplishments of the transition to the DMERC processing arrangement was the consolidation of diverse carrier medical policies for DMEPOS. Our initiative to configure geographical regions to process DMEPOS claims by consolidating DME workloads from the 34 carriers to 4 DMERCs greatly improved the rigor and consistency of medical review. Formerly, each carrier developed its own local medical review policies for DMEPOS claims with minimal guidelines and oversight from us. During the transition period, our coverage and medical review staff worked closely with the DMERC medical directors to streamline and standardize medical policy within and across the DMERC regions. Regionalization allowed the DMERCs to have a consistent uniform interpretation of coverage policies, local medical review policies, and pricing for similar items and services. Today, the DMERCs share essentially one approach to coverage and medical review for all DMEPOS items.

E. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes provisions set forth in the March 26, 2004 proposed regulation (69 FR 15755). In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

II. Provisions of the Proposed Regulations

(This rule uses the term ''carrier'' to describe the Durable Medical Equipment administrative contractor. Effective October 1, 2005, according to section 911(e) of the MMA, the term ''carrier'' should be read as ''Medicare Administrative Contractor.'')

We proposed a number of changes to § 421.210 which concern the designation of regional carriers to process claims for DMEPOS. Broadly speaking, we are seeking greater future flexibility to revise the number and boundaries of DMERC regional areas. We also desire greater flexibility in contracting for DMERC, NSC, and SADMERC functions. We have examined the statutory framework (section 1834(a)(12) of the Act, as set forth below at paragraph (a), ''Basis'') for § 421.210 and have concluded that the existing regulation is more restrictive on the Secretary's contracting discretion than required either by statute or the Medicare program's interest.

Specifically, we proposed to make the following changes to § 421.210 ''Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics, and supplies'':

- Paragraph (a), ''Basis.''

We proposed to revise paragraph (a) to more closely follow the actual language of section 1834(a)(12) of the Act that authorizes the Secretary to ''designate, by regulation under section 1842 of the Act, one carrier for one or more entire regions to process all claims within the region for covered items under this section.'' We therefore proposed to revise paragraph (a) to state that the Secretary is authorized to designate carriers for ''one or more entire regions'' rather than to designate carriers by ''specific'' regions.

- Paragraph (c), ''Region designation.''

We proposed to revise paragraph (c), designate the existing paragraph (c) as (c)(1), and add a new paragraph (c)(2).

In paragraph (c), we proposed to clarify the Secretary's authority to revise the number or configuration of DMEPOS regional areas in the future, based on appropriate factors and criteria.

The existing regulations in § 421.210(c) specify that there are four regional areas for DMEPOS claims and further specify that these areas be drawn to coincide with the Common Working File sectors. The regulations also specify, by name, which States and territories are assigned to each region for DMEPOS claims. To allow greater flexibility, in paragraph (c)(1), we proposed to add the word ''initial'' in front of the listing of the current DMERC service areas, to make clear that this configuration could change in the future.

In addition, we proposed to revise paragraph (c)(1) to remove a specific reference to the Common Working File sector framework as a determinant for the DMERC regions. Advances in technology have greatly diminished the importance of this consideration and, therefore, its inclusion in regulation is unnecessary.

The existing reference to Common Working File sectors in paragraph (c)(1), as a constraint for the DMERC region boundaries, illustrates the approach of the original rule. The June 18, 1992 final rule (57 FR 27290) acknowledged a technical Medicare claims processing system constraint that was significant at the time. Since that time, advances in our claims processing system have greatly reduced the impact of ''out of the area'' processing, and it is no longer necessary to structure the DMERCs around the Common Working File sectors.

New paragraph (c)(2) proposed a mechanism for us to revise the number and boundaries of DMERC regional service areas in the future based on appropriate factors and criteria. Our goal is to constantly strive to improve beneficiary and supplier satisfaction. Therefore, in our decisions, we will consider the effect of any service area changes on beneficiaries and suppliers. Examples of factors and criteria include population shifts or natural disasters that require a reallocation of workload, and workforce conditions that may make it difficult for DMERCs in certain areas to recruit and retain qualified employees. We specified in paragraph (c)(2) that this change would provide a mechanism for us to identify which States and territories are assigned to various DMERC regions by publication of a **Federal Register** notice. The **Federal Register** notice will identify the nature of any changes in the DMERC service areas, as well as our rationale for the changes.

Under the current regulation, we would have to maintain the current DMERC configuration even if our administrative and program needs change. Currently, the only existing mechanism for changing the structure of the DMERC regions is to undertake notice and comment rulemaking for each change. We believe that it is not the intent of the statute to constrain the Secretary's administrative discretion to this extent. In seeking this regulation change, we anticipate that new program circumstances may arise that would require alterations in the number or configuration of DMERC service areas. We believe that we would have a definite need to move swiftly and make DMERC service area changes without going through notice and comment rulemaking whenever administrative issues arise. Just as critical, we believe it is important to consider the effects of these kinds of changes on beneficiaries

and suppliers and to provide the public with an explanation of changes when they are made.

Under our March 26, 2004 proposed rule, we would not administer four DMEPOS areas, would not determine these DMEPOS areas based on the sector areas of the Common Working File, and would not go through notice and comment rulemaking to modify the assignment of the States and territories to revised DMEPOS areas.

In our March 26, 2004 proposed rule, we provided a hypothetical example of a situation that cannot be adequately addressed under the current regulation. In this example, DMERC X, which has historically performed well, is having difficulty serving all beneficiaries and suppliers in all of its assigned States, due to problems in recruiting a sufficient number of qualified personnel. At present, the regulations appear to limit our options to—(1) expecting that DMERC X will improve its performance; or (2) terminating DMERC X's contract for the entire service area and procuring and installing a replacement. We do not have the third option of removing a limited number of States from DMERC X's contract and attaching these service areas to another DMERC's service area (or setting up a fifth DMERC jurisdiction). However, under the proposed regulation, the third contract management option could yield many benefits, in that DMERC X could focus its resources on its remaining workload. Under the existing regulation, moving a State to another area, or setting up a fifth jurisdiction, would require an extended rulemaking process unless the rules take a more general approach, as we proposed.

• Paragraph (d), ''Criteria for designating regional carriers.''

Paragraph (d) under this section currently discusses our ''designation'' of regional carriers in a manner that does not explicitly acknowledge the fact that these designations must be premised on the awarding of Medicare carrier contracts in accordance with applicable law.

We also proposed to revise paragraph (d) under this section to make clear that we would designate regional carriers to process DMEPOS claims by awarding DMERC contracts in accordance with applicable law. We did not propose any changes to the current criteria under paragraphs (d)(1) through (d)(5) of this section, which we use in our procurement evaluation processes for this particular kind of contract.

• Paragraph (e), ''Carrier designation.''

In paragraph (e)(1), we proposed to make minor revisions to conform the language to the changes made in § 421.210(c).

We proposed to revise paragraph (e) to provide us with flexibility and discretion with respect to contracting for DMERC and related functions. The existing regulations in § 421.210(e) name the initial DMERC-contracting companies and also identify the particular region each company serves. The existing regulations could be interpreted as requiring that we constantly update our rules whenever our business partners change.

The proposed regulatory framework clarified our discretion not to name a contracting company in future regulations if we re-compete a DMERC contract after its conclusion or termination. This proposed change would potentially reduce the agency's administrative burden when a DMERC contract is not renewed. We proposed to notify affected beneficiaries and suppliers when we change contractors.

Specifically in paragraph (e)(2), we proposed to remove the names of the initial DMERCs from the regulation. This change clarified our future discretion to award a DMERC contract to process DMEPOS claims under the Medicare program (that is, designate a DMERC), without any obligation to name the new DMERC(s) in regulations or by **Federal Register** notice. We would, however, notify affected beneficiaries and suppliers to the change in contractors. Therefore, we proposed to revise paragraph (e)(2) to add that we would notify affected Medicare beneficiaries when we designate a regional carrier.

We proposed to revise paragraphs (e)(3) and (e)(4) to provide us with a mechanism to contract for the performance of NSC functions through either an amendment to a DMERC contract or through a non-DMERC Medicare carrier contract. In paragraph (e)(4), the existing regulations for NSC functions limit our selection of NSC contractors to one of the DMERCs. However, section 1834(j)(1)(E) of the Act more broadly permits any carrier with a contract under section 1842 of the Act to perform NSC functions. We believe that our regulations should reflect this broader discretion under the statute. Therefore, in paragraph (e)(4), we proposed to remove the limitation that restricts our list of contractors to only four DME regional carriers. This proposed revision gives us greater flexibility when we re-compete a DMERC contract after its conclusion or termination.

In addition, we proposed to delete the references to the SADMERC function in § 421.210(e)(3) and § 421.210(e)(4). SADMERCS are responsible for storing national DMEPOS claims history data, for distributing to the DMERCS national pricing files, and for conducting data analysis. Although we recognize the importance of the activities that the SADMERC provides to us and to the DMERCS, these activities are not identified elsewhere in the regulations, and we believe that little purpose is served by naming an entity in the regulations without any reference to its functions. Therefore, we do not believe it necessary to reference the SADMERC in our regulations.

By removing the existing reference to the SADMERC, including the constraint that this activity be included in a DMERC's contract, we would have the flexibility to include this function in a DMERC contract or to contract for the SADMERC activity through some other vehicle.

In summary, the March 26, 2004 proposed rule would provide a mechanism for us to change the geographical boundaries served by the regional contractors that process DME claims and to make other minor changes in contract administration of the DMERCS. We would have the mechanism to increase or decrease the number of DMERCS or change the boundaries of the DMERCs through a **Federal Register** notice. Further, we could name new contractors to perform the functions of the DMERC and NSC without going through notice and comment rulemaking. Instead, we would notify affected beneficiaries and suppliers of contractor changes through our outreach and education initiative.

III. Analysis of and Responses to Public Comments

We received a total of twelve timely public comments in response to the March 26, 2004 proposed rule (69 FR 15755). Commenters included national trade associations, health care providers, existing CMS contractors, and private citizens. All public comments were reviewed and grouped by like or related topics. The comments and our responses are summarized below.

Comment: A few commenters stated that the impacted business communities must receive sufficient notification of proposed changes and sufficient information to provide substantive comments.

Response: This final rule states that we consider the impact on beneficiaries and suppliers of any modifications to the boundaries or number of DMERC

jurisdictions. This analysis will include the question of whether providers, suppliers, and patients have reasonable access to payer decision-makers. We will provide sufficient public notification to affected Medicare suppliers and beneficiaries. We will publish any changes to DMERC service areas and their justifications in a **Federal Register** notice, rather than through notice and comment rulemaking. Furthermore, open door forums or town hall meetings will be held to give the public the opportunity to comment. Customer service and continuity of high quality service for both beneficiaries and suppliers remain our top priorities and any future changes will be consistent with our commitment. We will also consider the operational management and oversight structure impacts of any future changes.

Comment: A few commenters noted that CMS must provide more information so that the community can comment and understand the reason for any revised DMERC boundaries.

Response: On December 8, 2003, the President signed the MMA into law. Since we are developing our implementation plan and strategy, these changes will give us the flexibility to ensure coordinated implementation across all benefit types, enabling us to administer high quality, consistent service and benefit management to suppliers and beneficiaries. This final rule ensures that our changes are made in a more flexible manner. Our rationale for these changes was explained in the March 26, 2004 proposed rule. We will publish our rationale for any specific DMERC area changes in a **Federal Register** notice to ensure that we address the needs of beneficiaries and suppliers.

Comment: Two commenters stated that our proposal to explain any modifications to the boundaries or number of the DMERC jurisdictions in a **Federal Register** notice, with supporting criteria and considerations, is not adequate. These commenters asserted that we should fully identify the criteria that would be employed in any decision to modify the boundaries or number of the DMERC jurisdictions in our proposed changes to § 421.210(c). One of the two commenters argued that giving providers and patients reasonable access to payer decision-makers should be a factor in determining the scope of a contractor's territory.

Response: This final rule states that we consider the impact on beneficiaries and suppliers of any modifications to the boundaries or number of DMERC jurisdictions. This analysis would include the question of whether providers, suppliers, and patients have reasonable access to payer decision-makers. (We note, however, that we and our contractors can ensure this access through many means in addition to the specific design of the DMERC regions—for instance, through maintaining toll-free lines for providers and suppliers). The preamble to our proposed rule also outlined other possible supporting criteria and considerations for a particular change—for instance, we discussed how we might adjust the DMERC areas due to population shifts, or to address performance problems at contractors.

There are any number of other potential reasons that might lead us to consider adjusting the DMERC jurisdictions—for example, we are now considering this issue as part of our implementation of the Medicare contracting reform provisions under the MMA (section 911). We will make every effort to clearly identify the criteria used in any decision to modify boundaries or numbers of participants.

Comment: Several commenters voiced concerns about the potential impact of changing DMERC contractors through the competitive process, including changing the SADMERC and NSC, and the transition impact of this action to ongoing operations. The commenter asked about our methods to alleviate those perceived impacts.

Response: The intent of this rule is to provide the government a mechanism to expeditiously make changes to the DMERC service area boundaries without notice and comment rulemaking. Through this mechanism, we can change the geographical boundaries served by the regional contractors that process durable medical equipment claims through issuance of a **Federal Register** notice. Transition impacts are not addressed in this regulation; however, in the event that transitions would occur, CMS has considerable experience in workforce transitions and will ensure that supplier and beneficiary customer service and continuity of high quality service remain our top priority. Our normal practice, when transferring contractual responsibility for Medicare claims processing and related functions from one contractor to another, is to transfer all work-in-progress as of a certain date to the new contractor. We will consider the comments provided in our operational management of the DMERCs and any future transitions.

Comment: Two commenters offered constructive suggestions on having overall better performance and consistency of output, as well as a unified approach to DMERC policies, as a result of any CMS changes.

Response: Our proposed change to this regulation does not directly address these issues. Supplier and beneficiary customer service and continuity of high quality service remain our top priority. We will consider these suggestions in our operational management of the DMERCs and all contractors.

Comment: One commenter noted that suppliers must make adjustments in order to interact with a new DMERC, such as updating their patient accounts and electronic billing to reflect the new DMERC address, or adjusting their Medicare fee tables if the new DMERC pays claims differently. Because of these issues, the commenter asserted that the proposed rule would have a significant impact on small businesses and that a Regulatory Flexibility Analysis should have been conducted.

Response: We agree that suppliers must make adjustments in their billing when there are changes in DMERCs, but we do not believe that these adjustments are significant enough to warrant a Regulatory Flexibility Analysis, given the narrow scope of the proposed changes to the existing regulations.

First, all DMERCs—now and in the future—will be required to apply the proper Medicare fee tables developed in accordance with the statute, and so changes in the identity of DMERCs will not affect the payment allowances received by suppliers.

Suppliers will need to adjust their billing mechanisms when there is a new DMERC. These adjustments must be made whenever there is a change in the insurance coverage for any non-Medicare patient of the supplier. Further, these changes could occur even in the absence of the proposed regulation change, as existing regulations commit us to periodically re-compete the DMERC contracts. There is no guarantee that incumbent contractors will always retain their existing contracts in the competitive process. Finally, section 911 of the MMA requires the application of competitive procedures to all Medicare claims processing contracts, including these contracts, not less than once every 5 years.

We note that the original proposed and final rules pertaining to DMEPOS claims processing (56 FR 56612, 57 FR 27290, 58 FR 60789) did not require a Regulatory Flexibility Analysis, although their scope was broader and more significant than our proposed rule. For instance, those rulemaking actions consolidated the number of entities handling DMEPOS claims from more than thirty to four, established the

''beneficiary residence'' billing requirement, various business standards for Medicare suppliers, and some new information collection requirements. Our final rule, by contrast, only gives us some additional flexibility in modifying the DMERC jurisdictions and in structuring the DMERC contracts. Any adjustments to the DMERC jurisdictions that we might make under our final rule would have a very modest impact relative to the effects of our original rulemaking activities (which did not require a full Regulatory Flexibility Analysis).

Nonetheless, in the spirit of the Regulatory Flexibility Act, our final rule states that we will consider the impact on suppliers and beneficiaries of any future changes we make in DMERC jurisdictions, and we will discuss these issues in the **Federal Register** notice or notices as stated in our proposed rule.

Comment: Three commenters, including one who is a current contractor who performs DMERC, NSC, and SADMERC functions, expressed concern over the removal of the SADMERC and NSC functions from a DMERC.

Response: This regulation does not mandate removal of the SADMERC and NSC functions from a DMERC contract. Removing references to the SADMERC and NSC from the regulation does not mean we will not contract out for these services. The changes to the regulation give us flexibility in terms of how we contract out for the SADMERC and NSC functions. We will consider these comments in any future operational strategies for the processing of DMEPOS claims.

Comment: Two commenters asked how the Medicare contracting reform provisions of the MMA (section 911) would affect the underlying DMERC regulations at § 421.210, as well as our proposal to modify them. One of these commenters also asked whether we might adjust the DMERC regions or functions in our implementation of the Medicare contracting reform provision, while the other queried whether our proposal would affect the implementation of the other DME-related provisions in MMA (for instance, the DME competitive bidding program established by section 302 of the MMA).

Response: Section 911(e) of the MMA states that any statutes and regulations pertaining to Medicare intermediaries and carriers, if not modified by or contrary to the explicit provisions of the MMA, should be read as applying to the Medicare administrative contractors that will replace the intermediaries and carriers. Thus, our regulation change will continue to apply to our contracting for DMEPOS claims processing even after the effective date of section 911 of the MMA (October 1, 2005). We note that the MMA did not modify or repeal section 1834(a)(12) of the Act, which is one of the underlying authorities for this regulation and for our changes to the regulation. Further, we have made the decision to continue to operate specialized claims processing contractors for DMEPOS in our implementation plan for the MMA, at least for the initial round of competitive contracts let under the MMA authority.

The MMA will certainly affect our contracting activities with respect to DMEPOS claims processing; for instance, we will be required to re-compete each one of these contracts consistent with the MMA.

We are currently considering the question of whether to adjust the DMERC regions and functions as part of the broader implementation of Medicare contracting reform. Our specific plans on these issues will be made public in the near future.

We do not anticipate that our changes will affect the implementation of the other MMA provisions relating to DME, including the competitive bidding program established by section 302 of the MMA. For instance, we would see the DMERCs as implementing any pricing changes for DMEPOS items based on that provision. We have devoted and will continue to devote significant program management and transition planning efforts to analyzing and mitigating these issues to the greatest extent possible.

Comment: A commenter offered recommendations and suggestions regarding a medical approach to the payment provisions for prosthetic-orthotic services and supplies.

Response: The recommendations and suggestions submitted were coverage and policy issues, which are outside the scope of this regulation. We are forwarding this letter to the appropriate staff who can review and consider these recommendations in terms of our future policymaking decisions.

Comment: A commenter inquired as to how ''ongoing claims disputes'' are handled when there is a change in the DMERCs, and whether these issues are transferred to the new DMERC.

Response: Our normal practice, when transferring contractual responsibility for Medicare claims processing and related functions from one contractor to another, is to transfer all work-in-progress, including pending claims appeals, as of a certain date to the new contractor. We anticipate that we will generally follow this practice in regard to any changes in DMERC contractors, although it is possible that, under some circumstances, the outgoing contractor could agree to finalize some appeal cases under a subcontract with its successor.

It should be noted that recent statutory changes (in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554, enacted on December 21, 2000), as amended by the MMA) mandated significant changes to the Medicare appeals process. In the future, Medicare claims processing contractors, including the DMERCs, will handle only first-level re-determination requests on any claim. After the DMERC takes this action, a Qualified Independent Contractor (QIC) designated to process these DME appeals will handle the next review level for any claims-related appeals. Future interactions between an affiliated contractor and the QIC include: Consolidating the case file materials for the QIC and effectuating favorable decisions (either from the QIC, Administrative Law Judge, or the Departmental Appeals Board).

Comment: One commenter asserted that if we anticipate making major changes to the number or boundaries of the DMERC jurisdictions, then we should use the traditional notice and comment rulemaking process so that those who will be impacted by the changes are given sufficient opportunity to respond. A second commenter asked that our March 26, 2004 proposed rule include a description of the process by which the agency will seek public comment through a less formal means than rulemaking. This commenter believes that any formal or informal process should permit comments on proposed changes, with sufficient response time, before the changes are finalized. A third commenter also suggested that we should consult with beneficiary and supplier stakeholders before implementing these kinds of changes.

Response: We believe that the agency has many potential avenues outside of notice and comment rulemaking for obtaining input on planned changes in the number or boundaries of the DMERC jurisdictions. These include, but are not limited to, publishing the changes for comment on our Web site (*http://www.cms.hhs.gov*), holding industry conferences at either a national or local level, or holding a ''town hall''-type meeting.

We intend to conduct these types of exchanges, but do not believe that we have to identify these informal approaches to obtaining the views of

affected stakeholders in this final rule. Instead, we believe that our commitment to publish planned changes in a **Federal Register** notice, and to include our assessment of the effect of any change on beneficiaries and suppliers in our analysis (along with other information supporting the change) provides a sufficient commitment—from a regulatory perspective—to advance notification and fair process.

Under this regulation, if sufficient informal commentary has not been received, we are not precluded from requesting public comment through the required **Federal Register** notice. Indeed, if there should be a change of such magnitude as to warrant full notice and comment rulemaking, we have the option of employing that process.

It is our intention to advise and consult with affected stakeholders, especially suppliers and beneficiaries, about potential changes in the number or boundaries of DMERC jurisdictions well in advance of implementation. For instance, this will occur as a matter of course as we develop our planned approach to implementing Medicare contracting reform; any changes in contractor jurisdictions associated with that initiative will be well-publicized. Short of a public emergency, the agency would make these kinds of plans public at least several months before implementation. These practices, which we believe do not require codification in the regulations, will ensure that beneficiaries and suppliers have continuity in access to DMERC claims processing services.

Comment: One commenter stated that, when we make a change in a DMERC contractor, we should notify affected beneficiaries and suppliers through a **Federal Register** notice at least 90 days in advance.

Response: We completely agree that, when we replace any established Medicare claims processing contractor with a new contractor, the affected public, including suppliers and beneficiaries, must be informed. In fact, we always consider a potential replacement contractor's plan for conducting provider and beneficiary outreach during the transition period as a major element in our contract award process. Our program experience indicates that this kind of outreach effort is a critical success factor for any contractor transition. However, our program experience also indicates that using the **Federal Register** for this kind of activity is slow, ineffective, and cumbersome. There are many other, more efficient ways to introduce the new Medicare contractor to the affected stakeholders. We do not use the **Federal Register** to notify the public when we contract with a new intermediary or non-DMERC carrier, and there is no reason why this approach to notifying the public should be used when a DMERC is replaced.

IV. Provisions of the Final Regulations

This final rule incorporates the provisions of the proposed rule. The provisions of this final rule do not differ from those in the proposed rule.

V. Collection of Information Requirements

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

VI. Regulatory Impact

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order (E.O.) 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and E.O. 13132.

E.O. 12866 (as amended by E.O. 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). This final rule does not reach the economic threshold and thus is not considered a major rule. This rule merely provides the Secretary with greater contracting flexibility consistent with the statute and will not have any direct economic impact. Because this final rule only affects our administrative structures and does not change in any way the Medicare DMEPOS benefit (that is, neither coverage nor payment is changed), this rule will not affect the amount or distribution of the Medicare benefit payment for DMEPOS. Further, any possible restructuring of the DMERC regions in the future will not remotely approach a net economic impact of $100 million on either our administrative costs or the administrative costs of DMEPOS suppliers. Therefore, we do not believe that a regulatory impact analysis is necessary under E.O. 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. This final rule, as noted above, will not have any significant direct economic impact on DMEPOS suppliers, because it will not affect the scope of benefits, coverage, or payment rules for DMEPOS, nor will it affect the billing requirements for these services. This rule does not designate any particular reconfiguration of the DMERC areas. However, we agree to consider any effects on DMEPOS suppliers in any future reconfigurations of the DMERC regions. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities. We hereby certify, under 5 U.S.C. 605(b), that the final rule will not have a significant economic impact on a substantial number of small entities, including small businesses, organizations, and local governments.

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 of a Metropolitan Statistical Area and has fewer than 100 beds. This rule pertains to our processes for configuring and designating contractors to process DMEPOS claims and will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule will not have a consequential effect on

the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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. Since this regulation will not impose any costs on local governments, the requirements of E.O. 13132 are not applicable.

B. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

C. Alternatives Considered

We could have chosen to continue to operate under the constraints of our current regulations. This option would require that we periodically undertake notice and comment rulemaking to update the regulations with the names of new contactors. We have provided additional discussion in the preamble describing why we believe this is not the optimal solution. We believe our decision to make modest changes to our regulations will offer us greater flexibility in contracting with DMERCs and allow us to be more responsive to the needs of all key stakeholders.

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget.

List of Sections in 42 CFR Part 421

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

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, part 421 as set forth below:

PART 421—INTERMEDIARIES AND CARRIERS

■ 1. 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).

Subpart C—Carriers

■ 2. Section 421.210 is amended as follows:

■ A. Revise paragraph (a).
■ B. Revise paragraph (c).
■ C. Revise the introductory text of paragraph (d).
■ D. Revise paragraph (e).

The revisions read as follows:

§ 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.

* * * * *

(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—

* * * * *

(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.

* * * * *

Dated: December 23, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 22, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–3728 Filed 2–24–05; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket 98–67 and CG Docket No. 03–123; DA 05–140]

Telecommunications Relay Services and Speech-to-Speech Services for Individuals With Hearing and Speech Disabilities

AGENCY: Federal Communications Commission.

ACTION: Interpretation.