elsewhere in this issue of the Federal Register.

]]] [Reserved]. For further guidance, see § 1.861–9T(j).

Mark E. Matthews,
Deputy Commissioner for Services and Enforcement.

[FR Doc. 04–6620 Filed 3–25–04; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 61 and 63

[LA–69–2–7617b; FRL–7638–6]

Approval of the Clean Air Act Section 112(l) Program for Hazardous Air Pollutants and Delegation of Authority to the State of Louisiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Louisiana Department of Environmental Quality (LDEQ) has submitted updated regulations for receiving delegation of EPA authority for implementation and enforcement of National Emission Standards for Hazardous Air Pollutants NESHAPs for all sources (both part 70 and non-part 70 sources). These regulations apply to certain NESHAPs promulgated by EPA, as amended through July 1, 2002. The delegation of authority under this notice does not apply to sources located in Indian Country. EPA is providing notice as amended through July 1, 2002. The delegation of authority under this notice does not apply to sources located in Indian Country. EPA is providing notice that proposes to approve the delegation of certain NESHAPs to LDEQ.

DATES: Written comments must be received by April 26, 2004.

ADDRESSES: Comments must be submitted to Mr. Jeffery Robinson, Air Permit Section, Multimedia Planning and Permitting Division (6PD–R), U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in section I.B. of the Supplementary Information section of the direct final rule located in the Rules section of this Federal Register.

FOR FURTHER INFORMATION CONTACT: Mr. Jeffery Robinson, Air Permit Section, Air Permits Section, Multimedia Planning and Permitting Division (6PD–R), U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, at (214) 665–6435, or at robinson.jeffrey@epa.gov.

SUPPLEMENTARY INFORMATION: In the final rules section of this Federal Register, EPA is approving LDEQ’s request for delegation of authority to implement and enforce certain NESHAPs for all sources (both part 70 and non-part 70 sources). LDEQ has adopted certain NESHAPs by reference into Louisiana’s state regulations. In addition, EPA is waiving its notification requirements so sources will only need to send notifications and reports to LDEQ.

The EPA is taking direct final action without prior proposal because EPA views this as a noncontroversial action and anticipates no adverse comments. A detailed rationale for this approval is set forth in the preamble to the direct final rule. If no adverse comments are received in response to this action rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn, and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is published in the Rules section of this Federal Register.

Authority: 42 U.S.C. 7412.


Richard E. Greene,
Regional Administrator, Region 6.

[FR Doc. 04–6300 Filed 3–25–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 421

[CMS–1219–P]

RIN 0938–AL76

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would allow us to change the geographical boundaries served by the regional contractors that process durable medical equipment claims and to make other minor changes in the contract administration of the durable medical equipment regional carriers (DMERCs). It would allow us to increase or decrease the number of DMERCs, to change the boundaries of DMERCs based on criteria other than the boundaries of the Common Working File, and to name new contractors to perform statistical analysis or maintain the national supplier clearinghouse. We would publish the changes and their justifications in a Federal Register notice, rather than through notice and comment rulemaking.

Although we are proposing to allow changes to the number and configuration of regional carriers, we are not proposing to alter the criteria and factors that we use in awarding contracts.

The intent of this proposed rule would be to improve the contract process by swiftly meeting the challenges of the changing healthcare industry, addressing the changing needs of beneficiaries, suppliers, and the Medicare program, and facilitating our efforts to provide interested parties with the best value Medicare claims processing services. While we are not proposing to reconfigure the DMERC service boundaries at this time, the changes set forth in this proposed rule would provide a mechanism to swiftly make these kinds of changes without repeatedly invoking full rulemaking.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 25, 2004.

ADDRESSES: In commenting, please refer to file code CMS–1219–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit electronic comments to http://www.cms.hhs.gov/regulations/e comments or to http://www.regulations.gov; or you may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1219–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of
the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public Web site.

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

FOR FURTHER INFORMATION CONTACT: Kimberly Nyland, (410) 786–2289.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1219–P and the specific “issue identifier” that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7195.

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.access.gpo.gov/nara/index.html.

I. Background

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

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

Medicare has covered medically necessary items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under Part B since the inception of the 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 much review, we concluded that this structure was not the most effective one for administering DMEPOS claims under Medicare. 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 could do this easily by manipulating 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. The 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 27307) to implement this revised statutory authority. The rule provided the following:

- 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 42 CFR 405.874, 421.210, 421.212, and 424.57.

Finally, on October 31, 1994, the Congress enacted the Social Security Amendments of 1994, Public Law 103–432. Among other matters, this statute established section 1834(b)(1) of the Act, which incorporated and augmented the supplier business and operational standards established in the final rule of June 18, 1992. Paragraph (E) of this provision ratified the concept of using the NSC. However, this provision restricts the type of entity that may perform the NSC function exclusively to Medicare carriers holding contracts under section 1842 of the Act.

C. Provisions of the Existing DMERC Regulations (Especially §421.210)

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 could be viewed as the cornerstone regulation for the DMERC carrier structure. As we are proposing to amend this regulation, it is important to discuss its content in some detail.

We published and implemented the current regulations at §421.210 under the authority of sections 1842, 1834(a), and 1834(h) of the Act. The current regulation, which augments and expands on the underlying statutory provisions, 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)). Paragraph (e)(1) also specifies that in processing DMEPOS claims, the DMERCs will 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.

In section II of the preamble, we will discuss several changes we propose to make to paragraphs (a), (c), (d), and (e) of §421.210.

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 aforementioned 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).

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. The agency’s 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 under loose 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.

II. Provisions of This Proposed Rule

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

We are proposing to make 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

1The 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.
the current regulation and concluded that the current regulation is more restrictive on the Secretary’s contracting discretion than required either by statute or the program’s interest.

Specifically, we are proposing 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 are proposing to revise paragraph (a) 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 are therefore revising 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 are proposing to revise the language in paragraph (c), designate the current paragraph (c) as (c)(1), and add a new paragraph (c)(2).

In paragraph (c), we are proposing 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 current 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 are proposing 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 would 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 rule 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) would allow 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, we would consider the effect of any service area changes on beneficiaries and suppliers in our decisions. 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 specify in paragraph (c)(2) that this change would allow us future discretion to identify which States and territories are assigned to various DMERC regions by publication of a Federal Register notice. The Federal Register notice would identify the nature of any changes in the DMERC service areas, as well as our rationale for the changes.

Absent the proposed changes to these regulations, 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. Although we are not now proposing to alter the number or configuration of the four areas for DMEPOS claims, we anticipate that new program circumstances may arise that may require alterations in the number or configuration of DMERC service areas. We believe that we have a definite need for the capability 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 proposed rules, we would not be required to administer four DMEPOS areas, would not be required to determine these DMEPOS areas based on the name of the Common Working File, and would not be required to go through rulemaking to modify the assignment of the States and territories to revised DMEPOS areas.

We are providing a fictitious (but plausible) example of a situation, which cannot be addressed very well 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 difficulties in recruiting a sufficient number of qualified personnel. At present, the regulations would seem to limit our options to—(1) hoping that DMERC X improves 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, this kind of contract management action could yield many benefits, in that DMERC X could focus its resources on its remaining workload. Under the current 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 are proposing.

• 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 are proposing to revise paragraph (d) under this section to make clear that we will designate regional carriers to process DMEPOS claims by awarding DMERC contracts in accordance with applicable law. We are not proposing 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 are also proposing to make minor revisions to conform the language to the changes made in §421.210(c).

We are also proposing to revise paragraph (e) to provide that we have flexibility and discretion with respect to contracting for DMERC and related functions. The current regulations in §421.210(e) name the initial four DMERC contracting companies and also identify the particular region each company.

Specifically, we are proposing 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 are proposing to revise paragraph (a) 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 are therefore revising 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 are proposing to revise the language in paragraph (c), designate the current paragraph (c) as (c)(1), and add a new paragraph (c)(2).

In paragraph (c), we are proposing 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 current 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 are proposing 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 would 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 rule 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) would allow 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, we would consider the effect of any service area changes on beneficiaries and suppliers in our decisions. 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 specify in paragraph (c)(2) that this change would allow us future discretion to identify which States and territories are assigned to various DMERC regions by publication of a Federal Register notice. The Federal Register notice would identify the nature of any changes in the DMERC service areas, as well as our rationale for the changes.

Absent the proposed changes to these regulations, 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. Although we are not now proposing to alter the number or configuration of the four areas for DMEPOS claims, we anticipate that new program circumstances may arise that may require alterations in the number or configuration of DMERC service areas. We believe that we have a definite need for the capability 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 proposed rules, we would not be required to administer four DMEPOS areas, would not be required to determine these DMEPOS areas based on the name of the Common Working File, and would not be required to go through rulemaking to modify the assignment of the States and territories to revised DMEPOS areas.

We are providing a fictitious (but plausible) example of a situation, which cannot be addressed very well 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 difficulties in recruiting a sufficient number of qualified personnel. At present, the regulations would seem to limit our options to—(1) hoping that DMERC X improves 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, this kind of contract management action could yield many benefits, in that DMERC X could focus its resources on its remaining workload. Under the current 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 are proposing.

• 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 are proposing to revise paragraph (d) under this section to make clear that we will designate regional carriers to process DMEPOS claims by awarding DMERC contracts in accordance with applicable law. We are not proposing 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 are also proposing to make minor revisions to conform the language to the changes made in §421.210(c).

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

The proposed regulatory framework will clarify 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 are proposing, however, to notify affected beneficiaries and suppliers when we change contractors.

Specifically in paragraph (e)(2), we are proposing to remove the names of the initial DMERCS from the regulation. This change would also clarify 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. However, we will notify affected beneficiaries and suppliers to the change in contractors. Therefore, we are proposing to revise paragraph (e)(2) to add that we will notify affected Medicare beneficiaries when we designate a regional carrier.

We are proposing to revise paragraphs (e)(3) and (e)(4) to allow us discretion 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 current regulations for NSC functions limit the agency’s selection of NSC contractors to one of the DMERCS. However, section 1834(j)(1)(E) of the Act actually more broadly permits any carrier with a contract under section 1842 of the Act to perform NSC functions. We believe that our rules should reflect this broader discretion under the statute. Therefore, in paragraph (e)(4), we are proposing 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 are proposing 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 the DMERCS, these activities are not identified elsewhere in the regulations, and we believe that little purpose is served by naming an entity without any reference to its functions. Therefore, we do not believe it necessary to reference the SADMERC in our regulations.

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

In summary, this proposed rule would allow 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 be able to increase or decrease the number of DMERCS or change the boundaries of the DMERCS through a Federal Register notice. Further, we would 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. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact

A. Overall Impact

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

We have examined the impacts of this rule as required by Executive Order (E.O.) 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 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 reassigned 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 rule does not reach the economic threshold and thus is not considered a major rule. This rule only provides the Secretary with greater contracting flexibility consistent with the statute and would not have any direct economic impact. Because this proposed rule would only affect our administrative structures and does not change in any way the Medicare DMEPOS benefit (that is, neither coverage nor payment is changed), this rule would not affect the amount or distribution of the Medicare benefit payment for DMEPOS. Further, any possible restructuring of the DMERC regions in the future would not remotely approach a net economic impact of $100 million on either CMS’s 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 proposed rule, as noted above, would not have any direct economic impact on DMEPOS suppliers, because it would not affect the scope of benefits, coverage, or payment rules for DMEPOS, nor would it affect the billing requirements for these services. This rule would not commit us to 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 would not have a significant economic impact on a substantial number of small rural hospitals.

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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. The changes that this rule proposes pertain to our processes for configuring and designating contractors to process DMEPOS claims and would 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 would not have a consequential effect on the governments mentioned or on the private sector.

E.O. 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, preempt State law, or otherwise has Federalism implications. Since this regulation would 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 would 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 contractors. We have provided additional discussion in the preamble describing why we believe this is not the optimal solution. We believe our proposal to make modest changes to our regulations would 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, the Office of Management and Budget reviewed this regulation.

List of Subjects 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 proposes to amend 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. Amend §421.210 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(b) 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:


(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 may 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 will publish 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 area 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
We believe that these proposals will allow the Commission to obtain the necessary information regarding service disruptions in an efficient and expeditious manner and to achieve significant concomitant public interest benefits.

DATES: Comments must be filed on or before May 25, 2004, and reply comments June 24, 2004. Written comments on the proposed and/or modified information collection(s) must be submitted by the public, Office of Management and Budget (OMB), and other interested parties on or before May 25, 2004.

FOR FURTHER INFORMATION CONTACT: Charles Iseman at (202) 418–2444, charles.iseman@fcc.gov, Office of Engineering and Technology, TTY (202) 418–2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s Notice of Proposed Rule Making, ET Docket No. 04–35, FCC 04–30, adopted February 12, 2004, and released February 23, 2004. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission’s copy contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission’s Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554.