

flow from the existing narrative indications for the clinical diagnostic laboratory test. In other words, the requested change must be classified as a correction, an updating change, or a replacement to an existing code. Requests that, in effect, constitute requests to add new indications must use the NCD evidence-based process outlined in the April 27, 1999 and subsequent September 26, 2003 issues of the **Federal Register**.

The burden associated with the process referenced above is the time and effort necessary to submit a request in writing, clearly stating the rationale for the coding change. We believe that it will require one hour per request and that eight requests will be submitted on an annual basis.

However, based on the current number of submissions received on an annual basis (less than 10), this is not an information collection defined by the PRA (5 CFR 1320.3(c)(4)). If in the future we receive more than 10 responses on an annual basis, we will submit these information collection requirements to OMB for review and approval as required by the PRA.

VI. Regulatory Impact Statement

In this notice, we establish an abbreviated mechanism for making changes to the lists of ICD-9-CM and CPT codes that are included in the laboratory NCDs. We clarify when a specimen is considered archived for purposes of the date of service provision contained in the November 21, 2001 final rule. We do not expect this rule to impose any significant burden on laboratories. The established policy clarifications may lessen the burden on laboratories by establishing uniform procedures for reporting date of service on archived specimens. Should there be any unanticipated increase or decrease of burden, the effects will be minimal.

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

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We have reviewed this final notice and have determined it is not a major rule. Therefore, we are not required to perform an assessment of the costs and savings. The notice is purely procedural and, therefore, is not expected to impose any appreciable burden or generate compliance costs for laboratories.

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. For purposes of the RFA, approximately 80 percent of clinical diagnostic laboratories are considered small businesses according to the Small Business Administration's size standards with total revenues of \$29 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this final notice will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this final notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any notice 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 final notice will have no 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 final

notice that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final notice and have determined that it will not have a substantial effect on State or local governments.

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

Dated: September 1, 2004.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: November 9, 2004.

Tommy G. Thompson,
Secretary.

[FR Doc. 05-3727 Filed 2-24-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1219-N]

RIN 0938-AL76

Medicare Program; Changes in Geographical Boundaries of Durable Medical Equipment Regional Service Areas

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

ACTION: Notice.

SUMMARY: This notice announces changes to the geographical boundaries of the four Durable Medical Equipment (DME) service areas applicable to future awards of the Medicare Administrative Contracts (MACs). We identify which States and territories are assigned to each of the four DME service areas, and include the factors and criteria that we used to change the geographical boundaries.

DATES: *Effective Date:* This notice is effective on March 28, 2005.

Applicability Date: On March 28, 2005, the new geographical boundaries will apply to DME MACs and not current DME regional carrier contracts.

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

SUPPLEMENTARY INFORMATION:

I. Background

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 are now in sections 1832, 1834, and 1861 of the Act and their implementing regulations in 42 CFR 421.210 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.)

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. On June 18, 1992, we published a final rule with comment period entitled “Medicare Program; Carrier Jurisdiction for Claims for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues Involving Suppliers, and Criteria and Standards for Evaluating Regional DMEPOS Carriers” (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). The final rule established, among other requirements, four regional carriers (known as DME Regional Carriers or DMERCs) to standardize the coverage and payment of DMEPOS and designated the States and territories to be served by each DMERC.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was enacted on December 8, 2003. Section 911 of the MMA amended title XVIII of the Social Security Act by adding a new section 1874A to permit us to contract for Medicare functions in a more open marketplace using the Federal Acquisition Regulation (FAR). Using competitive procedures, we will replace our current claims payment contractors—fiscal intermediaries (FIs), carriers, DMERCs, and regional home health intermediaries (RHHIs) with new contract entities that we will refer to as Medicare Administrative Contractors

(MACs). The MMA requires that we recompute and transition all work to MACs by 2011.

MACs will assume the claims payment work that is now performed by FIs, carriers, RHHIs, and DMERCs. We plan to compete and award 23 MACs during the initial implementation phase (2005 through 2011). We will award 15 primary MACs servicing the majority of all types of providers, 4 specialty MACs serving the majority of home health and hospice (HH) providers, and 4 specialty MACs servicing DME suppliers.

The primary MACs will operate in 15 distinct, non-overlapping geographic jurisdictions, which will form the basis of the Medicare fee-for-service claims processing operation. The arrangements for the 8 specialty MACs (for DME and HH services) will reflect a realignment of the existing jurisdictions for the RHHIs and DMERCs to fit the boundaries of the 15 primary jurisdictions.

II. Provisions of the Notice

In this issue of the **Federal Register**, we are publishing a separate final rule entitled “Medicare Program; Durable Medical Equipment Regional Carrier (DMERC) Service Areas and Related Matters” (CMS–1219–F) regarding the process by which CMS may change the current geographical boundaries of the contractors that process claims related to durable medical equipment, prosthetics, orthotics, and supplies. Following that process, this notice announces changes to the geographical boundaries of the future DME service regions. It does not affect the jurisdictions of the existing DMERCs.

Currently, the States and territories serviced by each of the four DMERC regions are as follows:

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

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

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

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

Effective with future awards of the DME MACs, the geographical

boundaries of the DMERC service regions will be reconfigured as follows:

Region A: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.

Region B: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, and Kentucky.

Region C: Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virgin Islands, Virginia, and West Virginia.

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

Under the reconfiguration, the District of Columbia and the State of Maryland are moved from Region B to Region A; the States of Virginia and West Virginia are moved from Region B to Region C; and the State of Kentucky moves from Region C to Region B. As such, Region A gains the District of Columbia and one State; Region B loses three States and the District of Columbia; and Region C loses one State and gains two States. There are no changes in the geographical boundaries of Region D.

We believe reconfiguring the existing geographical jurisdictions of the DME service regions to fit with the boundaries of the 15 MAC primary jurisdictions and four RHH MAC jurisdictions is necessary to facilitate seamless claims processing activities, and interaction with our other partners. Our analysis of the changes in the DME geographical boundaries indicates these service area changes affect a relatively small percentage of providers and beneficiaries in the affected areas. We have considered how the jurisdictional changes may impact affected providers and beneficiaries and have taken steps to minimize the impact. Through this notice, we are giving advance notice to all affected parties of these changes before any anticipated transition of workload. Additionally, we will include in any future procurements using the revised geographical jurisdictions a requirement that successful bidders must take steps to minimize any adverse impact on providers and beneficiaries because of the transition to the new jurisdictions.

III. Collection of Information Requirements

This document does not impose 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. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 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 notice does not reach the economic threshold and thus is not considered a major rule.

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. We are not preparing an analysis for the RFA because we have determined that this notice will not have a significant economic impact on a substantial number of small entities.

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. 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. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 notice will have no 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 notice does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Section 1834(a)(12) and 1842 of the Social Security Act (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: December 23, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05-3729 Filed 2-24-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4088-N]

Medicare Program; Part D Reinsurance Payment Demonstration

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

ACTION: Notice.

SUMMARY: This notice informs interested Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations of an opportunity to participate in the Part D Reinsurance Payment Demonstration beginning in contract year 2006.

FOR FURTHER INFORMATION CONTACT:

Mark Newsom, (410) 786-3198; mnewsom@cms.hhs.gov. Jennifer Harlow, (410) 786-4549; jharlow@cms.hhs.gov.

Application Requirements: Organizations intending to offer a stand alone prescription drug plan must submit an application in accordance with the instructions found in the Solicitation for Applications from Prescription Drug Plans posted on the

CMS website on January 21, 2005.¹ Organizations intending to offer a prescription drug benefit in combination with a Medicare Advantage plan must submit a completed Medicare Advantage Prescription Drug application in accordance with the Solicitation for Applications from Medicare Advantage Sponsors posted on the CMS Web site on January 21, 2005.² Applications are due to CMS on or before March 23, 2005.

Eligible Organizations: All PDP sponsors may participate in option one as described below.³ Medicare Advantage organizations offering Prescription Drug Plans (MA-PD plans) are eligible to participate in options one and two (as described below)⁴ with the exception of the following: Program of All Inclusive Care for the Elderly (PACE), MA employer only plans, and employer direct contract plans.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative Authority

Section 402(a)(1)(A) of the Social Security Amendments of 1967 authorizes the Secretary to conduct demonstrations designed to test whether methods of payment or reimbursement will have the effect of increasing the efficiency and economy of programs without adversely affecting the quality of those programs' services.

Section 402(b) of the Social Security Amendments of 1967 authorizes the Secretary to waive requirements in title XVIII that relate to reimbursement and payment in order to carry out demonstrations authorized under section 402(a). Section 1860D-42(b) of the Act provides that the provisions of section 402 of the Social Security Amendments of 1967 apply with respect to Part D and Part C in the same manner as they apply to Parts A and B, except that any reference with respect to a trust fund in relation to an experiment or demonstration project relating to prescription drug coverage under this part will be deemed a reference to the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund.

B. Issue

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Conference Report notes that provisions of the new Part D benefit

¹ See <http://www.cms.hhs.gov/pdps/>. See section 2 of the application.

² Id.

³ See II(A) Demonstration Design—Two Part D Reinsurance Options.

⁴ Id.