

copies. Presenters may also make copies available for approximately 50 meeting participants. Presenters must address the new test code(s) and descriptor, the test purpose and method, costs, charges, and a recommendation with rationale for one of two methods (crosswalking or gap-fill) for determining payment for new clinical laboratory codes. The first method, called crosswalking, a new test is determined to be similar to an existing test, multiple existing test codes, or a portion of an existing test code. The new test code is then assigned the related existing local fee schedule amounts and resulting national limitation amount. The second method, called gap-filling, is used when no comparable, existing test is available. When using this method, instructions are provided to each Medicare carrier to determine a payment amount for its geographic area(s) for use in the first year, and the carrier-specific amounts are used to establish a national limitation amount for following years. For each new clinical laboratory test code, a determination must be made to either crosswalk or to gap-fill, and, if crosswalking is appropriate, to know what tests to which to crosswalk.

III. General Information

The meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In order to gain access to the building and grounds, participants must bring a government-issued photo identification and a copy of their registration confirmation. Security measures include inspection of vehicles, at entrance to the grounds, and the requirement for persons to pass through a metal detector when entering the building. All items brought to CMS, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection.

Special Accommodation: Persons attending the meeting who are hearing or visually impaired and have special requirements, or who have a condition that requires special assistance, must provide this information upon registering for the meeting.

Authority: Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh)

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 10, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4069-N]

Medicare Program; Open Public Meeting To Discuss Definitions of Regions for Regional Medicare Preferred Provider Organizations and Prescription Drug Plans Under the Medicare Modernization Act—July 21, 2004

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to provide beneficiaries, advocacy groups, managed care organizations, trade associations, potential prescription drug plans (PDPs), pharmacy benefit managers, providers, practitioners, and other interested parties an opportunity to ask questions and raise issues regarding options for the definition of regions for Medicare Advantage (MA) regional plans and PDPs under provisions of the Medicare, Prescription Drug, Improvement and Medicare Modernization Act of 2003 (MMA). The legislation requires that we implement these MMA provisions in 2006. The purpose of the meeting is to provide information about a variety of region definition options being considered both for regional MA plans and PDPs and to allow for public comment on these options.

DATES: *Meeting Date:* The meeting is scheduled for Wednesday, July 21, 2004 from 9 a.m. until 4 p.m., c.d.s.t.

Comment Deadline: Written comments must be received by 5 p.m., August 5, 2004.

ADDRESSES: The meeting will be held in Chicago, IL, at the Rosemont Conference Center/Donald E. Stephens Convention Center, (located on the grounds of O'Hare airport) at 555 North River Road, Rosemont, IL. The phone number for the Rosemont Conference Center is (847) 692-2220. The meeting will be organized by CMS' contractor, RTI International.

Written Statements and Requests:

We will accept written questions about meeting logistics or requests for meeting materials either before the meeting or up to 14 days after the meeting. Written submissions must be sent to: RTI International, ATTN: Nathan West, MPA, RTI Health Services and Social Policy Research, 3040 Cornwallis Rd. Research Triangle Park,

North Carolina 27709, Telephone Number: (919) 485-2661, Fax Number: (919) 990-8454, e-mail: medicaremeeting@rti.org.

Public Comments: Public comments should be sent to Angela Porter via e-mail to APorter@cms.hhs.gov or fax to Angela Porter at (410) 786-9963; or you may mail public comments to her at the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Mailstop S1-05-06, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: RTI International staff at

medicaremeeting@rti.org, or Nathan West at (919) 485-2661.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare, Prescription Drug, Improvement and Modernization Act (MMA) of 2003 (Pub. L. 108-173, enacted on December 8, 2003) requires a number of changes to the Medicare program including the addition of Medicare prescription drug insurance plans (PDPs), as well as the addition of new regional Medicare Advantage (MA) plans. To implement both new programs, we must define appropriate regions for MA regional plans under section 1858(a)(2)(D) of the Social Security Act (the Act) added by section 221 of the MMA, and for PDPs under section 1860(D)-(11)(a) of the Act, added by section 101 of the MMA.

A. Medicare Advantage Regions

Title II of the MMA makes changes to the Medicare+Choice (M+C) program under Part C, which it renames as the Medicare Advantage program. Existing M+C plans, now known as MA plans, are now referred to as "local MA plans". Title II of MMA also establishes new MA regional plans, which would encourage private plans to serve Medicare beneficiaries in larger regions.

The new MA regional plan program will begin in 2006. The legislation calls for the creation of between 10 and 50 MA regions within the 50 States and the District of Columbia by January 1, 2005. Plans that opt to participate in the program are required to serve an entire MA region and are encouraged to offer services in more than one region. The legislation states that MA regions should maximize the availability of regional plans to all eligible individuals regardless of health status. The MMA conference report further clarifies these requirements by providing additional considerations for configuring the regions. To the extent possible, each MA region should include at least one State and not divide a State across regions.

Metropolitan Statistical Areas (MSAs) that span more than one State should be included in a single region.

Furthermore, the conference report suggests that the required market study determine the best configuration of regions to maximize plan participation as well as the availability of plans to beneficiaries.

These statutory requirements and MMA conference report guidelines have several implications for the definition of MA regional areas. Geographic regions must be defined to meet multiple objectives and satisfy multiple constraints. Demographic data on the distribution of the aged population must be considered in conjunction with market factors that would impact insurance-supplier response. Incentives provided for in the legislation have the potential to offset unfavorable factors in the MA region and must also be considered in the analysis of these heterogeneous regions. In addition, the sizes and configuration of regions will themselves impact the entry behavior of plans.

B. Regional Definition for PDPs

Title I of the MMA establishes a prescription drug insurance benefit under a new Part D of Medicare and is intended to provide prescription drug coverage for beneficiaries enrolled in traditional Medicare FFS or MA plans. The law also provides for premium, deductible, and co-payment subsidies for certain low-income beneficiaries. The PDPs are effective in 2006.

To provide access to options for Medicare beneficiaries in all geographic areas, Medicare PDPs are intended to be regional in scope. Since private companies (with a public subsidy) will operate the PDPs, offering a plan in a region will be voluntary on the part of the plan operators. A plan must offer the same benefits and charge the same premiums and co-payments to all eligible beneficiaries in its region regardless of how the plan's costs vary within a region. If less than two full-risk plans are offered in a region (one of which must be a PDP), then we will approve any reduced risk plans that have applied to serve the region. In any regions or parts of regions that still lack two plans, we will arrange for a non-risk-bearing fallback plan to be offered.

The success of the Part D benefit will depend on the willingness of private plan operators to offer plans in the various regions and therefore, at least in part, on the region definitions selected by CMS. Implications for regional definition for PDPs include the trade-off of conforming to existing markets versus

encouraging plan choice in areas projected to be underserved.

The MMA mandates that there be between 10 and 50 PDP regions. In addition, we will establish regions for the territories as required in section 1860D-11(a)(2)(C) of the Act. We must define these regions by January 1, 2005. The legislative guidelines for the definition of regions are the same for regional MA plans. The MMA requires that PDP regions be the same as with MA regions "to the extent practicable." However, the PDP regions do not necessarily need to be identical to the MA regions if it can be shown that a different configuration of regions for PDPs improves beneficiaries' access to prescription drugs.

II. Meeting Topics and Format

The meeting will address the following topics:

- A presentation of proposed regional definitions for MA Regional Plans, followed by public comments and a question and answer period.
- A presentation of proposed regional definitions for PDPs, followed by public comments and a question and answer period.

Time for participants to ask questions or offer individual comments will be limited according to the number of registered participants.

The agenda will include presentations by CMS and RTI International (CMS' contractor) staff. We are interested in an open dialogue on the topic of defining regions for regional MA plans and PDPs under the MMA legislation, and believe that an active discussion will help us more clearly identify the key issues for consideration. In this public meeting, we plan to engage in a discussion of the scenarios for MA regional and PDP region configurations, particularly on regional scenarios where PDP and regional MA definitions may, or may not, overlap.

III. Registration

Registration for this public meeting is required and will be on a first-come, first-served basis, limited to two attendees per organization up to the 1,000 person capacity of the meeting room. A waiting list will be available for additional requests. The registration deadline will be July 14, 2004. Registration can be accomplished through three mechanisms:

1. A special on-line meeting Web site set up specifically for this meeting: <https://register.rti.org/medicaremeeting/>.
2. A specific meeting e-mail address: medicaremeeting@rti.org.

3. By contacting Nathan West, RTI International, at (919) 485-2661.

A confirmation notice will be sent to attendees upon finalization of registration. Information on hotel accommodations will be provided to registered individuals as part of their confirmation notice. General information regarding meeting logistics will also be available on the meeting Web site at <https://register.rti.org/medicaremeeting/>.

Persons who are not registered in advance will not be guaranteed attendance due to space limitations. Attendees will be provided with meeting materials at the time of the meeting.

To submit written questions regarding logistics of the meeting or to request material before the meeting, see instructions for *Written Statements and Requests* under the **ADDRESSES** section of this notice.

Written public comments are preferred following the meeting and will be accepted until August 5, 2004. See instructions for *Public Comments* under the **ADDRESSES** section of the notice.

(Authority: Sections 1851 through 1859 of the Social Security Act (42 U.S.C. 1395w-21 through 1395w-28)) (Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 19, 2004.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CM-3130-N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—July 14, 2004

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (MCAC). This Committee provides advice and recommendations about whether scientific evidence is adequate to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. The Committee will discuss and make