

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. We have determined that this notice does 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 an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. We have determined that this notice 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, local, or tribal governments, preempts State law, or otherwise has Federalism implications. We have determined that this notice does not have an economic impact on State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 13, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04-16659 Filed 7-22-04; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3142-NC]

Medicare Program; Evaluation Criteria and Standards for Quality Improvement Program Contracts

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

ACTION: Notice with comment period.

SUMMARY: This notice describes the evaluation criteria we intend to use to evaluate the Quality Improvement Organizations (QIOs) under their contracts with CMS, for efficiency and effectiveness in accordance with the Social Security Act. These evaluation criteria are based on the tasks and related subtasks set forth in the QIO's Scope of Work (SOW). The current 7th SOW includes Tasks 1 through 4, with subtasks included under all tasks, excluding Task 4. QIOs were awarded contracts for the 7th SOW, or 7th Round, for three years, with staggered starting dates beginning August 2002, November 2002, and February 2003.

DATES: To be assured of consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 23, 2004.

ADDRESSES: In commenting, please refer to file code CMS-3142-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to <http://www.cms.hhs.gov/regulations/ecomments> or to www.regulations.gov (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* 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-3142-NC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address,

please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 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 received after the comment period.

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

FOR FURTHER INFORMATION CONTACT: Maria Hammel, (410) 786-1775.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this notice with comment period to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-3142-NC and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: 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 website. 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.

I. Background

[If you choose to comment on issues in this section, please include the caption "BACKGROUND" at the beginning of your comments.]

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of Pub. L. 97-

248) amended Part B of Title XI of the Social Security Act (the Act) to establish the Peer Review Organization (PRO) programs. The PRO program (now called the Quality Improvement Organization (QIO) program) was established to redirect, simplify and enhance the cost-effectiveness and efficiency of the medical peer review process. Sections 1152, 1153(b) and 1153(c) of the Act define the types of organizations eligible to become QIOs, and establish certain limitations and priorities regarding QIO contracting.

The Secretary enters into contracts with QIOs to perform three broad functions:

- Improve quality of care for beneficiaries by ensuring that beneficiary care meets professionally recognized standards of health care;
- Protect the integrity of the Medicare Trust Fund by ensuring that Medicare only pays for services and items that are reasonable and medically necessary and that are provided in the most economical setting;
- Protect beneficiaries by expeditiously addressing individual cases such as beneficiary quality of care complaints, contested hospital issued notices of noncoverage (HINNs), alleged Emergency Medical Treatment and Labor Act (EMTALA) violations (patient dumping), and other statutory responsibilities.

Section 1154 of the Act requires that QIOs review those services furnished by physicians; other health care practitioners; and institutional and non-institutional providers of health care services, including health maintenance organizations and competitive medical plans. Section 109 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, amended section 1154(a)(1) of the Social Security Act to expand the scope of review of QIOs to include Medicare Advantage Organizations, and prescription drug sponsors. Section 109 of the MMA also created a new section 1154(a)(17) of the Act, which requires QIOs to offer to providers, practitioners, Medicare Advantage Plans and prescription drug sponsors quality improvement assistance pertaining to prescription drug therapy. Because these provisions of sections 1154(a)(1) and (a)(17) are new, we will not evaluate QIOs on these provisions in the current SOW.

Section 1153(h)(2) of the Act requires the Secretary to publish in the **Federal Register** the general criteria and standards that would be used to evaluate the efficient and effective performance of contract obligations by QIOs and to provide the opportunity for

public comment. The QIO contracts for the 7th SOW were awarded for 3 years with starting dates staggered into three approximately equal groups (rounds) starting August 2002, November 2002 and February 2003 respectively.

II. Measuring QIO Performance

[If you choose to comment on issues in this section, please include the caption "MEASURING QIO PERFORMANCE" at the beginning of your comments.]

Under the 7th Round contracts, QIOs are responsible for completing tasks in the following 4 areas, with additional subtasks contained in the first three areas:

Task 1—Improving Beneficiary Safety and Health Through Clinical Quality Improvement

- a. Nursing Home
- b. Home Health
- c. Hospital
- d. Physician Office
- e. Underserved and Rural

Beneficiaries

- f. Medicare+Choice Organizations (M+COs), now called Medicare Advantage Organizations (MAs)

Task 2—Improving Beneficiary Safety and Health Through Information and Communications

- a. Promoting the Use of Performance Data
- b. Transitioning to Hospital-Generated Data
- c. Other Mandated Communications Activities

Task 3—Improving Beneficiary Safety and Health Through Medicare Beneficiary Protection Activities

- a. Beneficiary Complaint Response Program
- b. Hospital Payment Monitoring Review Program
- c. All Other Beneficiary Protection Activities

Task 4—Improving Beneficiary Safety and Health Through Developmental Activities

(Special Studies defined as work that CMS directs a QIO to perform or work that a QIO elects to perform with CMS approval which is not currently defined in the Tasks, but falls within the scope of the contract and section 1154 of the Act).

Under this contract, to merit having its contract renewed non-competitively, the QIO must meet the performance criteria (including a score of 1.0 or greater for Tasks 1a through 1e and 2b) on 10 of 12 subtasks (9 of 11 for states with no MA plans) of Tasks 1 through

3 of the 7th SOW, provided that for both of the subtasks which do not meet the criteria, the QIO has: (1) Achieved a score of 0.6 or better on all quantitative subtasks, and (2) for the remaining subtasks only, in the judgment of the Project Officer, the QIO expended a reasonable effort to address these subtasks, developed and implemented an appropriate initial work plan, which was assessed during the contract period to determine if it was achieving results likely to lead to success in meeting contractual performance expectations, and had made appropriate adjustments to its work plan based on these results.

To be considered successful (meeting the criteria outlined in the J-7 found at www.cms.hhs.gov/qio/2.asp), though not meriting a non-competitive renewal, the QIO shall meet the performance criteria (including a score of 1.0 or greater for Tasks 1a through 1e and 2b) on 9 of 12 subtasks (8 of 11 for states with no MA plans) of Tasks 1 through 3 of the 7th Round Contract, provided that for the subtasks that do not meet the criteria, the QIO must: (1) Achieve a score of 0.6 or better on all quantitative subtasks, (2) for the remaining subtasks only, in the judgment of the Project Officer, the QIO has expended a reasonable effort to address these subtasks, developed and implemented an appropriate initial work plan which was assessed during the contract period to determine if it was achieving results likely to lead to success in meeting contractual performance expectations, and had made appropriate adjustments to its work plan based on these results, and (3) failed to meet the criteria in no more than two subtasks of any one task. For Task 4, except as provided in Task 3b, all special studies approved under this task will be evaluated individually, based on study-specific evaluation criteria. The QIO's success or failure on a special study will not be factored into the evaluation of the QIO's work under Tasks 1-3.

However, meeting the minimum performance standards does not guarantee a noncompetitive renewal of its contract. For example, an organization within a particular State meeting the definition of a QIO may express interest in competing for a contract currently held by a QIO from outside that state, pursuant to section 1153(i). In this case, we will compete the contract despite acceptable performance by the current QIO. We will make a final decision on renewal/non-renewal by the end of the 30th month of the 7th Round contract. We will issue a "Notice of Intent to Non-renew the QIO Contract" letter to all

QIOs that do not meet the minimum performance standards no later than the end of the 33rd month of the contract. The QIO will be considered to have met minimum performance standards if the QIO had demonstrated acceptable performance in each Task area as specified in Section III of this Notice, Standards for Minimum Performance.

If the QIO has not met the criteria to merit a noncompetitive renewal, it shall be notified of CMS' intention not to renew its contract and will be informed of its right to request an opportunity to provide information pertinent to its performance under the contract to a CMS-wide panel. The panel will be made up of representatives from each of the 4 QIO Regional Offices and the Central Office. The QIO's Project Officer will not be eligible to represent the Regional Office on the panel when it reviews the work of his/her QIO. However, the Project Officer will be available to answer any questions the panel may have. The QIO will also be given the opportunity to provide additional information. The panel will have the right to create its own procedures, but must apply them consistently to all QIOs it reviews. At a minimum, the panel will use the criteria listed below for all Tasks:

- The degree of collaboration the QIO exhibited with the Quality Improvement Organization Support Centers (QIOSCs) and other QIOs, both by sharing the lessons and tools it developed and by adopting practices and tools developed by other QIOs;
- Whether the QIO was a new contractor in the 7th SOW;
- Whether specific identifiable circumstances uniquely interfered with the QIO's efforts;
- Evidence suggesting that the QIO has done exceptional work in one or more of the other Task areas; and
- Any other issues which the panel may deem relevant. Upon completion of its review, the panel will make a recommendation for a final disposition to the Director of CMS' Office of Clinical Standards and Quality (OCSQ).

III. Standards for Minimum Performance

[If you choose to comment on issues in this section, please include the caption "STANDARDS FOR MINIMUM PERFORMANCE" at the beginning of your comments.]

General Criteria

CMS will evaluate the QIO's performance on each sub-task by some combination of the following elements:

- Statewide improvement on the quality measure(s);

- Improvement on the quality of care measure(s) among a group of identified participants as defined within each subtask;

- Satisfaction among providers and practitioners regarding their interaction with the QIO.

Satisfaction will be assessed using a survey, the purpose of which will be to:

- Measure satisfaction as one component of the QIO's evaluation.
- Identify opportunities where the QIO can improve satisfaction.

Task 1 (including subtasks a through e) and subtask 2b will be evaluated quantitatively. Their success will be measured by assessing the QIO's relative improvement on each evaluation criterion. The term "improvement" as used in the 7th Round Contract shall be defined mathematically to mean the relative reduction in the failure rate. The expected minimum improvement level will serve as the reference point for each calculated relative improvement.

In a number of the Task 1 subtasks, statewide improvement will be averaged with the improvement among a set of identified participant providers. In these cases CMS has set a target percentage of identified participant providers, and the relative weights of the statewide improvement and of identified participants' improvement will combine to equal 80 percent and will be a function of the percentage of the target (up to 150 percent) that the QIO identifies as participants. Tasks 1f, 2a, 2c and all of Task 3 will be evaluated by the Project Officer using qualitative measures based on information provided in reports developed from data provided by the QIOs on the QIO's status to date.

Task Specific Standards

Task 1—Improving Beneficiary Safety and Health Through Clinical Quality Improvement

Task 1a—Nursing Home Quality Improvement—The QIO will be held accountable for improvement in the quality of care measure rates for all nursing homes in the state and for identified participant nursing homes. QIOs will be evaluated based on the following components: statewide improvement on the set of 3 to 5 publicly reported quality of care measures which the QIO has selected in consultation with stakeholders, improvement for the selected CMS nursing home publicly reported quality of care measures for identified participants, and nursing home satisfaction based on a survey of identified participating nursing homes.

To view the weighting criteria for each component, go to www.cms.hhs.gov/qio/2.asp for a copy of the J-7.

Task 1b—Home Health Quality Improvement—the QIO will be held accountable for improvement in the Outcome Based Quality Improvement (OBQI) quality of care measure rates for a set of home health agencies that are identified participants. The QIOs will be evaluated based on the following components: The extent to which the number of participating home health agencies, with significant improvement in a targeted outcome, equals or exceeds 30 percent of the total number of home health agencies in the state, and the identified participant satisfaction which will be measured by a survey of identified participant home health agencies using a composite measure of satisfaction that reflects the type of activities that QIOs are expected to have undertaken with these providers.

Task 1c—Hospital Quality Improvement—QIOs will be evaluated on the following criteria: statewide improvement on the quality of care measures listed in the 7th Round Contract, and hospital satisfaction based on feedback from the hospitals in the state. To view the specific criteria, go to www.cms.hhs.gov/qio/2.asp for a copy of the J-7.

Task 1d—Physician Office Quality Improvement—QIOs will be evaluated based on the following general criteria: statewide improvement of quality of care measures, improvement on diabetes and cancer screening quality of care measures for identified participant physicians, and physician satisfaction based on feedback from physician designees in the state who participated with the QIO. To view the specific criteria for this task, go to www.cms.hhs.gov/qio/2.asp for a copy of the J-7.

Task 1e—Underserved and Rural Beneficiaries Quality Improvement—The QIO's work on this task will be primarily evaluated on the success of the QIO's efforts to reduce disparity between the targeted underserved group and their geographically relevant non-underserved reference group from baseline to re-measurement. To be judged to have performed minimally successful on this task, the QIO must demonstrate disparity reduction. QIOs will also be evaluated on three factors that collectively demonstrate knowledge generated by the QIO about the underserved target group, the interventions planned upon the basis of that knowledge, the use of literature on effective interventions, and by demonstrating the effectiveness of their interventions through analyses

comparing the intervention group and a contrast group. To view the specific criteria for this task, go to www.cms.hhs.gov/qio/2.asp for a copy of the J-7.

Task 1f—Medicare + Choice Organizations (M+COs) (now called Medicare Advantage Organizations (MAs) Quality Improvement—QIOs will be expected to have demonstrated appropriate activity to include MAs in Tasks 1a to 1e as determined by the Project Officer. CMS will survey MAs that have worked with the QIO using a composite measure of satisfaction that reflects the types of activities that QIOs are expected to have undertaken with these organizations. CMS will further use the results of the Medicare+Choice Quality Review Organizations (M+CQRO) or accreditation organization evaluation of the Quality Assessment and Performance Improvement (QAPI) projects to determine if expected improvement was demonstrated.

Task 2—Improving Beneficiary Safety and Health Through Information and Communications

Task 2a—Promoting the Use of Performance Data—QIO success will be assessed on the timely completion and submission of a project work plan, timely completion and submission of all required reports and deliverables, and the extent to which the QIO uses information provided by CMS as well as any other feedback the QIO receives to refine its project activities to achieve the desired outcome.

Task 2b—Transitioning to Hospital-Generated Data—The evaluation for this task will be based on the following. CMS will determine the completeness of the assessment survey information for each hospital. CMS will review hospital data submitted to the national repository via QualityNet Exchange to determine the proportion of hospitals within the State that have implemented a data abstraction system to abstract quality of care measures. CMS will review hospital satisfaction with the QIO data abstraction support. To view specific criteria for this task, go to www.cms.hhs.gov/qio/2.asp for a copy of the J-7.

Task 2c—Other Mandated Communication Activities—QIO success on this task will be assessed on the following elements: The establishment and use of a Consumer Advisory Council to advise and provide guidance regarding consumer related activities, the QIO's success at broadening consumer representation on the QIO Board of Directors, the successful operation of a Beneficiary

helpline, and the publication and distribution of an annual report.

Task 3—Improving Beneficiary Safety and Health Through Medicare Beneficiary Protection Activities

Task 3a—Beneficiary Complaint Response Program—QIO success will be assessed by the timeliness of completed reviews, quality improvement activities as the result of beneficiary complaints, reliability of the review, and beneficiary satisfaction with the complaint process.

Task 3b—Hospital Payment Monitoring Review Program—The QIO must complete reviews within the prescribed timeframes. The QIO must also meet one of the following criteria: With respect to the absolute payment error rate, the follow-up payment error rate must be no greater than 1.5 standard errors above the baseline error rate, or the QIO must have made acceptable progress in improving provider performance in relation to any and all projects approved or directed by CMS.

Task 3c—Other Beneficiary Protection Activities—The QIO will be assessed on the timeliness of reviews for HINN/ NODMAR, EMTALA review, other case review activities and post review activities.

In accordance with the provisions of Executive Order 12866, this notice with comment period was not reviewed by the Office of Management and Budget.

Authority: Section 1153 of the Social Security Act (42 U.S.C. 1320c-2) (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 4, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04-16432 Filed 7-22-04; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4074-N]

Medicare Program; Meeting of the Advisory Panel on Medicare Education—September 9, 2004

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a) (Pub.

L. 92-463), this notice announces a meeting of the Advisory Panel on Medicare Education on September 9, 2004. The Panel advises and makes recommendations to the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

DATES: The meeting is scheduled for September 9, 2004 from 9 a.m. to 4 p.m., e.d.t.

Deadline for Presentations and Comments: September 2, 2004, 12 noon, e.d.t.

ADDRESSES: The meeting will be held at the Wyndham Washington Hotel, 1400 M Street, NW., Washington, DC 20005, (202) 429-1700.

FOR FURTHER INFORMATION CONTACT:

Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, mail stop S2-23-05, Baltimore, MD 21244-1850, (410) 786-0090. Please refer to the CMS Advisory Committees' Information Line (1-877-449-5659 toll free)/(410-786-9379 local) or the Internet (<http://www.cms.hhs.gov/faca/apme/default.asp>) for additional information and updates on committee activities, or contact Lynne Johnson by e-mail at ljohnson3@cms.hhs.gov. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION: Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, grants to the Secretary of the Department of Health and Human Services (the Secretary) the authority to establish an advisory panel if the Secretary finds the panel necessary and in the public interest. The Secretary signed the charter establishing the Advisory Panel on Medicare Education (the Panel) on January 21, 1999 (64 FR 7849) and approved the renewal of the charter on January 21, 2003. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.