

requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from our receipt of a completed application to publish approval or denial of the application.

The purpose of this proposed notice is to inform the public of our receipt of JCAHO's request for approval of continued deeming authority for ASCs. This notice also solicits public comment on the ability of JCAHO requirements to meet or exceed the Medicare conditions for coverage for ASCs.

III. Evaluation of Deeming Authority Request

On April 15, 2002, JCAHO submitted all the necessary materials concerning its request for reapproval as a deeming organization for ASCs to enable us to make a determination. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accreditation organizations), our review and evaluation of JCAHO will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of JCAHO standards for an ASC as compared with our comparable ASC conditions of coverage.
- JCAHO's survey process to determine the following:
 - The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
 - The comparability of JCAHO processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
 - JCAHO's processes and procedures for monitoring providers or suppliers found out of compliance with JCAHO program requirements. These monitoring procedures are used only when JCAHO identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

- JCAHO's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
- JCAHO's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.
- The adequacy of JCAHO's staff and other resources, and its financial viability.
- JCAHO's capacity to adequately fund required surveys.
- JCAHO's policies with respect to whether surveys are announced or unannounced.
- JCAHO's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

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 will respond to the public comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights, roles, or responsibilities of States, local, or tribal governments.

Authority: Sec. 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 19, 2002.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3082-NC]

Medicare Program; Revised Evaluation Criteria for the End-Stage Renal Disease (ESRD) Networks

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

ACTION: Notice with comment period.

SUMMARY: This notice describes the criteria we will use to evaluate the performance of the ESRD Network Organizations. We are required by the Social Security Act to publish standards, criteria, and procedures used to evaluate the performance of ESRD Network Organizations under the Medicare program to ensure the effective administration of ESRD program benefits.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 27, 2002.

ADDRESSES: In commenting, please refer to file code CMS-3082-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3082-NC, P.O. Box 3016, Baltimore, MD 21244-3016.

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 three copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

(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 commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

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

FOR FURTHER INFORMATION CONTACT:
Linda Okimoto, (410) 786-6877.

SUPPLEMENTARY INFORMATION:

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, please call Yolanda Hayes at (410) 786-7195.

I. Background

The Social Security Amendments of 1972 (Pub. L. 92-603) extended Medicare coverage to individuals with end-stage renal diseases (ESRD) that require maintenance dialysis treatments or kidney transplantation. The ESRD Amendments of 1978 (Pub. L. 95-292) amended title XVIII of the Social Security Act (the Act) by adding section 1881. Section 1881(c) of the Act authorized the establishment of, among other things, ESRD network areas and Network Organizations under the Medicare program, to ensure the effective administration of the ESRD program benefits. This amendment provided an approach for Network operation and performance as well as other quality assurance issues that relate to treatment of ESRD. Section 9335(d)(1) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509) amended section 1881(c) of the Act to require us to publish in the **Federal Register** criteria, standards, and procedures with which to evaluate an applicant organization's ability to perform, or actual performance of, required network functions.

Section 1881(c)(2) of the Act requires the Network Organizations to perform the following functions:

- Encourage participation in vocational rehabilitation programs, and develop criteria and standards relating to this participation.
- Evaluate the procedures used by facilities and providers in the network to assess patients for placement in appropriate treatment modalities.
- Implement a procedure for evaluating and resolving patient grievances.
- Conduct onsite reviews of facilities and providers using standards of care established by the Network

Organization to ensure proper medical care, as a medical review board or as we have determined.

- Collect, analyze, and validate the data that are necessary to prepare the required annual report to the Secretary and to ensure the maintenance of a national ESRD registry.
- Identify facilities and providers that are not cooperating toward meeting network goals, and assist those facilities and providers in developing plans for correction, as well as report on those facilities and providers that are not providing appropriate care.
- Submit an annual report to the Secretary on July 1 of each year.

II. Current Evaluation Criteria

The criteria, standards, and procedures that we used to evaluate the performance of Network Organizations have not been revised since they were published on October 2, 1987 in the **Federal Register** (52 FR 37018). The criteria, standards, and procedures were based on reviewing individual cases to identify errors in treatment. To respond to the need to improve the quality of care of Medicare ESRD patients, we reshaped the role of the ESRD Networks program approach to quality assurance and improvement. This approach, implemented July 1, 1994 by the ESRD networks, has been named the ESRD Health Care Quality Improvement Program (HCQIP). HCQIP gives us, along with the Networks an opportunity to demonstrate that health care furnished to Medicare renal beneficiaries can be measurably improved. HCQIP is based on the principle that the Networks can do more to improve the quality and cost effectiveness of care by bringing typical care into line with the best practices rather than by inspecting individual cases to identify erroneous treatment. We are also planning to publish a proposed rule to update the ESRD conditions for coverage of suppliers of end-stage renal disease services (found at 42 CFR 405) in the **Federal Register**.

The goals for updating the ESRD conditions, which were implemented in 1976, include: Transitioning to a more patient centered focus; reflecting the current standards of practice; shifting from a procedural approach to a more outcome oriented approach; and improving the quality of care. Clinical performance measures are important in meeting these goals and will be proposed in the rule.

In its June 2000 report entitled "External Quality Review of Dialysis Facilities—A Call for Greater Accountability," the Office of Inspector General (OIG) made two main recommendations to CMS: (1) CMS

should hold individual dialysis facilities fully accountable for the quality of care they provide; and (2) CMS should hold the Networks and State survey agencies fully accountable for their performance in overseeing the quality of care furnished by dialysis facilities. Under its first recommendation, OIG suggested that CMS focus its efforts on two central areas: (1) How effectively Network Organizations draw on standardized performance data to improve the overall clinical performance of facilities in their region and ensure that poor performers meet minimum standards of care; and (2) how effectively Network Organizations use a complaint system as a quality of care safeguard.

III. Measuring ESRD Network Organizations Performance

Currently, the ESRD Network Organizations are awarded contracts for 1 base year and 2 option years. The current contracts were effective July 1, 2000. In conjunction with the ESRD Network Organizations, we have developed in-depth evaluation criteria based on contract tasks and deliverables. In addition, a score calculator was developed to score each Network Organization based on the results of the evaluation elements. The final scores are used to determine how well a Network Organization has performed and if a performance improvement plan or other action (that is, termination) is warranted. The four contract task categories to be scored are the following:

- Quality Improvement.
- Community Information and Resources.
- Administration.
- Information Management.

The tasks listed above are specified in the Network Organization's Statement of Work, which can be found on the web site at: <http://www.hcfa.gov/quality/5d2.htm>.

The Quality Improvement section contains performance indicators that pertain to the Network Organization's quality improvement projects, clinical performance measures, and other quality improvement activities.

The Community Information and Resources section contains elements that pertain to the Network Organization's provision of educational information and technical assistance, and its resolution of difficult situations and grievances.

The Administration section contains elements that pertain to the organizational structure of the Network, the Network staff, required administrative reports, the Network's

internal quality control program, our meetings, cooperative activities with State agencies and Peer Review Organizations, and sanctions and referrals.

The Information Management section contains elements on maintaining, updating, validating, and submitting data.

The Network Organization must meet the performance standards for each of the four contract task areas to be eligible for a noncompetitive renewal in the next contract cycle. The success of the Network Organization's work in the four contract task areas will be judged on the basis of subjective, qualitative assessments.

IV. Standards for Minimum Performance

Included in the evaluation criteria document that is assessed by the project officers are indicators to judge the performance of the Network Organization on improving current clinical performance measures. Since the regional office project officers evaluate ESRD Network Organizations on an annual basis, the intention is to compare the current year's performance to that of the past total 3-year contract. The ESRD Network Organization's work will be judged to have been successful for each of the categories only if it conducts the work in accordance with the requirements set forth in Parts 1 through 9 of the ESRD Manual and its ESRD contract.

The Network Organization must score at least 80 percent on the overall score with a minimum of 80 percent in each of the major contract category areas to meet the standards for minimum performance level. If the initial assessment suggests that the Network Organization has scored at least 80 percent on its overall score, but has not met or exceeded the 80 percent minimum criteria scoring for one or more of the four contract areas, it will have passed the evaluation, but its performance of the contract area(s) will be subject to a performance improvement plan. If the Network Organization does not achieve at least 80 percent on its overall score, it will fail the evaluation and will be subject to a performance improvement plan and a more in-depth assessment of its contract performance up to and including possible nonrenewal or contract termination.

Task-Specific Standards

1. Quality Improvement

a. Quality Improvement Projects

The Network Organization is required to implement two Quality Improvement Projects (QIPs) during its 3-year contract period. We will evaluate the success of the Network Organization's work in two ways. We will assess whether the Network Organization has achieved measurable improvement on the quality indicators, particularly when the projects have employed project tools and indicators that have previously been well developed. In the event that a project fails to achieve measurable improvement, we will use as a second standard of success the amount of knowledge that has been gained through the experience of the project. We will consider these projects successful only if the Network Organization completed the proposed projects according to its narrative project plans. This includes all dimensions of the plans, including, but not limited to populations and facilities including all aspects of study design, intervention, analyses, and timelines. The project officer must have approved all significant changes to the project (deviations from the project plan) in advance. In the final evaluation of a project, contractual compliance in completion of QIPs is defined as adherence to the approved project plan, including any modifications agreed to by the Network and the project officer before their implementation, including timelines and milestones.

b. Clinical Performance Measures and Other Quality Improvement Activities

The Network Organization will be required to submit a plan to its regional office Project Officer that specifies what types of activities are planned for each of the targeted clinical performance outcome measures and the rationale for its decision. The project officer will assess the success of the Network Organization's efforts on the level of activity relating to attaining or maintaining these target performance levels.

2. Community Information and Resources

The project officer will continuously review the work of the Network Organization under Community Information and Resources primarily on the required quarterly reports and through reports generated from the Standard Information Management System (SIMS) reporting system. The Network Organization's work will be judged to be successful for each of the

categories and mandated activities only if it conducts the work in accordance with the requirements in its contractual statement of work and Parts 2, 6, and 7 of the ESRD Network Organization Manual.

3. Administration

The Network Organization must have an organizational structure, basic administrative staff, and infrastructure to operate its statutory requirements and other work activities, as required in its contract. The project officer will continuously review the work of the Network Organization under this contract task area primarily on the required administrative reports. The principal evaluation element for this task will be the timeliness and completeness of all required reports.

4. Information Management

The project officer will continuously review the work of the Network Organization to perform data management and reporting activities using SIMS. We use the data collected by the Networks to report various dialysis facility characteristics and specific quality measures on its Dialysis Facility Compare website (<http://www.medicare.gov/Dialysis/Home.asp>). The Network Organization will be determined to be successful if it conducts the work in accordance with the requirements set forth in Part 4 of the ESRD Network Organizations Manual, and its data management system provides for collection, analyses, verification, and timely reporting.

V. 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.

VI. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 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 annually). We have determined that this notice is not a major rule because it does not impose a significant economic impact to preferred provider organizations or the Medicare program.

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. For purposes of the RFA, most preferred provider organizations are considered to be small entities, either by nonprofit status or by having revenues of \$6 to \$29 million or less annually. (For details, see the Small Business Administration's regulation that set forth size standards for health care industries (65 FR 69432).) The criteria described in this notice will not significantly impact the ESRD Network Organizations that are considered small entities because the notice reflects what is already being done. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

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 not mandate any requirements for State, local, or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a notice with comment that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this notice under these requirements and have determined that it will not impose

substantial direct requirement costs on State or local governments.

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

Authority: Section 1881 of the Social Security Act (42 U.S.C. 1395rr). (Catalog of Federal Domestic Assistance Program No. 93.774 Medicare—Supplementary Medical Insurance Program)

Dated: December 19, 2001.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Editorial note: This document was received at the Office of the Federal Register June 25, 2002.

[FR Doc. 02-16410 Filed 6-27-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1198-NC]

RIN 0938-AL16

Medicare Program; Update to the Prospective Payment System for Home Health Agencies for FY 2003

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

ACTION: Notice with comment period.

SUMMARY: This notice with comment period sets forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies.

DATES: *Effective Date:* The rate updates in this notice with comment period are effective on October 1, 2002.

Comment Period: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 27, 2002.

ADDRESSES: In commenting, please refer to file code CMS-1198-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1198-NC, 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 three copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

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

FOR FURTHER INFORMATION CONTACT: Susan Levy, (410) 786-9364; Chester Robinson, (410) 786-6959

SUPPLEMENTARY INFORMATION:

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) 786-7197.

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This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office.

I. Background

Payment to Home Health Agencies

A. Balanced Budget Act of 1997

The Balanced Budget Act of 1997 (BBA), Public Law 105-33, enacted on August 5, 1997, significantly changed the way Medicare pays for Medicare home health services. Until the implementation of a home health