DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 484

RIN 0938–AI00

Medicare and Medicaid Programs; Revision of the Conditions of Participation for Home Health Agencies and Use of the Outcome and Assessment Information Set (OASIS) as Part of the Revised Conditions of Participation for Home Health Agencies

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Introduction to proposed rules.

SUMMARY: In this Part IV—of this issue of the Federal Register, we are publishing two notices of proposed rulemaking relating to revised conditions of participation that home health agencies must meet to participate in the Medicare and Medicaid programs. This introduction explains the background for the two proposed rules and the interrelationship of the two documents.

FOR FURTHER INFORMATION, CONTACT: Susan Levy, (410) 786–9364 and Mary Vienna, (410) 786–6940.

SUPPLEMENTARY INFORMATION: As part of the President's and Vice President's regulatory reform initiative, the Health Care Financing Administration (HCFA) is committed to changing current regulations that focus largely on requirements for measuring procedural standards. One of HCFA's key initiatives in Reinventing Government (REGO) is to revise many of its conditions of participation (COP) to focus on outcomes of care and to eliminate unnecessary procedural requirements. HCFA is working in partnership with the rest of the health care community to institute better, more common sense ways of operating. Within the coming year, HCFA plans to propose revisions to the COP for home health agencies (HHAs), hospitals, and end stage renal disease (ESRD) facilities and also to mount additional research in the area of ESRD to provide the basis for future changes.

A. Common Efforts

1. Reinventing Government (REGO) Initiative

To meet our REGO commitment, we are focusing on an approach for all sets of COP that is:

- Transitional toward a patient outcome based system.
- Intended to stimulate improvements in processes, outcomes of care, and patient satisfaction.
- Patient centered.
- Supported by patient outcomes data.
- Interdisciplinary in the approach to care delivery, reflecting the team approach to health care delivery.

The COP generally adhere to these basic requirements, varying in some degree due to the unique environment and patient case mix of the provider type.

2. Transitional Framework

The transitional framework for each set of COP—

- Begins shifting the oversight focus toward patient health outcomes and away from burdensome and costly procedural requirements, restructures the traditional COP along essential conditions centered on patient care, reflects an interdisciplinary team approach to patient care.
- Prepares the foundation for provider adoption and use of more detailed patient outcome measures developed through private sector experience and research.
- Provides a flexible framework for incorporating better measures as they are developed and tested.

3. Structure

The basic structure of all of the COP follows the Joint Commission on Accreditation of Healthcare Organizations'' (JCAHOs) ''Agenda for Change.'' This structure involves reducing the number of conditions in crosscutting categories; focusing on comprehensive assessment and patient outcomes; and deleting, where possible, process requirements that are not specifically mandated by the statute or believed likely to produce outcomes vital to the protection of patient safety.

Each set of COP has the same essential four conditions that reflect the cycle of patient centered care. The essential four conditions are:

- Patient rights.
- Patient assessment.
- Care planning and coordination of services.
- Quality assessment and performance improvement.

It is important to note that each of the sets of COP requirements are tailored to specific statutory requirements, the historical context of the provider type, the unique form of care delivery, and patient case mix.

4. Professional Input

For each set of COP, national meetings of provider and practitioner groups and beneficiary representatives, and our partners in State survey agencies were consulted about our approach and provided comments. Each proposed set of COP reflects extensive consultation with these groups. We recognize the importance of collaboration and communication with the industry and invite further public comment on the proposed COP and related rules.

B. Challenge for Home Health

The challenge for revising the home health COP has been to—

- Emphasize a regulatory approach that:

+ Moves toward a patient outcome based system;

+ Focuses on quality assessment and performance improvement;

+ Centers on the patient; and

+ Reflects the interdisciplinary team approach to home health care delivery;

- Develop a standard core assessment tool that will: 1) be useful as a management tool for providers; and, 2) eventually enable providers, government agencies, and health care consumers to compare patient indicators and outcomes across more than 9000 HHAs.

What follows in this issue of the Federal Register are two discrete documents:

l. Revised HHA COP. These COP include the refinements discussed above.

The fundamental principles guiding the development of the revised HHA COP are to:

- Stress quality improvements, incorporating to the greatest extent possible, outcome oriented, data supported quality assessment and performance improvement. The quality assessment and performance improvement program is of the HHA's own design and allows the HHA flexibility to create its own tailored program of continuous improvement. HHAs could be increasingly flexible and creative in their approach to patient care and delivery of services as they use their own information to assess and improve patient services, outcomes, and satisfaction. HCFA has developed the OASIS core standard assessment data set to support this proactive approach to quality improvement.
- Facilitate flexibility in how an HHA meets our performance requirements. For example, HCFA is proposing to adopt the REGO approach to personnel qualifications by indicating, in cases where personnel qualifications are not statutorily required, the HCFA personnel qualification requirements

would apply only in States without a licensing requirement.

- Eliminate unnecessary administrative requirements. Process oriented requirements are included only where we believe they remain highly predictive of ensuring desired patient outcomes and protect patient safety.
- Assure patients rights.
- Focus on continuous, integrated care centered around patient assessment, care planning, coordination of service delivery, and quality assessment and performance improvement. The four ''core conditions'' are Patient Rights, Patient Assessment, Care Planning and Coordination of Services, and Quality Assessment and Performance Improvement.
- Incorporate the program integrity approaches.

2. The Proposed Implementation of the Outcomes and Assessment Information Set (OASIS).

This proposed rule would revise the new conditions of participation for HHAs by requiring an HHA to incorporate the 79-item, core standard assessment data set, referred to as the OASIS, into its comprehensive patient assessment, as well as use OASIS information as part of its internal quality assessment and performance improvement program. The OASIS will serve as the foundation for future reliance on patient outcomes in provider decision making, regulatory oversight and consumer choice. This proposed rule does not require the HHA to collect and report OASIS to a national data system.

This proposed rule is an integral part of the Administration's larger efforts to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs. It is a fundamental component in the transition to a quality assessment and performance improvement approach based on measurable patient outcomes of care and satisfaction with the Medicare home health benefit. In order to reach the point where we can build and use a national data set of measures of outcomes and satisfaction, we must begin with a requirement that all HHAs use the same valid and reliable core standard assessment data set. By integrating a core standard assessment data set into its own more comprehensive assessment system, an HHA can use such a valid and reliable data set as the foundation for its quality assessment and performance improvement program.

We expect to receive positive and constructive comments on both of these documents. We have published these documents as separate rules. They reflect discreet steps in the transition toward a regulatory system based on patient outcomes. While linked in important ways, they have different impacts on the provider community. We have published them in the same Federal Register because together they reflect a more complete picture of the Department's patient outcome based strategy.

We have published the description of the OASIS as a separate proposed rule following the proposed HHA COP in this Part of this issue of the Federal Register. Please note that the implementation of OASIS would change only §§ 484.55 and 484.65 of the revised HHA COP. We have included several notes in the HHA COP to direct the reader to the OASIS notice for more comprehensive information.

(Catalog of Federal Domestic Assistance Programs No 93.774, Medicare—Supplementary Medical Insurance, and No. 93,778, Medical Assistance Program)

Dated: January 21, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: January 30, 1997.

Donna E. Shalala,

Secretary.

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42 CFR Part 484

[BPD–819–P]

RIN 0938–AG81

Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule revises the existing conditions of participation that home health agencies must meet to participate in the Medicare program. The proposed requirements focus on the actual care delivered to patients by home health agencies and the results of that care, reflect an interdisciplinary view of patient care, allow home health agencies greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care, while at the same time reducing procedural burdens on providers.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on June 9, 1997, except for comments on information collection requirements, which must be received on or before May 9, 1997.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–819–P, P.O. Box 7519, Baltimore, MD 21207–0519.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–11–17, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–819–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building Washington, DC 20503, Attention Allison Herron Eydt, HCFA Desk Officer.

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