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.

[FR Doc. 97–5314 Filed 3–5–97; 9:45 am]

BILLING CODE 4120–01–P

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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.

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8.00.

As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

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

SUPPLEMENTARY INFORMATION:

I. Introduction

As the single largest payer for health care services in the United States, the Federal Government has a critical responsibility for the quality of care delivered under its programs. Historically, the Health Care Financing Administration (HCFA) has adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum Federal standards. These problems would either be corrected or would lead to the exclusion of the provider from participation in the Medicare or Medicaid programs. However, we have found that this problem-focused approach has inherent limits. Trying to ensure quality through the enforcement of prescriptive health and safety standards, rather than trying to improve quality of care for all patients, has resulted in HCFA expending much of its resources on dealing with chronic problems with marginal providers, rather than on stimulating broad-based improvements in quality of care.

We believe that a different approach toward achieving quality health care for Federal beneficiaries is needed both to take advantage of the continuing advances in the health care delivery field and to keep up with growing demands for services. This approach necessitates revising our requirements to focus on the expected patient-centered outcomes of Medicare services. Thus, for home health services, we have developed a core set of requirements encompassing patient rights, comprehensive assessment, and patient care planning and coordination. Tieing these requirements together is a fourth core requirement—quality assessment and performance improvement—that rests on the assumption that a provider's own quality management system is the key to improved performance. Our objective is to achieve a balanced approach combining HCFA's responsibility to ensure that essential health and quality standards are achieved and maintained with a provider's responsibility to monitor and improve its own performance.

To achieve this objective, we are now developing revised requirements for several major health care provider types, including the new HHA requirements set forth in this proposed rule as well as revised requirements for hospitals, hospices, and end-stage renal disease facilities. In addition, elsewhere in today's issue of the Federal Register, we are publishing a proposed rule (Use of the OASIS As Part of the Conditions of Participation for Home Health Agencies) that describes the core standard assessment data set that we are proposing to require HHAs to incorporate into the comprehensive assessment process. This proposed rule is discussed below in section II.D of this preamble. All of these proposals are directed at (1) Improving outcomes of care and satisfaction for patients, (2) reducing burden on providers while increasing flexibility and expectations for continuous improvement, and (3) increasing the amount and quality of information available on which to base health care choices and efforts to improve quality.

We note that HCFA's revised approach to its quality assurance responsibilities is linked closely both to the Administration's commitment to reinventing health care regulations and to HCFA's own strategic plan that sets forth our future goals. This regulation is a regulatory reform initiative included in the President's and Vice President's July 1995 report entitled ''Reinventing Health Care Regulations''. In accordance with the President's Reinventing Health Care Regulations initiative, HCFA is revising the HHA COPs to eliminate unnecessary process regulations and focus on outcomes of care. Thus, these initiatives share three common themes. First, they promote a partnership between HCFA and the rest of the health care community, including the provider industry, practitioners, health care consumers, and the States. Second, they are based on the belief that we should retain only those regulations that represent the most cost-effective, least intrusive, and most flexible means of meeting HCFA's quality of care responsibilities. Finally, they rely on the principle that making powerful data available to consumers and providers can produce a strong nonregulatory force to improve quality of care. We believe that the revised HHA requirements proposed below, and the revisions that will follow for other providers, will provide the foundation for a health care system in which this type of information is readily available. In addition, certain provisions in this HHA COP rule support the Administration's reinvention initiative combating fraud and abuse. Such provisions are designated as serving this objective when appropriate.

II. Background

A. Home Health Care Benefit

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program and are described in section 1861(m) of the Social Security Act (the Act). These services must be furnished by, or under arrangement with, an HHA that participates in the Medicare program, be provided on a visiting basis to the beneficiary's home, and may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered nurse.
- Physical therapy, speech-language pathology, and occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program.
- Services at hospitals, SNFs, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

Section 1861(o) of the Act specifies certain requirements that a home health agency must meet to participate in the Medicare program. (Existing regulations at 42 CFR 440.70(d) specify that HHAs participating in the Medicaid program must also meet the Medicare conditions of participation.) In particular, section 1861(o)(6) provides that an HHA must meet the conditions of participation specified in section 1891(a) of the Act and such other conditions of participation as the Secretary finds necessary in the interest of the health and safety of patients of HHAs. Section 1891(a) of the Act establishes specific requirements for HHAs in several areas, including patient rights, home health aide training and competency, and compliance with applicable Federal, State, and local laws.

Under the authority of sections 1861(o) and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in Medicare. These requirements are set forth at 42 CFR Part 484, Conditions of Participation: Home

Health Agencies. The conditions of participation (COPs) apply to an HHA as an entity as well as the services furnished to each individual under the care of the HHA, unless a condition is specifically limited to Medicare beneficiaries. Under section 1891(b) of the Act, the Secretary is responsible for assuring that the COPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA and to promote the effective and efficient use of Medicare funds. To implement this requirement, State survey agencies generally conduct surveys of HHAs to determine whether they are complying with the conditions of participation.

B. Why Revise the Conditions of Participation?

The conditions of participation for HHAs were originally promulgated in 1973 and have been revised in part on several occasions. In particular, we made significant revisions to the COPs in 1989 (54 FR 33354) and 1991 (56 FR 32967), largely to implement provisions of section 4021 of the Omnibus Budget Reconciliation Act of 1987 (OBRA ''87, Public Law 100–203), which added section 1891 of the Act. Most recently, we made minor revisions to the HHA COPs on December 20, 1994 (59 FR 65482). However, many of the current COPs have remain unchanged since their inception.

Our decision to propose major changes to the existing conditions is based on several considerations. First, as discussed above, the revision of the HHA requirements is part of a larger effort by HCFA to bring about improvements in the quality of care furnished to Federal beneficiaries through a new approach to our quality of care responsibilities. Moreover, nowhere is the need for change more acute than in home health services. During the 1980's and early 1990's, major changes have taken place in the home health benefit, the provider industry, home health care practices, and the characteristics of home health care users that have combined to make home health services the most rapidly growing segment of Medicare expenditures.

In response to challenges associated with the expanding use of home health services, HCFA in 1994 began the Medicare Home Health Initiative (Initiative) to identify opportunities for improvement in the Medicare home health benefit. The Initiative is an agency-wide effort that routinely solicits input and feedback on a wide variety of issues from HCFA's partners in the home health care community. Representatives from HCFA, consumer groups, the home health care industry, professional associations, regional home health intermediaries, and States (including State Medicaid agencies) have convened in a series of collaborative meetings during 1994 and 1995. Among the Initiative's primary recommendations is that HCFA develop HHA COPs that include a core standard assessment data set and patient-centered, outcome-oriented performance expectations that will stimulate continuous quality improvement in home health care.

The existing HHA COPs do not provide patient-centered, outcome-oriented standards, nor do they provide for the operation of a quality assessment and performance improvement program. Historically, we set requirements for participation in the Medicare program by establishing requirements that address the structures and processes of health care. These requirements are largely the result of professional consensus, since there are no data supporting the link between structure and process requirements and positive patient outcomes. The combination of process-oriented requirements with an enforcement approach that focuses on identifying providers that do not have the required structures and procedures in place will not be adequate to meet the growing challenges associated with the changing home health care environment. Thus, we have concluded that significant revisions to the HHA conditions of participation are essential.

C. Transforming the HHA Conditions of Participation

As we began to develop new proposed COPs for HHAs, we solicited the advice and suggestions of the home health industry, professional associations and practitioner communities, as well as consumer advocates and State and other governmental agencies with an interest or responsibility in HHA regulation and oversight. The fundamental principles that guided the development of new COPs were the need to:

- Focus on the continuous, integrated care process that a patient experiences across all aspects of home health services, centered around patient assessment, care planning, service delivery, and quality assessment and performance improvement.
- Adopt a patient-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and how they interact with each other to meet the patient's needs. A home care patient encounters many services and is exposed to several disciplines, given the interdisciplinary approach to home health care delivery. An interdisciplinary team approach offers a more accurate portrayal of overall patient care outcomes across interdependent functions. Thus, we would eliminate requirements that encourage ''stovepipe'' administrative and enforcement structures.
- Stress quality improvements, incorporating to the greatest possible extent an outcome-oriented, data-driven quality assessment and performance improvement program. Thus, the new COPs would invest our principal expectations for performance in a powerful requirement that each HHA participate in its own quality assessment and performance improvement program.
- Facilitate flexibility in how an HHA meets our performance expectations, and eliminate outdated process requirements about which there was little consensus or evidence that they were predictive of good outcomes for patients or necessary to prevent harmful outcomes for patients.
- Require that patient rights are assured.

Finally, in order for the HHA conditions to move from a process/structure orientation toward an outcome orientation, outcome measures must be identified, developed, and validated. As discussed below, we have already taken several steps toward the development and implementation of a core standard assessment data set that will ultimately provide home health consumers, providers, and the regulators the data they need to improve quality and focus enforcement, as detailed elsewhere in today's issue of the Federal Register.

Based on these principles, we are proposing new HHA conditions of participation that revise or eliminate many existing requirements and incorporate critical requirements into four ''core conditions.'' These four COPs—Patient Rights, Patient Assessment, Care Planning and Coordination of Services, and Quality Assessment and Performance Improvement—would focus both provider and surveyor efforts on the actual care delivered to the patient, the performance of the HHA as an organization, and the impact of the treatment furnished by the HHA on the health status of its patients. The first, Patient Rights, emphasizes an HHA's responsibility to respect and promote the rights of each home health patient. The second proposed core condition, Patient Assessment, reflects the critical nature of a comprehensive assessment in determining appropriate treatments and accomplishing desired health outcomes. Third, the Care Planning and

Coordination of Services COP would incorporate the interdisciplinary team approach to providing home health services. The fourth proposed core COP, Quality Assessment and Performance Improvement, would then charge each HHA with responsibility for carrying out a performance improvement program of its own design to effect continuing improvement in the quality of care furnished to its customers.

In the revised COPs, we are proposing to include process-oriented requirements only where we believe they remain highly predictive of ensuring desired outcomes and the prevention of harmful outcomes (for example, home health aide competency and supervision and timeliness of patient assessment). Far more frequently, however, we have eliminated process details from the existing requirements and instead included the related area of concern as a component that must be evaluated by the HHA as part of the HHA's overall quality assessment and performance improvement responsibilities. For example, we removed the process requirements under existing § 484.12(c) that an HHA and its staff must comply with accepted professional standards and principles. We transformed the approach by incorporating current clinical practice guidelines and professional standards applicable to home care as a factor to be considered in the HHA's overall quality assessment and performance improvement program. The practical effect of this approach would be to stimulate the HHA to find its own performance problems, fix them, and continuously strive to improve patient outcomes and satisfaction, as well as efficiency and economy.

We believe that the proposed COPs based on these principles reflect a fundamental change in HCFA's regulatory approach, a change that to a large extent establishes a shared commitment between HCFA and Medicare providers to achieve improvements in the quality of care furnished to HHA patients. The proposed COPs invest HHAs with internal responsibility for improving their performance, rather than relying on an externally-based approach in which prescriptive Federal requirements are enforced through the punitive aspects of the survey process. This change would enable HCFA and the States to use our resources principally in joining with HHAs in partnerships for improvement. This change in our regulations to a patient-centered, outcome-oriented approach will also likely fundamentally change our approach to the survey process. For example, since the proposed regulation sets a performance expectation that an HHA constantly improve, it may be possible to alter significantly, or possibly eliminate altogether, the current Functional Assessment Instrument (FAI) that surveyors use to assess the outcomes of care through home visits and some record review. In an expanded review of the agency's approach to quality assessment and performance improvement, we may approach this task differently, with greater flexibility than the current FAI affords. We anticipate fewer compliance surveys and the reduced need to threaten or take adverse actions that could jeopardize a HHA's reputation, viability as a going concern, and participation in the Medicare and Medicaid programs. Yet these requirements provide the Secretary and State Medicaid agencies with more than adequate regulatory basis for compelling improved performance or termination of participation based on failure to correct seriously deficient performance that can or does threaten the health and safety of patients, or seriously impairs the HHA's capacity to provide needed care and services to patients.

We recognize that the successful implementation of these proposed regulations will depend largely on how effectively State and Federal surveyors are able to learn, use, and internalize this patient-centered, outcome-oriented approach and incorporate it into the survey process. The approach embodied in these regulations, is consistent with the approach that we have taken in survey and certification, beginning as early as 1985 (in intermediate care facilities for the mentally retarded) and 1986 (in nursing homes). In concert with the States, we have trained surveyors to develop information from the survey process that leads to conclusions about how the provider's performance has impacted—positively and negatively—on patients, especially in terms of the care and services that patients actually experience. For example, for many years, in nursing homes surveyors have been trained to interview residents and family members, seeking information that contributes to their assessment of how the nursing home's performance is experienced by the residents and their families. Before the use of outcome oriented surveys, surveyors focused on record reviews and observing care processes and organizational structures.

These proposed regulations contain two critical improvements that support and extend our focus on patient-centered, outcome-oriented surveys. First, the proposed regulations are designed to enable surveyors to focus explicitly on assessing outcomes of care, because the regulations would specify that each individual receiving the care, his or her assessed needs demonstrate is necessary (rather than focusing simply on the services and processes that must be in place). Second, the addition of a strong quality assessment and performance improvement requirement not only stimulates the provider to continuously monitor its performance and find opportunities for improvement, it also affords the surveyor the ability to assess how effectively the provider has been pursuing a continuous quality improvement agenda. All of the changes are directed toward improving outcomes of care.

We have already begun the process of identifying the tasks necessary to train surveyors and their supervisors and managers effectively in this refined, expanded approach. In addition, HCFA is implementing a new State survey agency quality improvement program that is designed to help State survey agencies increase their focus on improvement strategies in the survey and certification process. As more sources of performance data and other performance information become available, we will work with State survey agencies to determine how to use the data effectively to target scarce survey resources and to identify and implement opportunities for improvement (such as reduction in pressure sores or improvements in medication management in home care patients).

We believe that the proposed COPs would decrease the regulatory burden on HHAs and provide them with greatly enhanced flexibility. At the same time, the proposed requirement for a program of continuous quality assessment and performance improvement would increase performance expectations for HHAs in terms of achieving needed and desired outcomes for patients and increasing patient satisfaction with services provided.

We recognize that there are those who fundamentally believe that regulations, particularly when they directly affect the health and safety of people, should be prescriptive in their detail in order to ensure that providers do not engage in practices that threaten patient health and safety or to increase the clarity of intent, just as there are those who support strongly our change in approach. We invite comment on this fundamental shift in our regulatory approach and any other concerns HHAS may have regarding their ability both operationally and financially to undertake this new approach. We are

especially interested in comments that address how HCFA could improve this approach, what additional flexibility could be provided, what (if any) process requirements that are critical to patient care and safety should be added, and how well HCFA's investment in the HHA's participation in a strong continuous quality assessment and performance improvement program of their own design will achieve our stated and intended goal of improving the efficiency, effectiveness, and quality of patient outcomes and satisfaction.

D. Incorporation of a Core Standard Assessment Data Set into the HHA Conditions of Participation

Elsewhere in today's issue of the Federal Register, we are proposing to require HHAs to incorporate a core standard assessment data set, the Outcomes and Assessment Information Set (OASIS), into the comprehensive assessment process and the quality assessment and performance improvement programs. The incorporation of OASIS represents the first step toward implementing HCFA's plans to use outcome-based quality measures in home health services.

The details of how the OASIS was developed and tested, as well as how it can be used are explained in the OASIS proposed rule, along with the specific proposed regulatory language intended to achieve the stated purpose of introducing the OASIS into the HHA program.

III. Provisions of the Proposed Regulations

A. Overview

Under our proposal, the HHA conditions of participation would continue to be set forth in regulations under 42 CFR part 484. However, since many of the existing requirements in part 484 would be revised, consolidated with other requirements, or eliminated, we are proposing a complete overhaul of the existing organizational scheme. The most significant change would be our proposal to group together all COPs directly related to patient care and place them near the beginning of part 484. COPs concerning the organization and administration of an HHA would follow in a separate subpart. We believe this organization is in keeping with the patient-centered orientation of these regulations and helps illustrate our view that patient assessment, care planning, and quality assessment and improvement efforts are central to the delivery of high quality care.

The proposed organizational format for part 484 is as follows:

PART 484—CONDITIONS OF PARTICIPATION: HOME HEALTH AGENCIES

Subpart A—General Provisions

Sec.
484.1 Basis and Scope
484.2 Definitions

Subpart B—Patient Care

484.50 Condition of Participation: Patient Rights
484.55 Condition of Participation: Comprehensive Assessment of Patients
484.60 Condition of Participation: Care Planning and Coordination of Services
484.65 Condition of Participation: Quality Assessment and Performance Improvement
484.70 Condition of Participation: Skilled Professional Services
484.75 Condition of Participation: Home Health Aide Services

Subpart C—Organizational Environment

484.100 Condition of Participation: Compliance with Federal, State, and Local Laws
484.105 Condition of Participation: Organization and Administration of Services
484.110 Condition of Participation: Clinical Records
484.115 Personnel Qualifications for Skilled Professionals

B. Proposed Subpart A, General Provisions

Like the existing COPs, the revised conditions would begin with a brief section (proposed § 484.1) that would specify the statutory authority for the ensuing regulations. The only change proposed in this section would be the elimination of the reference to the statutory authority for an HHA's institutional planning responsibilities (existing § 484.1(a)(2)). This change reflects our proposal to eliminate from the HHA COPs a restatement of the statutory requirements at section 1861(z) of the Act concerning institutional planning. See section III.D of this proposed rule for a further discussion of this issue.

Under proposed § 484.2, we would set forth definitions for terms used in the HHA COPs that we believe need clarification. We are proposing to eliminate existing definitions for several terms for which we believe meaning is self-evident, such as ''HHA,'' ''nonprofit agency,'' or ''bylaws,'' as well as for terms that would not be included in the revised COPs. We are proposing to delete the current definitions for ''subdivision'' and ''subunit'' because the terms draw distinctions for participation and payment for which there are no differences. We are proposing to delete the current definitions for ''clinical note,'' and ''progress note,'' and ''summary report'' because the terms are commonly accepted as documentation requirements reflecting good medical practice to assess the individual's reaction or response to services furnished. We believe that the focus should be on documentation of the actual care provided to the individual via the interdisciplinary team within the comprehensive assessment, plan of care, and clinical record rather than the term used to describe the entry. We are deleting the definition for supervision from this section and incorporating the concept under the proposed skilled professional services COP. We are soliciting comments on the feasibility of a consolidated definition section in the Code of Federal Regulations (CFR) for definitions that are applied consistently throughout the Medicare program.

The definitions that would be included under proposed § 484.2 are as follows:

Branch means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Parent HHA means the agency that develops and maintains administrative control of branches.

Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care that has been empirically shown to be predictive of access, care outcomes, or satisfaction.

With the exception of ''quality indicator,'' all of these terms are defined in the same way as in existing § 484.2. We are adding a definition for the term ''quality indicator'' because, as discussed above, the use of quality indicators is central to an HHA's successful implementation of a quality assessment and performance improvement program.

We note that we would not retain the provisions of existing § 484.4, Personnel qualifications, under proposed subpart A, General Provisions. As discussed in detail in section III.D of this preamble, we are proposing major modifications to the prescriptive personnel qualification requirements now in place. Remaining requirements would be set forth under proposed § 484.115.

C. Proposed Subpart B, Patient Care

1. Patient Rights (Proposed § 484.50)

Section 1891(a)(1) of the Act establishes as a Medicare COP that an HHA must protect and promote the rights of each individual under its care. These rights encompass being informed in advance regarding the care to be provided and having an opportunity to participate in care planning; voicing grievances; confidentiality of records; respect for property; being informed about specific coverage and noncoverage of services; and availability of information in writing and through a home health services hotline. These statutory provisions are incorporated in existing regulations at § 484.10.

We would retain these statutory provisions in the proposed regulations and redesignate existing § 484.10 as proposed § 484.50, the first core COP, and also the first COP in proposed Subpart B, Patient Care. We are proposing one substantive change to the patient rights provisions. Specifically, we would expand the standard under existing paragraph (c)(l) relating to informing the patient in advance regarding care and treatment to be provided by the home health agency. We propose to specify that the patient must also be informed about ''expected outcomes'' of treatment and ''barriers'' to treatment. We believe that these revisions represent an additional safeguard of patient health and safety. Open communication between HHA staff and the patient and access of the patient to treatment information are vital tools for enhancing the patient's participation in his or her coordinated care planning. In addition, there are many environmental factors (for example, lack of nutrition and lack of family and emotional support) that are barriers that could impact the effectiveness of treatment decisions.

2. The Cycle of Care: Assessment, Planning, and Delivery

The patient care assessment, planning, and treatment process that is embodied in the next three COPs can be seen as a cycle. Through the use of a comprehensive assessment, accurate and timely patient information is made available for use in the patient treatment process. The treatment process is the actual interdisciplinary care furnished to the patient. The patient treatment process results in an effect on the patient's condition, whether it is positive, negative, or neutral. An HHA's assessment of the effect of treatment then enters into subsequent treatment decisions, and the cycle of comprehensive assessment continues. Through this cycle, accurate patient information yielded from each comprehensive assessment will result in more effective and appropriate treatment decisions, thus generating a positive effect on treatment decisions and yielding desired outcomes.

a. Comprehensive Assessment of Patients (Proposed § 484.55)

Introduction The proposed Comprehensive Assessment of Patients COP reflects the patient-centered, interdisciplinary approach of the proposed COPs and underscores our view that systematic patient assessment is essential to improving quality of care and patient outcomes.

Patient assessment contributes to quality of care improvements in three closely linked stages. First, the information generated from an interdisciplinary, comprehensive assessment of each patient is a vital tool for developing a patient's care plan and making individual treatment decisions. An HHA would then track the patient's progress towards achieving the desired care outcome and make appropriate changes to the patient's plan of care and treatment. As an HHA carries out this process on a repeated basis, the second contribution of patient assessment becomes clear. That is, the HHA is able to evaluate the results of its treatment decisions on an aggregate basis. Thirdly, accurate patient information yielded from the comprehensive assessment process would inform the HHA's future care planning process, generating continuing improvements in an HHA's treatment decisions and ability to produce desired patient outcomes. We believe that these internal quality improvement strategies reflect contemporary standard practice for many HHAs, and we are proposing to revise the COPs to support this outcome-oriented approach.

These first two uses for comprehensive patient assessment data basically involve short-term strategies that can be implemented by individual HHAs. In this proposed rule, however, we are also laying the foundation for a long-term strategy in which HCFA would use assessment information from many HHAs to define and measure care outcomes for home health care users. As discussed above, these quality indicators could then be built into a national data system for use by HHAs to improve the quality of care they provide and by HCFA to monitor patient outcomes.

Proposed Patient Assessment Requirements

The primary requirement under the proposed COP would be that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare patients, identifying the need for home care would include the assessment an individual's homebound status. An individual's homebound status is a critical eligibility requirement. This requirement would promote program integrity because it is the first regulatory requirement that directly evaluates homebound status.

Under our proposal, each HHA would have the responsibility and the flexibility to determine the content and process of its own patient assessment, within the broad requirement that it identifies the patient's care and discharge planning needs. The intent of requiring patient-specific comprehensive assessments is to avoid the use of ''canned'' patient assessments that do not reflect the individual needs of each patient. The comprehensive assessment must fully reflect each individual patient situation.

We are also proposing to require that the assessment must incorporate the use of a core standard assessment data set that is established by HCFA as a regulatory requirement under the comprehensive assessment condition elsewhere in this issue of the Federal Register. The data set includes only information necessary to measure outcomes of care for quality indicators; thus, our intent is not to develop a complete patient assessment but rather to identify standardized data elements that fit within the HHA's overall comprehensive assessment responsibilities. That is, the incorporation of the core standard assessment data set will complement the HHA's current approach to comprehensive assessment.

The existing COPs contain several requirements that address the need for patient assessment, including most notably a long and detailed list of items under existing § 484.18(a) that are required to be covered in a plan of care, such as pertinent diagnoses, mental status, and functional limitations. In place of this requirement, we would emphasize the importance of the comprehensive assessment by establishing patient assessment as a separate COP, specifying the desired outcome of the assessment (that is, the identification of a patient's care needs), and then allowing HHAs the flexibility to determine how best to achieve this outcome. We believe that this approach is consistent with current accepted practices in HHAs and that most HHAs

now perform a comprehensive assessment for most of their patients.

The first standard under the proposed comprehensive assessment COP concerns drug regimen review (proposed § 484.55(a)). Under this standard, we would retain the existing requirement of a drug regimen review from § 484.18(c), but would clarify the requirements by eliminating the identification of ''adverse actions'' and ''contraindicated medications'' and substituting the more concise requirements of review for drug interactions, duplicative drug therapy and noncompliance with drug therapy. This modification narrows the scope of the drug regimen review, provides accountability, and focuses the assessment toward data predictive of a significant patient outcome.

The second proposed standard sets forth the requirements for the initial assessment visit. Specifically, at proposed § 484.55(b), we propose that a registered nurse must perform an initial assessment visit based on physician's orders to determine the immediate care and support needs of the patient either within 48 hours of referral or within 48 hours after the patient's return home, or within 48 hours of the physician-ordered start of care date, if that is later. If rehabilitation therapy services are the only services ordered by the physician, the initial assessment would be made by the appropriate rehabilitation skilled professional. We welcome comments on the appropriateness of using competent individuals other than a registered nurse or appropriate therapist to perform initial patient assessments. We also invite comments on the feasibility of permitting the delegation of nursing responsibilities within the scope of State nurse practice acts to competent individuals.

The third standard (proposed § 484.55(c)) would specify the timeframe in which the HHA must complete the comprehensive assessment. We propose that the HHA must complete the comprehensive assessment in a timely manner consistent with the patient's immediate needs, but no later than 5 working days after the start of care.

The fourth standard (proposed § 484.55(d)) concerns updates of the comprehensive assessment. We would provide that the comprehensive assessment must discuss the patient's progress toward clinical outcomes and be updated and revised as frequently as the patient requires, but no less frequently than every 62 days from the start of care date, which is when the patient's plan of care is revised for physician review and when the patient is discharged.

These proposed standards essentially would replace the requirements concerning the duties of the registered nurse under the existing skilled nursing services COP (§ 484.30(a)). Currently, a registered nurse must regularly reevaluate the patient's nursing needs, initiate the plan of care and necessary revisions, prepare clinical and progress notes, coordinate services, and inform the physician and other personnel of changes in the patient's condition and needs. The existing requirement emphasizes the patient information process. In contrast, the proposed comprehensive assessment COP would focus on ensuring that all critical information concerning a patient is routinely incorporated through timely assessments that identify a patient's initial and changing needs.

Under proposed § 484.55 (b) and (c), we are proposing specific timeframes for the initial assessment, completion of the assessment, and interim updates to the patient assessment. We believe that these requirements, though process-oriented, are predictive of good patient care and safety, as well as necessary to prevent harm to the patient. Our rationale for these timeframes is that by definition, a new patient being referred to a home health agency for initiation of services is at a point of immediate and serious need, especially as patients are returned home from hospital care sooner than ever before. Likewise, as the complexity of the care needs of patients increases, so does the need for comprehensive assessment of the patient, and the importance of implementing an effective care plan promptly becomes paramount.

We believe that these requirements pose little or no burden for the well-managed home health agency since they would in all likelihood be performed in the absence of regulations. However, the proposed timeframes serve as a strong performance expectation for HHAs that may not have adequate resources (financial and human resources) by setting the outside acceptable time for these activities to occur. If too many patient referrals occur together, some patients might be neglected or harmed by the HHA's inability to see the patient quickly or to conduct and complete the needed comprehensive assessment so effective service delivery can begin. Thus, if an HHA recognizes that its workload is such that it is not capable of beginning work with a patient virtually immediately upon referral, the patient should not be accepted for care.

Under proposed § 484.55(d), we are proposing that the comprehensive assessment be updated as frequently as the patients condition requires but not less frequently than every 62 days, for several reasons:

(1) Especially in the early stages of care, patient needs, progress, and circumstances can change greatly, and changes in the status of the patient can and should prompt changes in approaches to care, so reassessment as needed helps to inform the revision of the care plan and service delivery;

(2) When HCFA and the home health community are prepared to begin collecting and utilizing quality indicator data (which will come from the core standard assessment data set), it will be necessary for the HHA to report the data on a regular basis. The developers of the core standard assessment data set have found the roughly 2-month timeframe to be an effective interval for data points for comparison purposes, which also coincides well with the recertification timeframe in item (3) below; and

(3) An HHA is required to have the patient recertified for continued care every 62 days, which serves as a logical point for updating an assessment if no updates have already been completed.

We welcome comments on whether the specific proposed timeframes in the regulation text are reasonable and consistent with current medical practice, and whether the timeframes should be used as benchmarks to reflect patient health and safety concerns involving the timeliness of the assessment components.

3. Care Planning and Coordination of Services (Proposed Section 484.60)

Currently, the condition of participation concerning the plan of care is set forth at § 484.18. We propose to revise the contents of this section, and place them in a new condition, ''Care planning and coordination of services'' (proposed § 484.60). This condition would contain four standards that reflect the interdisciplinary approach to home health care delivery. The standards are discussed in detail below.

This proposed COP would first state the fundamental requirement that the patient's plan of care must specify the care and services necessary to meet the patient's specific needs as identified by the physician and in the comprehensive assessment, and the measurable clinical outcomes that the HHA expects will occur as a result of implementing the plan of care. Again, a clinical outcome can be defined as a change in an individual's health between two or more points in time. We would retain the existing requirement that patients are accepted for treatment on the basis of a

reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence.

In accordance with our goal of eliminating prescriptive requirements that do not directly relate to patient care, we have simplified the plan of care standard at existing § 484.18(a). The first standard under this condition, ''Plan of Care,'' set forth at proposed § 484.60(a), would require that all home health services must follow a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine in accordance with § 409.42. We would specify that all patient care orders must be included in the plan of care. We believe that our proposal would decrease the burden on HHAs and would allow agency staff to develop care plans that best suit the needs of the patients they serve.

Under the second proposed standard, ''Review and revision of the plan of care'', we would add to the language at existing § 484.18(b). The current requirement that the physician and the HHA review the plan of care as frequently as the patient's condition requires but not less than once every 62 days would be retained, with the additional clarification that this period begins with the date of start of care. We would continue to require that the HHA promptly alert the physician to any changes in the patient's condition that suggest a need to alter the plan of care. We would also extend the current requirement to specify that the HHA must promptly alert the physician if measurable outcomes are not being achieved. If measurable outcomes are not being achieved, the HHA must review, assess, and document the patient's responses to his or her current medical and environmental situation (including barriers to care), and implement a physician's revised plan of care as often as necessary to meet the patient's needs. At a minimum, revised plans of care should be established and implemented when a patient experiences significant changes in his or her medical condition or functional capacity. An example of an environmental situation that would be considered a barrier to care would be a patient who was not receiving proper nutrition. In such a case, the agency staff would document the situation and revise the plan of care accordingly. We believe that these requirements would reflect our outcome-oriented approach to patient care in that they would require the HHA to focus on the patient's responses to treatment decisions. Additionally, these requirements would not impose a burden on HHAs since agencies are already required to complete a plan of care for each patient. These requirements would be set forth at proposed § 484.60(b)(1). We are soliciting comments on the need for frequent regular physician reviews of plans of care for patients who are only receiving personal care services.

Under § 484.60(b)(2), we propose to require that a revised plan of care must include current information from the patient's comprehensive assessment and information concerning the patient's progress toward outcomes specified in the plan of care. We are soliciting comments on the utility of adding an additional requirement that would require the original plan of care that initiates care to be reviewed and revised in a timely manner consistent with the patient's immediate needs, but no later than 5 to 10 working days after the completion of the comprehensive assessment. This would ensure that the plan of care would be revised to reflect the incorporation of the completed comprehensive assessment, which must be completed in a timely manner consistent with the patient's immediate needs, but no later than 5 working days after the start of care. This additional requirement would ensure the link between the completed comprehensive assessment and a revised plan of care.

In the third standard, ''Conformance with physician orders'', we would retain language at existing § 484.18(c). In December 1994, we revised this standard to require that oral orders be put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist responsible for furnishing or supervising the ordered services (59 FR 65482). We also provided that oral orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. We would include these standards in the Care planning and coordination of services condition under proposed § 484.60(c).

We propose to add a new standard, Coordination of care, at § 484.60(d). This standard would incorporate provisions at existing § 484.14(g) (Organization, services, and administration, Standard: Coordination of patient services), which requires that all personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the plan of care, and that the HHA must document such liaison. Our proposed standard would go beyond this requirement by linking the level of the coordination of services, caregivers and the patient to identifiable care need and barriers to care and by requiring HHAs to adjust the degree of coordination to meet the needs of the patient. Specifically, we would require the HHA to maintain a system of communication and integration of services, whether provided directly or under arrangement, that ensures the identification of patient needs and barriers to care, the ongoing liaison between all disciplines providing care, and the contact of the physician for relevant medical issues. Additionally, we would require the HHA to identify the level of coordination necessary to deliver care to the patient and involve the patient and the caregiver in the coordination of care.

We believe that this standard is appropriate for a number of reasons. Since a home care patient may encounter many services delivered at different times by a variety of individuals with different skills, efficient communication and integration among members of the home health team is essential in responding to patient needs in a timely and effective manner. Further, effective coordination of services is necessary to avoid duplicative or conflicting services. Finally, we recognize that an interdisciplinary approach to the delivery of home health services reflects actual practice for most home health agencies, and we believe that, when possible, our regulations should coincide with current industry practice.

4. Quality Assessment and Performance Improvement (Proposed Section 484.65)

We are proposing to eliminate two conditions of participation, existing § 484.52, Evaluation of the agency's program, and existing § 484.16, Group of professional personnel, and replace them with a single, new quality assessment and performance improvement condition of participation. Existing regulations for HHAs do not provide for the operation of a quality assessment and performance improvement program whereby the HHA examines its methods and practices of providing care, identifies opportunities to improve its performance, and then takes actions that result in better outcomes of care and satisfaction for the HHA's patients. In light of our intention to raise the performance expectations for HHAs seeking entrance into the Medicare program as well as those currently participating, HCFA is proposing that each HHA develop, implement, and maintain an effective, data-driven quality assessment and performance improvement program. We believe this

requirement would stimulate an HHA to continuously monitor and improve its own performance and to be responsive to the needs, desires, and satisfaction of its patients. This proposed new requirement epitomizes the approach of these new COPs in that it provides a constant expectation for improved performance, in contrast to the current approach that only sets a floor of structural and procedural requirements that are intended to be surrogate measures for ensuring quality. This condition is intended to set up a self-sustaining system for improvement, under which an HHA monitors its performance to a point that surveyor findings would confirm an HHA's own assessment of where performance improvements are needed.

We have not prescribed the structures and methods for implementing this requirement, and have focused the condition of participation on the expected results of the program, that is, quality indicators and other outcome-oriented measures. This provides flexibility to the HHA, as it is free to develop a creative program that meets the HHA's needs and reflects the scope of its services.

Currently, the first COP that addresses quality of care (existing § 484.52, Evaluation of the agency's performance), provides for the evaluation of the agency's total program at least once a year. The agency must have written policies requiring the evaluation, the evaluation must include a review of the HHA's policies and administrative practices, and the results of the evaluation must be separately recorded and maintained as administrative records. The agency must also review a sample of open and closed clinical records at least on a quarterly basis. The second condition of participation that addresses quality of care (existing § 484.16, Group of professional personnel), requires a group of professional personnel, which includes at least one physician and one registered nurse, to establish and annually review the agency's policies governing the scope of services offered, admission and discharge policies, medical supervision of plans of care, clinical records, personnel qualifications and program evaluation. This group is required to meet frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program and assist in liaison functions. Minutes of the group's meetings must be documented. These requirements focus on the meetings and documentation of the agency's evaluation of their quality of care and do not account for the outcome of these activities.

Instead of continuing to prescribe the structures and processes by which an HHA evaluates its services, we have identified the outcomes expected of an agency that assesses its performance and improves the services that it provides to beneficiaries and set forth under proposed § 484.65 the required major components of an effective quality assessment and performance improvement program. Our expectation is that the HHA will successfully operate a continuous quality assessment and performance improvement program on behalf of its beneficiaries. We believe this is a reasonable expectation, for which the HHA can and should be held accountable.

Previously, the only motivation for quality improvement for some HHAs was the adverse effect of having been found by surveyors to be out of compliance with one or more conditions of participation and threatened with termination from the Medicare program. With an effective quality assessment and performance improvement program, the HHA can identify and reinforce the activities that it is doing well and seek out and respond to opportunities for improvement on a continuous basis. The desired outcome of this proposed requirement is that the HHA itself, rather than the survey process, will be the driving force for continuous improvements, enabling HCFA to focus its resources on supporting that effort and on HHAs that fail to meet the requirements, even after efforts have been made to improve performance.

The proposed condition requires the HHA to develop, implement, and evaluate an effective, data-driven quality assessment and performance improvement program. The program must reflect the complexity of HHA's organization and services (including those provided directly or under arrangement). The HHA must take actions that result in improvements in the HHA's performance across the spectrum of care.

The first standard at proposed § 484.65(a) requires that an HHA's quality assessment and performance improvement program must include, but not be limited to, the use of objective measures to demonstrate improved performance with regard to:

(1) Quality indicator data (derived from patient assessments) to determine if individual and aggregate measurable outcomes are achieved compared to a specified previous time period. The terms ''quality indicators,'' ''performance measures,'' and ''outcome measures'' are often used interchangeably, though technically, they vary somewhat in meaning. Regardless, they all refer to attributes of care and satisfaction that can be used to gauge quality of care in specific aspects of care. For example, the degree and rate of improvement in a functional area (such as the ability to walk after a hip replacement) can be shown to be a quality indicator. The method of defining and measuring that improvement is the ''performance measure'' or ''outcome measure.'' These measures assign a specific value to the care dimension being measured. The appropriateness of the combination of services reflected on the plan of care, the effectiveness of the communication among the interdisciplinary team, or the competency of the mix of professionals used on the team to implement the services could all be possible indicators of the outcome-oriented performance expectations that should stimulate ongoing quality improvement in home health care delivery.

Some measures, though, are of processes of care that are predictive of outcomes of care. These process measures quantify one or more dimensions of the manner in which care is actually provided or administered (or negatively, is not provided or administered). A process measure such as the number of times a service is provided may be directly related to the rate of improvement (or lack of improvement) of the patient. So, a valid and reliable process measure can be shown to be predictive of patient outcomes, therefore, a quality indicator.

The core standard assessment data set, described in detail elsewhere in today's issue of the Federal Register, contains tested and validated indices of functional status over time and satisfaction of patients that have been shown to reflect quality of care. Once we have completed the rulemaking necessary to implement the use of this data set, each HHA will collect and evaluate these standard data as a part of providing care and managing the quality assessment and improvement program, but will not be required to report it. This information will help the HHA to improve its services and the outcomes and satisfaction that patients experience. Later, when we subsequently implement the requirement to begin reporting the quality indicator data, the HHA will be able to receive the aggregated and analyzed data from the universe of HHAs to compare its performance with others.

(2) Current clinical practice guidelines and professional practice standards applicable to home care. Contemporary care practices in an increasingly complex and fragmented

health care environment are rapidly changing. Home care is now provided routinely to very ill persons and persons with severe physical, medical, and other challenges. We expect an HHA to pursue the latest clinical practice guidelines and professional standards for use in its quality assessment and performance improvement program. Continuous improvement is only possible through the identification and use of continuously improved information, techniques, and practices. Much of this information also can be used by patients and their families to enable them to be more independent and play a more effective role in the home care process. While HCFA is not imposing any specific standards of practice, this proposed requirement establishes the expectation that the HHA will seek and utilize the latest standards as a routine part of its daily business.

(3) Utilization data, as appropriate. HHAs currently collect and monitor utilization data in order to evaluate their fiscal and competitive well-being. This information can also be used to evaluate the quality of care, as HHAs become aware of how their performance compares with other HHAs. Eventually, we intend that the HHA will use the utilization data from its own practices to compare with other HHAs across the nation. The purpose of including utilization data in the HHA's quality assessment and performance improvement program is to help the HHA ensure the patient receives only the number of visits that are necessary to achieve needed and desired outcomes. Utilization data will also be used as part of HCFA's external quality assurance monitoring, enabling the agency to target reviews of HHAs whose utilization data suggest, for example, that patients may be receiving fewer (or more) visits than necessary to achieve expected outcomes.

(4) Patient satisfaction measures. Beneficiary satisfaction with home health services is an important element of a quality assessment and performance improvement program. Under our proposal, an HHA would develop and implement specific measures on an ongoing basis to determine from patients and their families whether they are satisfied with services provided and outcomes achieved and the extent to which the HHA respected their rights. We expect that an HHA would use this information to search for opportunities to improve services and patient satisfaction. We do not intend to prescribe to specific tools for measuring patient and family's views, but we do intend to ask the HHA during a survey to demonstrate its patient rights and satisfaction measurement system and how it is used as part of the overall internal quality assessment and performance improvement program.

(5) Effectiveness and safety of services (including complex high technology services, if provided), including competency of clinical staff, promptness of services, and whether patients are achieving treatment goals and measurable outcomes. For patients to experience the needed and desired outcomes that the Medicare home health benefit is intended to achieve, staff must be able to demonstrate the skills and competencies necessary to enable patients to achieve needed and desired outcomes. The HHA is expected to include data-based, criterion-referenced performance measures of staff skills, to utilize that data to ensure that staff maintain skills, and to provide training as new techniques and technologies are introduced and as new staff arrive. We intend that the HHA would be able to demonstrate that it has a system of appropriate complexity for keeping track of the skills and competencies of the staff and that effectively identifies and addresses training needs. These ''data'' should be an integral part of the HHA's internal quality assessment and performance improvement program, providing continuous feedback on staff performance. The physicians and other staff are in a unique position to provide the HHA's management with structured feedback on the performance of the HHA and ways in which the performance can be improved. The physicians and other staff are customers also, whose needs and contributions to quality improvements are significant. The HHA's internal quality assessment and performance improvement program is expected to view staff as full partners in quality improvement, and we expect the HHA to demonstrate how physicians and staff contribute to the internal quality improvement of the HHA. This proposed requirement is linked directly to the proposed requirement that the HHA include in its quality assessment and performance improvement program current clinical practice guidelines and standards of practice.

Thus, we expect that the HHA will immediately correct problems that are identified through the quality assessment and performance improvement program that actually or potentially affect the health and safety of patients. For example, if the quality assessment and performance improvement program identifies problems with the accuracy of medication administration, it is not enough for the HHA to consider this area as a candidate for an improvement program that may or may not be chosen from a list of potential projects. Rather, since the accuracy of medication administration is critical to the health and safety of patients, the HHA must intervene with a correction and improvement approach immediately.

When we use the word ''measure,'' we mean that the HHA must use objective means of tracking performance that enable both the HHA and the survey agency to identify the differences in performance between two, points in time. For example, a measure that states an HHA is ''doing better'' as a result of an improvement approach would be unacceptable. There must be identifiable units of measure that any reasonably knowledgeable person would be able to distinguish as evidence of change. Not all objective measures must have been shown to be valid and reliable (that is, subjected to scientific development), to be useable in improvement approaches, but they must at least identify a start point and end point stated in objective terms that actually relate directly to the objectives and expected/desired outcomes of the improvement program.

Under the second standard at § 484.65(b), we are proposing that the HHA must take actions that result in performance improvements and must track performance to assure that improvements are sustained over time. This requirement links the quality assessment and performance improvement program to a pattern of actions over time. The focus is on the pattern of behavior recognized by the HHA and how the HHA used its own experience to continuously strive for improvements.

The third standard under the Quality Assessment and Performance Improvement Program at proposed § 484.65(c) states that the HHA must set priorities for performance improvement, considering prevalence and severity of identified problems, and giving priority to improvement activities that affect clinical outcomes. However, any identified problems that directly or potentially threaten the health and safety of patients must be corrected immediately. Prioritizing areas of improvement is essential for the HHA to gain a strategic view of its operating environment and to ensure the consistent quality of care provided over time. Overall, an HHA would be expected to give priority to improvement activities that most affect clinical outcomes. Conditions that may threaten the health and safety of patients must be immediately and

directly addressed when they are identified.

The fourth standard under the Quality Assessment and Performance Improvement COP, at proposed § 484.65(d), would require the HHA to participate in periodic, external quality improvement reporting requirements as may be specified by HCFA. An example of participation in an external quality improvement activity would be the future requirement for the HHA to report quality indicator data (as discussed elsewhere in today's issue of the Federal Register). Participation in the survey process is another example. A different example might be that the Secretary, reviewing the quality indicator data (or other information), decides to embark on a national project to improve the management of multiple medications from multiple doctors of HHA patients. This proposal would require the HHA to participate in this external quality improvement project. Another example might be a national effort to increase the number of HHA patients who receive flu shots each year. This proposed requirement is entirely consistent with HCFA's strategic plan to improve the health status of Medicare and Medicaid beneficiaries, and many of these projects will reach beneficiaries well beyond individuals being served under specific benefit programs such as home health.

Development of the revised COPs is part of the Administration's reinventing government initiative. The COPs were revised to emphasize a focus on outcomes of health care rather than process and procedural requirements. Our revitalized approach reflecting the use of quality indicators and outcome measures as part of future external quality improvement reporting requirements as specified by the Secretary stem from the statutory authority governing the HHA COPs. Section 1891(b) of the Act states, ''It is the duty and responsibility of the Secretary to assure that the conditions of participation * * * and the enforcement of such conditions * * * are adequate to protect the health and safety of individuals under the care of a home health agency and to promote the effective and efficient use of public moneys.'' Congress mandated broad authority to allow the Secretary to keep up with the myriad of changes in quality health care delivery that reflect the state of the art. The use of outcome measures is a significant feature of accreditation for organizations such as the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) Agenda for Change and Community Health Accreditation Program's (CHAP) Benchmarks for Excellence in Home Care.

The use of quality indicators and outcome measures as part of external quality improvement reporting requirements stems, in part, from the statutory requirement that surveys of HHAs employ quality indicator data. Specifically, section 1891(c)(2)(C)(i)(II) of the Act states, ''A standard survey conducted under this paragraph with respect to an HHA shall include (to the extent practicable), for a case-mix stratified sample of individuals furnished items or services by the agency * * * a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care.''

Looking beyond the actual service delivered toward the outcome resulting from that service allows the HHA the opportunity to incorporate that information to change patterns of behavior or policies and continually improve future performance. Although reaching the desired outcome is beneficial, the revised approach focuses on continuous change in an HHA's behavior over time. The regulatory approach to outcome measures is not predicated on punishing those who do not reach desired outcomes, but on examining how the HHA used its own experience to change behavior and ultimately improve performance over time.

Finally, this condition includes a standard about infection control at proposed § 484.75(e). We expect the HHA to maintain an effective infection control program as part of its overall quality assessment and performance improvement program. We recognize that an HHA cannot be directly responsible for the maintenance of an infection free home environment, especially since the HHA cannot be physically present in the home at all times. However, it can be responsible for (1) ensuring that all staff know and use current best practices themselves to ensure they are not the source of the spread of infection in the course of providing home health services, and (2) on educating families and other caregivers on best practices for the control of the spread of infections within the home during the course of the family/caregivers'' interactions with the patients. One example of the use of ''current best practices'' is the universal precaution of the use of gloves when handling blood or blood products. HCFA is not proposing any specific approaches to meeting this requirement, but would expect to see clear evidence that the HHA aggressively seeks to minimize the spread of infection through the use of infection control techniques by its staff and through the efforts made to help families and caregivers to minimize the spread of infection.

5. Skilled Professional Services (Proposed Section 484.70)

Existing regulations at §§ 484.16, 484.30, 484.32, and 484.36 specify standards that identify detailed tasks that must be performed by agency staff in the provision of skilled nursing services, therapy services, and medical social services respectively.

We propose to delete §§ 484.16, 484.30, 484.32, and 484.36 and replace them with a more simplified new condition on skilled professional services. Instead of specifically identifying tasks, we are broadly describing the expectations of the skilled professionals who participate in the interdisciplinary team approach to home health care delivery.

We would specify that skilled professionals who provide services to HHA patients directly or under arrangement must participate in all aspects of care, including an ongoing interdisciplinary evaluation and development of the plan of care, and be actively involved in the HHA's quality assessment and performance improvement plan. We are reducing the concentration on process requirements and shifting the focus to outcomes. The expected outcome is the coordinated, comprehensive, interdisciplinary delivery of appropriate and effective skilled professional services delivered and supervised by health care professionals who practice under State licensure requirements and the HHA's policies and procedures. Skilled professional services for purposes of this section include: skilled nursing care, physical therapy, speech language pathology, occupational therapy (as defined in § 409.44) and medical social services and home health aide services (as defined in § 409.45).

At proposed § 484.70(a), we provide that skilled professional services are authorized, delivered, and supervised (that is, given authoritative procedural guidance) only by health care professionals who meet the appropriate qualifications specified under § 484.115 and who practice under the HHA's policies and procedures. We believe that this approach to supervision provides clarity to the current definition.

We are proposing to require that an HHA ensure that a majority of at least 50 percent of the total skilled professional services are routinely provided directly by the HHA. We are

proposing to phase in this new approach over 3 years. In the first year, HHAs would be required to ensure that at least 30 percent of the skilled professional services are provided directly. In the second year, HHAs would be required to ensure that at least 40 percent of skilled professional services are provided directly. By the third year of enactment, HHAs would be required to ensure that at least 50 percent of the skilled professional services are provided directly.

We are requesting comments on the use of a standard that would limit the use of contract care by Medicare certified HHAs. We believe such limits may be needed as a means of preventing the establishment of ''shell'' HHAs that are merely a fax machine and a nurse used as a billing system. Further, we believe that this type of standard would protect against provider fraud and abuse. Mass delegation of care has led to problems in evaluating the accountability of providers. This is a program integrity approach that seeks to ensure continuity of care via the significant use of contractual care in the decentralized environment of home health delivery.

Medicare makes a distinction between providing services directly, as opposed to providing services under arrangement. The most common way services are provided directly is through the use of employees. The common law definition of ''employee'' fundamentally relates to whether a person is under control by the entity or individual providing the services, so by and large producing a W–2 form would constitute providing the services directly. The ''Stark Provisions'' at section 1877(h)(2) of the Act references the IRS ''employee'' definition. Section 1877(h)(2) provides that—

An individual is considered to be ''employed by'' or an ''employee of'' an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).

We are exploring a more concise method of defining the provision of direct services as opposed to services provided under arrangement.

We believe that the excessive use of contracting could be an indication that an HHA may be exceeding its patient capacity, leading to possible instability that can result in disruptions to patient care. Excessive contracting is also a potential indication that the HHA may not be exercising full control over quality of care. This performance safeguard seeks to ensure continuity and quality of care through the restriction of the significant use of contracted care in home care.

A major home health care association has supported the establishment of limits on Medicare certified HHAs' use of contracted care as a way to establish performance expectations for the quality of care provided. The proposed direct services requirement is an attempt to address our concerns with the growth in ''shell'' operations and provider accountability. It is important to note that HHAs currently report employment data on their cost reports. We welcome comments on the percentage approach to the proposed direct services standard to control the excessive use of the contracting of services. We welcome comments on this shift in our approach and on any concerns HHAs may have regarding their ability, both operationally and financially, to undertake this new approach.

6. Home Health Aide Services (Proposed Section 484.75)

Section 1891(a) of the Act requires the Secretary to establish minimum standards for home health aide training and competency evaluation programs. Section 1861(m)(4) of the Act requires Medicare covered home health aide services to be furnished by an individual who has successfully completed a training and/or competency evaluation program that meets the requirements established by the Secretary.

Currently, the condition of participation concerning home health aide services is set forth at § 484.36, (Condition of Participation: Home health aide services). For the most part, we would retain the existing requirements although in some cases we have made organizational or editorial changes in the interest of brevity or clarity. In addition, we are soliciting comments on some possible alternatives for future revisions. Under our reorganization scheme, this condition would be located at proposed § 484.75.

Standard: Home Health Aide Qualifications

Currently, provisions concerning the qualifications for home health aides are set forth at § 484.4, Personnel Qualifications. As discussed in detail below, we are proposing substantial revisions to the personnel qualifications section. In light of our proposed revisions and our reorganization of part 484, we believe that the qualifications for home health aides would be more appropriately located in this section. Thus, at proposed § 484.75(a) we would provide that a qualified home health aide is an individual who has successfully completed a State-established or other training program that meets the requirements of proposed § 484.75(b) and a competency evaluation program or State licensure program that meets the requirements of proposed § 484.75(c), or a competency evaluation program or State licensure program that meets the requirements of proposed § 484.75(c), or has completed a nurse aide training and/or competency evaluation program approved by the State as meeting the requirements of existing §§ 483.151 through 483.154 and is currently listed in good standing on the State nurse aide registry. We are soliciting comments on our proposed change to the home health aide personnel qualification, which would include the interchangeable paraprofessional training and/or competency standards for home health aides and nurse aide requirements at requirements at existing §§ 483.151 through 483.154 (part of the Long-Term Care Facilities Requirements for Participation). The home health aide workforce is ridden with high turnover rates. We believe that the proposed changes to the home health aide personnel qualifications yield flexibility to HHAs in their ability to retain equally competent paraprofessionals from a wider pool of employment prospects.

Under proposed § 484.75(a)(2), we would retain (with clarification) the current personnel qualification requirements governing home health aide employment status during a continuous period of 24 consecutive months. An individual is not considered to have completed a training and competency evaluation program or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in § 409.40 of this chapter for compensation. If an individual has not furnished services described in § 409.40 for compensation during a continuous period of 24 consecutive months, then the individual must complete another training and competency evaluation program or competency evaluation program as described in paragraph (a)(1) of this section.

Standard: Home Health Aide Training

We propose to retain the same requirements for content and duration of training as those under the current requirements at § 484.36(a)(1). However, we propose more concise language.

Specifically, at proposed § 484.75(b)(1), we would provide that the home health aide training must include classroom and supervised practical training that totals at least 75 hours. A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training.

Proposed § 484.75(b)(1)(i) would clarify provisions regarding communication skills currently located at § 484.36(a)(1)(i) (Standard: Home health aide training-(1) Content and duration of training). We would provide that communication skills include the ability to read, write, and make brief and accurate oral and written presentations to patients, caregivers, and other HHA staff. We propose to retain current requirements under § 484.36(a)(1) (ii) through (xii) at proposed § 484.75(b)(1) (ii) through (xii) (Standard: Content and duration of training). We propose to retain current § 484.36(a)(1)(xiii) with clarification at proposed § 484.75(b)(1)(xiii). We propose to modify the current language, ''Any other task that the HHA may choose to have the home health aide perform'' by adding the following: ''The HHA is responsible for training the home health aide, as needed, for skills not covered in the basic checklist.''

At proposed § 484.75(b)(2) and (3), we would essentially retain the provisions governing conduct of training by organizations and qualifications of instructors under existing §§ 484.36(a)(2) (i) and (ii).

At proposed § 484.75(b)(4), we would essentially retain the documentation of training requirement under existing § 484.36(a)(3) to include State approved nurse aide training and competency evaluation as reflected in the definition of the personnel qualifications for home health aides.

We propose to separate existing § 484.36(b)(Standard: Competency evaluation and inservice training) into two separate standards, Competency Evaluation and Inservice Training. These standards would be set forth at proposed § 484.75(c) and (d) respectively.

Standard: Competency Evaluation

In order to simplify this standard, at proposed § 484.75(c) we would combine the current requirements for an HHA's responsibility for the applicability of the competency evaluation requirements under existing § 484.36(b)(1) and the limitations on the applicability of the competency evaluation requirements for personal care attendants under a State Medicaid Personal Care benefit under existing § 484.36(e)(2). An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section. We propose that the HHA must ensure that all individuals who furnish home health aide services to patients meet the competency evaluation requirements of this section. The only exception would be for personnel care aides who exclusively provide personal care services to Medicaid patients under a State Personal Care benefit.

We propose to combine the requirements for competency evaluation under existing § 484.36(b)(2) with the subject area requirements under existing § 484.36(b)(3)(iii). We propose the competency evaluation must address each of the subjects listed in § 484.36(a)(1) (ii) through (xiii). Subject areas § 484.36(a)(1) (iii), (ix), (x), and (xi) must be evaluated by observing the aide's performance with a patient. The remaining subject areas may be evaluated through written examination, oral examination or after observation of the home health aide with a patient. These provisions would be set forth at proposed § 484.75(c)(2).

At proposed § 484.75(c)(3) we would to retain the current requirements for the conduct of competency evaluations by organizations under § 484.36(b)(3)(i). A competency evaluation program may be offered by any organization except as specified in existing § 484.36(a)(2)(i).

At proposed § 484.75(c)(4) we would retain the current requirement at § 484.36(b)(3)(ii) that the competency evaluation must be performed by a registered nurse. However, we recognize the interdisciplinary approach to home health care and propose the requirement that the registered nurse should perform the competency evaluation in consultation with other skilled professionals, as appropriate. At proposed § 484.75(c)(5), we would retain the current requirements for competency determinations under § 484.36(b)(4).

At proposed § 484.75(c)(6), we propose to retain the current requirements for documentation of competency evaluation currently located at § 484.36(b)(5). We propose to delete the effective date requirements under existing § 484.36(b)(6) because they refer to a timeframe in 1990 and are no longer necessary.

Standard: Inservice Training

At proposed § 484.75(d) we would retain the requirements for the amount of in-service training located at existing §§ 484.36(b)(2) (ii) and (iii). We propose to clarify the 12-month period to address calendar year and anniversary date issues. We would combine the current requirements to propose that the home health aide must receive at least 12 hours of inservice training in a 12-month period. During the first 12 months of employment, hours may be prorated based on the date of hire. The in-service training may occur while the aide is furnishing care to a patient.

At proposed § 484.75(d)(2) we would revise the current requirements for the conduct of inservice training by organizations under § 484.36(b)(3)(i). We would provide that an inservice training program may be offered by any organization except as specified in § 484.75(b)(2).

We propose to revise the current requirement for instructors of inservice training under § 484.36(b)(3)(ii). The current requirement states that inservice training generally must be supervised by a registered nurse with specific experience requirements. Thus, at proposed § 484.75(d)(3), we would provide that the inservice training must be supervised by a registered nurse. The revised language does not include the current experience requirements because we believe it is appropriate to give the HHA flexibility to utilize qualified professionals to instruct and evaluate aides in an appropriate manner in order to meet the outcome which is ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.

Standard: Home Health Aide Assignments

At proposed § 484.75(e), we would retain the revisions to existing § 484.36(c), Standard: Assignments and duties of the home health aide, published in December 1994 (59 FR 65482), with one additional requirement. Specifically, at proposed § 484.75(e)(3), we propose to restore the requirement that home health aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to the registered nurse or other appropriate skilled professional and complete appropriate records in compliance with the HHA policies and procedures. This requirement was inadvertently removed in the December 1994 final rule. Home health aides may observe changes in patient needs that are crucial to future treatment decisions and should be reported to the appropriate professional in order to implement effective and appropriate changes in care.

Standard: Supervision

At proposed § 484.75(f), we would retain the home health aide supervision

requirements under existing §§ 484.36(d) (1), (2), (3), and (4).

We have concerns about whether quality supervision can be done without the requirement of an aide's presence performing a direct patient service. We have discussed several alternatives, including a requirement that the registered nurse or appropriate skilled professional must make an onsite visit to the patient's home while the home health aide is providing patient care no less frequently than every 30 days. We welcome comments on changing the current indirect supervision requirement and will address the issue in the final rule.

We are also soliciting comments on the idea of focusing aide supervision on individual aides rather than each patient. The purpose of the supervisory visit is to determine if services are being provided, to assess relationships with the patient, competency with tasks, and evaluation of the employee's contribution to the organization's goals to provide high quality care.

Generally, assessing patient needs, developing a plan of care, care coordination, and other skilled visits are performed at a frequency that generally exceeds a biweekly aide supervision schedule. These visits traditionally encompass supervision functions by the nature of being home and ascertaining whether the patient's needs are being met. Therefore, the current supervisory requirements may not add the quality measure of care and may duplicate functions that are inherently provided by the interdisciplinary team. Aides who have performed well and have satisfactory ratings may not need to be supervised as often as new or unsatisfactory rated aides. Centering the supervisory visits on an individual aide rather than on a patient would allow aides to be included in the HHA's human resource management policies that apply to all staff within the organization, and encourage the employer-employee relationship to reflect quality of patient care.

We welcome comments on the following draft standard and will address the issues in the final rule:

Standard: Paraprofessional Supervision

(1) If the patient receives skilled care and paraprofessional services, or paraprofessional services without skilled care, the HHA must not only ensure that the aide is competent to perform the necessary skills (see competency evaluation), but also evaluate the aide's ability to perform such functions on a continual basis. Supervision must be provided by the appropriate professional to ensure the health and safety of the patient, especially when specialized tasks and delegated functions have been added to the competency subjects.

(2) The frequency of routine supervision is established by the HHA's policies which promote high quality patient care through the employment evaluation processes. These evaluation tools should begin at the time of employment and are evaluated thereafter on a regular employment basis, allowing for variations to accommodate time in service with the hiring HHA and the employees' recorded evaluation ratings with that HHA. Employment status should be calculated by the most appropriate method for the organization to ensure regular evaluations. HHAs who arrange for aide services through a non-Medicare certified HHA must ensure equivalent supervision requirements in the arrangement contract with the primary HHA responsible for compliance with these requirements.

(3) The evaluation process includes, but is not limited to, measuring the aide's continual ability to perform routine tasks, specialized tasks, reporting problems to the HHA with care plan tasks, recognizing and reporting barriers to the anticipated outcomes, and patient satisfaction issues.

(4) Nonroutine supervision is also essential to monitor the need for paraprofessional care plan revisions. For example, HHAs could perform spot home visits (direct or indirect observation), telephone interviews, and other mechanisms to ensure protection of the health and safety of the patient and respect for patient's privacy and property. Nonroutine supervisory techniques provide a forum for open and frequent communication to obtain essential and timely feedback. Feedback can also be obtained from other care providers (formal and informal), significant family, and others deemed necessary to properly evaluate the paraprofessional.

(5) In accordance with HHA policies, the aide should also provide feedback on his or her employment environment and the evaluation processes.

Additionally, we welcome comments on the efficacy of using competent individuals other than a registered nurse to perform training, competency evaluation, and assignment or supervision functions for home health aides.

Standard: Medicaid Personal Care Aide Services—Medicaid Personal Care Benefit

At proposed § 484.75(g) we would retain the current requirements under § 484.36(e) (1) and (2). A Medicare certified HHA that provides personal care aide services to Medicaid patients under a State Medicaid Personal Care Benefit must determine and ensure the competency of individuals who perform those Medicaid approved services.

Alternatives for Future Revisions

Home care patients are a vulnerable and confined population. It is necessary to ensure the provision of safe quality care to patients in their homes. We are proposing one specific measure in this proposed rule—a criminal background check of home health aides as a condition of employment (§ 484.75(h)). In addition, we are considering the utility of several other process measures that could be included in this regulation that are predictive of the desired outcome of delivering safe quality care in the patient's home. One possibility would be to adopt the language that is currently used in the Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded (ICF/MR) at § 483.420, modified to reflect the HHA environment and population served. The ICF/MR provisions governing client protections at §§ 483.420(d)(1)(iii), (2), (3), and (4) state:

- The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.
- The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.
- The facility must have evidence that all alleged violations are thoroughly investigated and must prevent further potential abuse while the investigation is in progress.
- The results of all investigations must be reported to the administrator or designated representative or to other officials in accordance with State law within 5 working days of the incident and, if the alleged violation is verified, appropriate corrective action must be taken.

Proposing criminal background checks as a condition of employment for home health aides is one vehicle to guard beneficiaries from abusive practices in the sanctity of their homes.

We are soliciting comments on the costs and benefits of requiring criminal background checks for home health aides and the possible adoption of the additional patient safeguards modified to reflect the HHA environment.

D. Proposed Subpart C—Organizational Environment

1. Compliance with Federal, State, and Local Laws (Proposed Section 484.100)

Currently, provisions concerning compliance with Federal, State, and local laws are located at § 484.12, Condition of Participation: Compliance with Federal, State, and local laws, disclosure of ownership information and accepted professional standards and principles. We would retain most of the provisions contained in this condition with minor changes, which are discussed in detail below. Under our proposed reorganization scheme, discussed above, this condition would be set forth at § 484.100.

Under the first standard, compliance with Federal, State, and local laws and regulations, at proposed § 484.100(a), we would revise the language at existing § 484.12(a). That is, we would require that the HHA and its staff must operate and furnish services in compliance with all Federal, State, and local laws and regulations applicable to home health agencies. If a State has established licensing requirements for HHAs, all HHAs must be approved by the State licensing authority as meeting those requirements whether or not they are required to be licensed by the State. The Secretary may find an HHA to be out of compliance with these conditions of participation if the HHA is found out of compliance with any Federal, State, or local law or regulation by the appropriate enforcement agency for that law or regulation and the Secretary determines that the law or regulation affects the HHA's ability to deliver home health services safely and effectively. When a facility is actually found out of compliance and is cited by that agency for a violation, HCFA will exercise discretion in determining whether that violation should be cited as a violation under these conditions. Clearly it is not in the interest of patients or providers to decertify facilities or to require corrective action plans for certain reasons (for example, a facility's failure to pay its local property taxes on time or building a fence 3 feet over the property line). We would not cite an agency whose problem was remedied (for example, the facility paid its taxes). However, HCFA intends to cite agencies when their violations of Federal, State, or local laws or regulations affect the health and safety of patients, the ability of HHAs to deliver quality services, the rights and well-being of patients, and/or the management of the agency and its ability to recruit qualified staff. We welcome comments on this interpretation.

Similarly, in the second standard, Disclosure of ownership and management information, we propose to retain the requirements at existing § 484.12(b). We would continue to require that the HHA comply with the requirements of §§ 420.200 through 420.206 regarding disclosure of ownership and control information. Additionally, the second standard would continue to require that the HHA also disclose the following information to the State survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

- The name and address of all persons with an ownership or control interest in the HHA as defined in §§ 420.201, 420.202, and 420.206.
- The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in §§ 420.201, 420.202, and 420.206.
- The name and address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

Existing § 484.12(c) provides that an HHA must comply with accepted professional standards and principles. To reflect an emphasis on the importance of continuity of care and our focus on quality, regardless of the site of service, we propose to move the current provisions at § 484.12(c) and incorporate the performance expectation of the provisions into the quality assessment and performance improvement program. HCFA has long used the term ''in accordance with accepted standards of practice'' in its various provider and supplier requirements both to set a performance expectation and to serve as an enforcement tool should grossly divergent practices be identified in the survey process.

We believe that requiring an HHA to participate in a strong, quality assessment and performance improvement program would stimulate an aggressive effort to identify and use the best practices available for all care providers in the HHA. As discussed above, for the HHA to be successful in its quality assessment and performance improvement program, it will be obliged to seek out best practices continuously. HCFA's survey effort can then be devoted to assessing how the HHA has sought out and adopted best practices in the field as part of the surveyor's evaluation of the quality assessment and performance improvement requirements, rather than HCFA prescriptively defining ''accepted professional standards''.

At proposed § 484.100(c), we would provide that the HHA and its branches must be licensed in accordance with State licensure laws, if applicable, prior to providing Medicare reimbursed services. This provision seeks to ensure that HHA patients receive the same level of quality care from the appropriate personnel at all sites of service. The requirement that HHAs comply with State licensure laws before providing services to Medicare beneficiaries would apply to the HHA as an entity as well as its staff furnishing services to HHA patients directly or under arrangements.

Finally, we propose to move the current requirements at § 484.14(j), Organization, services and administration, Standard: Laboratory services, to proposed § 484.100(d). We believe that the laboratory services standard is a Federal requirement that is better suited under the revised condition of participation governing compliance with Federal, State, and local laws.

2. Organization and Administration of Services (Proposed Section 484.105)

The proposed COP on organization and administration of services would revise existing regulations at § 484.14 (Condition of participation: organization, services and administration) and replace the existing regulations at § 484.38 (Condition of participation: Qualifying to furnish outpatient physical therapy or speech-language pathology services). The proposed new condition simplifies the structure of the current requirements and provides flexibility to the HHA by replacing the current focus on organizational structures with new performance expectations for the administration of an HHA as an organizational entity. With the wide diffusion of home health organization and management structures, it is imperative to ensure accountability within HHAs by setting performance expectations for the clear, unambiguous, and accountable operation of all

services. The overall goal of the proposed condition is clear, accountable organization, management, and administration of an HHA's resources to attain and maintain the highest practicable functional capacity for each patient in terms of medical, nursing, and rehabilitative needs as indicated on the plan of care.

One of the most critical responsibilities for the governing body of the HHA to meet is stated explicitly at the beginning of proposed § 484.105: The HHA is expected to ''attain and maintain the highest practicable functional capacity for each patient * * *'' This language derives from section 1891(c)(2)(C)(i)(I) of the Act, which directs the Secretary to devise a survey process that includes home visits to a case-mix sample of patients ''for the purpose of evaluating * * * the extent to which the quality and scope of items and services furnished by the agency attained and maintained the highest practicable functional capacity of [E]ach such individual * * * '' Thus, the expectation for performance of the HHA, as stated throughout these proposed rules, especially in the comprehensive assessment, care planning and coordination, and quality assessment and performance improvement COPs, is to achieve outcomes of care that are commensurate with a patient's condition and expectations for returning to improved functional status as much as possible. The placement of this requirement in the COP that includes the governing body is intended to express clearly our intention that the responsibility for achieving the best outcomes possible for the patients served lies with the administration of the HHA, including its governing body and administrator.

This requirement lends support to the importance of the HHA using current best practices within a strong quality assessment and performance improvement program. It promotes the HHA's seeking out and using comparative data where available and using its own data compared to previous points in time to demonstrate internal improvements in outcomes over time.

We recognize that there is no single test of this requirement; each patient is unique and the expectations for outcomes vary in every case. Yet, we will expect surveyors to determine that the HHA, overall, has aggressively pursued this statutory expectation for outcomes for patients and either achieves it, or demonstrates its efforts to achieve it when desired outcomes are not successfully achieved.

In the proposed organization and administration of services condition, we revise the current standard on governing body (§ 484.14(b)), retain, with only minor changes, the current standard on services furnished (§ 484.14(a)), retain, with only minor editorial changes, the requirements with respect to services under arrangements that are now stated in § 484.14(h), delete the current standards on administrator (484.14(c)), delete the current standards on supervising physician or registered nurse (§ 484.14(d)), delete the current standards on personnel policies (§ 484.14(e)), delete the current standards on institutional planing (§ 484.14(i)), relocate the existing condition, qualifying to furnish outpatient physical therapy or speech-language (§ 484.38) under this condition, and relocate the current standard on laboratory services (§ 484.14(j)) under the compliance with Federal, State and local laws COP.

In developing the proposed governing body standard, we emphasize the responsibility of the HHA governing body (or designated persons so functioning) for the management and provision of all home health services, fiscal operations, quality assessment, performance improvement, and the appointment of the administrator. We have retained the necessary administrative features that promote and protect patient health and safety from the current standard on governing body at § 484.14(b) while providing flexibility in the actual approach to the performance expectation of the provision of quality care to all patients. Thus, in the proposed governing body standard, the actual approach to the administration of the HHA as an organization is left to the discretion of the governing body of each HHA. The proposed governing body standard reflects our goal of promoting the effective management and administration of the HHA as an organizational entity without dictating prescriptive requirements for how an HHA must meet that goal.

In the proposed governing body standard, the HHA's governing body (or designated persons so functioning) must assume the full legal authority and responsibility to ensure the performance expectation of the sound fiscal operation of the HHA, appoint a qualified administrator who is responsible for the day-to-day operation of the program, and may appoint designated persons to carry out those functions. We believe the proposed standard on governing body encompasses the performance expectation of an HHA administrator and of organizational fiscal operations, and, therefore, propose to delete the current prescriptive standards on the administrator at § 484.14(c) and on institutional planning at § 484.14(i). We propose to replace the current process-ridden institutional planning standard at § 484.14(i) with the performance expectation of the HHA governing body's responsibility for the fiscal operation of the HHA.

We propose to remove the current statutorily based institutional planning requirements from the HHA conditions of participation. Because the HHA conditions of participation are primarily intended to reflect patient health and safety standards, we feel the COPs are an inappropriate location for the institutional planning provisions found under section 1861(z) of the Act. The proposed standard requires the governing body to assume full legal authority and responsibility for fiscal operations and appointment of an administrator who is responsible for the day-to-day operation of the program without specifying the means to achieve the goal. This outcome-oriented approach provides flexibility to the HHA in the administration of the HHA as an organizational entity. However, it is important to note that the statutory requirements of section 1861(z) of the Act continue to apply to an HHA's institutional planning and capital expenditure activities, even though we would not include them in the revised COPs.

The second proposed standard under the organization and administration of services condition would specify that the HHA that accepts the patient is the primary HHA and has the responsibility to meet the care needs of the patient. Primary home health agency means the agency that accepts the patient becomes the primary HHA and assumes responsibility for the interdisciplinary coordination and provision of services and continuity of care, whether the services are provided directly or under arrangement. We are proposing the new primary HHA standard to ensure continuity of quality care. Mass delegation of care has led to problems in evaluating the accountability of providers and quality of care. This standard was proposed to address the problem of HHAs accepting patients for only specific services. For example, one HHA accepts a patient, treats the patient for a specific condition, and then refers the patient to several other agencies for the rest of his or her treatment. Under our proposal, the HHA that accepts a patient would become the primary HHA and would be held responsible for the interdisciplinary coordination and provision of services ordered under the patient's plan of care. We welcome

comments as to whether the primary HHA standard is an appropriate tool to address the problem of mass delegation and fragmentation of care.

We are also proposing a new standard to address the parent/branch relationship. We want to establish clear requirements regarding the parent/branch relationship in order to protect patient health and safety and to ensure a consistent level of care throughout the HHA as an organizational entity. Although the existing regulations define ''branch office'' and ''parent HHA'', we have found that some HHAs have several branch offices that are actually operating as full-fledged HHAs while the parent offices are used as billing shells for the branches. We have concerns about branches, which are not required to independently meet the conditions of participation, acting as an independent HHA and the effect on program integrity and the consistency of quality care provided. We do not anticipate that this standard will disrupt current business practice because the current definitions of parent and branch provide a performance expectation for HHAs as organizational entities as a condition of participation for Medicare certification.

In the proposed rule, we have retained the current definitions, and we are also incorporating the previous definition material into the organization and administration of services COP in order to clarify that this is a management responsibility of the organization. The standard states that a parent home health agency provides direct support and administrative control of branches. The branch office is located sufficiently close to effectively share administration, supervision, and services in a manner that renders it unnecessary for the branch to separately meet the COPs as an HHA. We have added ''teeth'' to the current definition of the parent and branch by making it a standard level requirement. This will enable surveyors to cite a deficiency when the performance by an HHA's branch does not ensure that the branch is meeting the HHA requirements applicable to its operation. Since the parent/branch reference in the current rule is only a definition, surveyors cannot presently cite a deficiency.

We are proposing at § 484.105(e) to revise the current services furnished requirement at existing § 484.14(a). Specifically, we would retain the current requirement that part-time or intermittent skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis in a place of residence used as a patient's home. We would revise the second part of the standard to state that an HHA must provide at least one of the qualifying services directly, but may provide the second qualifying service and additional services under arrangements with another agency or organization. Medicare makes a distinction between services provided directly as opposed to under arrangement. As discussed above, the most common way services are provided directly is through the use of employees. The common law definition of ''employee'' fundamentally relates to whether a person is under control by the entity or individual providing the services, so by and large producing a W–2 form would constitute providing the services directly. We are exploring a straightforward way to define the provision of direct services as opposed to services provided under arrangement.

3. Clinical Records (Proposed section 484.110)

We are proposing a new COP, clinical records, that embodies several of the requirements in existing § 484.48, Condition of participation: Clinical records. In this condition we would retain only those process requirements that are essential to protect of patient health and safety.

The primary requirement under the proposed clinical records condition of participation is that a clinical record containing pertinent past and current findings is maintained for every patient who is accepted by the HHA for home health services. We propose to add the requirement that the information contained in the clinical record must be accurate, made available to the physician and appropriate HHA staff and may be maintained electronically. The accuracy of the clinical record must exhibit consistency between the diagnosed condition and the actual experience of the patient. Accuracy can be reflected in the appropriate link between patient assessment information and the services and treatments ordered and furnished in the plan of care. In light of the decentralized nature of HHAs, that is, patient care is not furnished in a single location, we believe that members of the interdisciplinary team must have access to patient information in order to provide quality services. Many HHAs maintain electronic records and we recognize this technological change in the home health environment.

The first standard of the condition, contents of the record, would include several elements that we currently require HHAs to include in the clinical record. We would retain the requirement that the record include clinical/progress notes, a discharge summary, and the plan of care. To give HHAs flexibility in maintaining clinical records, we would no longer specify that the record must include appropriate identifying information, name of physician, drug, dietary, treatment and activity orders, and copies of summary reports sent to the attending physician. Finally, we would add requirements to this standard that reflect our outcome oriented approach to patient care. Specifically at proposed § 484.110(a), we would require that the clinical record include: (1) The patient's current comprehensive assessment, clinical/progress notes, and plan of care; (2) responses to medications, treatments, and services; (3) a description of measurable outcomes that have been achieved; and (4) a discharge summary that is available to physicians upon request. We believe that these requirements would give HHAs flexibility in maintaining clinical records as well as ensure that the records contain information necessary to provide high quality patient care.

We propose to add a new standard at proposed § 484.110(b) to provide for authentication of clinical records. We would require that all entries be clear, complete, and appropriately authenticated. Authentication must include signatures or a computer secure entry by a unique identifier of a primary author who has reviewed and approved the entry. The move to computerized records has resulted in transcription of doctor's orders and electronic signatures. This standard is currently in the COPs for hospitals, and addresses technological changes in information management.

Under proposed § 484.110(c) we would retain the current requirement under § 484.48(a) (Standard: Retention of records). That is, we would continue to require that clinical records be retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. HHA policies provide for retention of records even if the HHA discontinues operations. If the patient is transferred to another health facility, a copy of the record or an abstract is sent with the patient.

We also propose to incorporate into this condition the first requirement under existing § 484.48(b) (Standard: Protection of records). At proposed § 484.110(d) we would provide that patient information and the record are safeguarded against loss or

unauthorized use. We believe the other requirements under existing § 484.48(b) concerning the release of clinical record information are best incorporated into the new standard at proposed § 484.50 (Patient Rights: Confidentiality of clinical records).

4. Personnel Qualifications (Proposed section 484.115)

Currently, provisions concerning the qualifications of HHA personnel are located at § 484.4. This section now includes very specific credentialing requirements and provides that any staff required to meet the conditions of participation must meet our qualifications. In keeping with our goal of eliminating process requirements that are not predictive of good outcomes for patients or necessary to prevent harmful outcomes for patients, we are proposing significant revisions to the personnel qualifications COP. Specifically, we would provide that in cases where personnel requirements are not statutory, or do not relate to a specific payment provision we would apply State certification or State licensure requirements. Under our proposal, the personnel qualifications would fall into three basic categories, personnel for which there is a statutory set of qualifications, personnel for which we have specified requirements since all States do not have licensure or certification requirements, and personnel for which all States have licensure or certification requirements. Under our proposed reorganization of part 484, the personnel qualifications would be located at proposed § 484.115. We discuss the personnel qualifications in detail below.

The first category of personnel qualifications are those in which we would defer to State law. At proposed § 484.115(a), we would specify that skilled professionals who provide services directly by or under arrangements with the HHA must be legally authorized (licensed or if applicable, certified or registered) to practice by the State in which he or she performs, and must act only within the scope of his or her State license or State certification.

The second category would consist of personnel for which there is a statutory set of qualifications. Section 1861(r) of the Act essentially defines a physician as a doctor of medicine, osteopathy, or podiatry legally authorized to practice medicine and/or surgery by the State in which such function or action is performed. We would refer to this definition at proposed § 484.115(b). The Act also contains a definition of a speech language pathologist. Specifically, section 1861(ll)(3)(A) defines a qualified speech language pathologist as an individual with a master's or doctoral degree in speech-language pathology who is licensed as a speech-language pathologist by the State in which the individual furnishes such services, or in the case of an individual who furnishes services in a State which does not license speech-language pathologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed a national examination in speech-language pathology approved by the Secretary. The Act also defines the qualifications for home health aides at section 1891(a). We believe that the description of qualifications for home health aides would be more appropriately located under the home health aide services COP. Thus, the requirement will be cross-referenced at proposed § 484.75(a).

The third category of personnel qualifications would include those persons for whom all States do not currently have a licensing or certification requirement. If a State has licensing or certification requirements for a professional included in this section, then the State qualifications would apply. If a State does not have licensing or certification requirements, then the HHA would apply the qualifications specified below. This category would consist of all current personnel qualifications found under § 484.4 with the exception of audiologists and practical (vocational) nurses. We propose to delete the current requirements for audiologists and practical (vocational) nurses. The existing requirement for practical (vocational) nurses is State licensure in the State practicing; thus it is self-explanatory in our deference to State law. We believe the audiologist requirement is no longer relevant to the home care environment.

We contemplated changing the current requirements for social workers consistent with our approach to deferring to State licensing laws, when applicable, but have not done so in this rule because of the absence of data and outcome measures. We are requesting comments on alternative approaches to personnel qualifications for social workers and the submission of data that would support the retention or change to the current personnel qualifications for social workers in this rule.

We propose to revise the existing personnel qualifications for HHA administrators. An administrator is a person who is licensed as a physician; or holds an undergraduate degree and is a registered nurse; or has education and experience in health service administration, with at least one year of supervisory or administrative experience in home health care or a related health care program and in financial management.

We propose to revise the definition of administrator to provide that an administrator who is a registered nurse must possess a bachelor's degree. Additionally, we would specify the type of education or experience that an administrator who is not a physician or a registered nurse must have. Specifically, as stated above, such a person would need education or experience in home health care or a related health care program and in monitoring the financial aspects of program management. In light of the fact that many HHAs experience financial difficulties as a result of poor or inefficient management, we believe that our proposed requirement that the administrator have education or experience in financial management would be beneficial. Additionally, we believe that this proposed requirement is necessary since inefficient financial management of an HHA can ultimately lead to low quality patient care. We note that States do not have licensing requirements for HHA administrators; thus, as in the past, HHAs would continue to apply our requirements.

In addition, in the event that a State does not have any licensure or certification for the following professions, the HHA would apply the qualifications specified below:

Occupational Therapist—A person who: (a) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or (b) is eligible for the National Registration Examination of the American Occupational Therapy Association; or (c) has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial

qualification as an occupational therapist after December 31, 1977.

Occupational therapy assistant—A person who: (a) Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or (b) has 2 years appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

Physical therapist—A person who: (a) Has graduated from a physical therapy curriculum approved by: (1) The American Physical Therapy Association; or (2) The Committee on Allied Health Education and Accreditation of the American Medical Association; or (3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or (b) Prior to January 1, 1966 (1) Was admitted to membership by the American Physical Therapy Association, or (2) was admitted to registration by the American Registry of Physical Therapist, or (3) has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or (c) has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualifications as a physical therapist after December 31, 1977; or (d) was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which the services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or (e) if trained outside of the United States (1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy; (2) meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

Physical therapy assistant—A person who: (1) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or (2) has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

Public health nurse—A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content approved by the National League for Nursing for public health nursing preparation.

Registered nurse—A licensed graduate of an approved school of professional nursing.

Social worker assistant—A person who: (1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or (2) has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualifications as a social work assistant after December 31, 1977.

Social worker—A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

Our approach to personnel credentialing would be as flexible as possible. Our objective is to rely upon State licensure to the extent that States license practitioners required under these conditions of participation. However, the diverse nature of State licensure provisions make it necessary for us to continue to write and apply requirements in some cases. For example, where a State does not license a type of practitioner required in these conditions of participation, a Federal definition is needed to enable HHAs and surveyors to define and meet the requirement. An example of this situation would be a State that does not license occupational therapists. There are also instances when the specific credential applicable to a practitioner is specified in the law. An example of this is a physician, which is defined in section 1861(r) of the Act. Finally, the credentialing philosophy that we have described here would not apply under Medicare Part B, when a specific level or education or training is specified as a pre-condition for reimbursement. Thus, the definitions contained in this section generally apply for HHA certification purposes only in States where there are no State licensure or certification requirements.

IV. Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless we certify that a proposed rule such as this would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all home health agencies are considered small entities. States and individuals are not considered small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operation of a substantial number of small rural hospitals. Such an 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 50 beds. We are not preparing a rural impact statement since we have determined, and certify, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Although the provisions proposed in this rule do not lend themselves to a quantitative impact estimate, we do not anticipate that they would have a substantial economic impact on home health agencies. However, to the extent that our proposals may have significant effects on providers or beneficiaries, be viewed as controversial, or be mandated by statute, we believe it is desirable to inform the public of our projections of the likely effects of the proposals.

As discussed in detail above, this proposed rule sets forth new HHA COPs that revise or eliminate many existing requirements and incorporate critical requirements into four ''core conditions.'' These four COPs—Patient Rights, Patient Assessment, Care Planning and Coordination of Services,

and Quality Assessment and Performance Improvement would focus both provider and surveyor efforts on the actual care delivered to the patient, the performance of the HHA as an organization, and the impact of the treatment furnished by the HHA on the health status of its patients. The impact of the proposed rule to incorporate OASIS into the HHA COPs is separately detailed in that proposed rule (which is set forth elsewhere in today's issue of the Federal Register). In developing these proposed COPs, we have retained structure and process-oriented requirements only where we believe they are essential to achieving desired patient outcomes or preventing harmful outcomes (for example, home health aide competency and supervision, timeliness of patient assessment).

Under the proposed Comprehensive Assessment COP, we are proposing specific timeframes for the initial assessment, completion of the assessment, and interim updates to the patient assessment. We believe that these requirements, though process-oriented, are predictive of good patient care and safety, as well as necessary to prevent harm to the patient. Our rationale for these timeframes is that by definition, a new patient being referred to a home health agency for initiation of services is at a point of immediate and serious need, especially as patients are returned home from hospital care sooner than ever before. Likewise, as the complexity of the care needs of patients increases, so does the need for comprehensive assessment of the patient. The importance of coming to closure and implementing an effective care plan becomes paramount.

We believe that these timeframe requirements pose little or no burden for the HHA since they would in all likelihood be performed in the absence of regulations. However, the proposed timeframes serve as a strong performance expectation for HHAs that may not have adequate resources (financial and human resources) by setting the outside acceptable time for these activities to occur. If too many patient referrals occur together, effective service delivery to some patients might be delayed by the HHA's inability to see the patient quickly or to conduct and complete the needed comprehensive assessment. Thus, if an HHA recognizes that its workload is such that it is not capable of beginning work with a patient virtually immediately upon referral, the patient should not be accepted for care.

We welcome comments to address whether the specific proposed timeframes in the regulation text are reasonable and consistent with current medical practice, and whether the timeframes should be used as benchmarks to reflect patient health and safety concerns involving the timeliness of the assessment components.

Provision of an assessment would be necessary to provide the appropriate information for compliance with the current plan of care requirements. The existing COPs contain several requirements that address the need for patient assessment, including most notably a long and detailed list of items under existing § 484.18(a) that are required to be covered in a plan of care, such as pertinent diagnoses, mental status, and functional limitations. In place of this requirement, we would emphasize the importance of the comprehensive assessment by establishing patient assessment as a separate COP, specifying the desired outcome of the assessment (that is, the identification of a patient's care needs), and then allowing HHAs the flexibility to determine how best to achieve this outcome. We believe that this approach is consistent with current accepted practices in HHAs and that most HHAs now perform a comprehensive assessment for most of their patients. We need to balance the possible short-term increase in costs or other administrative burden, if any, on the HHA with the long-term fundamental positive effect on patient health resulting from an organized and timely comprehensive assessment. As stated above, we are soliciting comments on the utility of specific timeframes for the comprehensive assessment.

We are proposing to require that HHAs ensure a majority of at least 50 percent of the total skilled professional services are provided directly. We are proposing to phase in this new approach over 3 years. In the first year, HHAs would be required to ensure that at least 30 percent of the skilled professional services are provided directly. In the second year, HHAs would be required to ensure that at least 40 percent of the skilled professional services are provided directly. By the third year of enactment, HHAs would be required to ensure that at least 50 percent of the skilled professional services are provided directly.

Currently, an HHA must provide at least one of the qualifying services directly, but may provide the second qualifying service and additional services under arrangements with another agency or organization. We believe that the excessive use of contracting could be an indication that an HHA may be exceeding its patient capacity, leading to possible instability that can result in disruptions to patient care. Excessive contracting is also a potential indication that the HHA may not be exercising full control over the provision of quality care. Participants in a series of home health initiative meetings agreed that this process requirement is a strong predictor of appropriate management and in proposing this approach we are relying on the judgement of the industry. This is a performance safeguard that seeks to ensure continuity and quality of care through the restriction of contracted care in the home care environment.

It is important to note that HHAs currently report employment data on their cost reports (freestanding HHAs: Form-HCFA–1728–S–3 and hospital-based HHAs: Form-HCFA–2552–H–S–4). We invite comment on this shift in our approach and on any concerns HHAs may have regarding their ability, both operationally and financially, to undertake this new approach. We also invite comment on any other creative approaches that could be used to limit the use of contracted care in the home care industry.

We are proposing that HHAs conduct criminal background checks of home health aides as a condition of employment to safeguard beneficiaries from abusive practices in their home. This proposed requirement may have some impact though not significant, on HHAs, which are considered small entities. We already have similar patient protection requirements in other rules governing other Medicare-participating providers. These protections are especially necessary in the decentralized environment of home health delivery. We are soliciting comments on the impact on the HHA to operationally comply with this requirement.

We are proposing a new standard to address the parent/branch relationship to ensure a consistent level of care throughout the HHA as an organizational entity. We added strength to the current definitions by raising them to standard level requirements. This will enable surveyors to cite a deficiency when the performance by an HHA's branch does not ensure that the branch is meeting the HHA requirements applicable to its operation. HCFA has concern about branches that are not required to independently meet the conditions of participation, but act as an independent HHA and the affect of that situation on the consistency and quality of care provided. We estimate that this standard will not disrupt current business practice because the current definitions of parent and branch office provide a performance

expectation for the HHA as an organizational entity as a condition of participation for Medicare certification. The current definitions provide a clear expectation that the parent office develops and maintains administrative controls of branches; and the branch office is location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency and is part of the HHA and is located sufficiently close to share administration, supervision and services in a manner that renders it unnecessary for the branch to independently meet these conditions of participation as a home health agency.

More often though, we have eliminated structural or process-oriented requirements that we no longer believe are necessary (such as personnel policies or the prescriptive details concerning the duties of a registered nurse versus those of a licensed practical nurse), in favor of an approach that, through the proposed core COP on quality assessment and performance improvement, invests HHAs with internal responsibility for improving their performance. This approach is intended to incorporate into our regulations current best practices in well-managed HHAs, relying on the HHA to identify and resolve its performance problems in the most effective and efficient manner possible.

We believe that the proposed COPs would decrease the administrative burden on HHAs to comply with detailed Federal requirements, thus reducing the costs incurred by the typical HHA in meeting the Medicare conditions of participation. (See the information collection section below for examples of specific changes in the recordkeeping and paperwork burden of HHAs that would be associated with this proposed rule.) Instead, the proposed COPs would provide HHAs with much more flexibility to determine how best to pursue our shared quality of care objectives in the most cost-effective manner. We expect HHAs to develop different approaches to compliance based on their varying resources and patient populations, differences in laws in various localities (such as those concerning personnel standards), and other factors. Given the uncertainties over the behavior of individual HHAs under the proposed new COPs, quantitative analysis of the effects of these proposed changes is not possible. However, even in situations where the proposed requirements could result in some immediate costs to an individual HHA (for example, for an HHA that would need to upgrade its existing performance evaluation program), we believe that the changes that the HHA would make would produce real but difficult to estimate long-term economic benefits (such as more cost-effective performance practices or higher patient satisfaction that could lead to increased business for the HHA.)

We believe that the proposed COPs would decrease the regulatory burden on HHAs and provide them with greatly enhanced flexibility. At the same time, the proposed requirement for a program of continuous quality assessment and performance improvement would increase performance expectations for HHAs in terms of achieving needed and desired outcomes for patients and increasing patient satisfaction with services provided. This patient-centered, outcome oriented change in approach to the regulation will also likely fundamentally change our approach to the survey process. For example, since the proposed regulation sets performance expectations for the HHA to constantly improve, it may be possible to alter significantly, or possibly eliminate altogether the current Functional Assessment Instrument (FAI), which surveyors use to assess the outcomes of care through home visits and some record review. In an expanded review of the agency's approach to quality assessment and performance improvement, we may approach this task differently, with greater flexibility than the current FAI affords. We invite comment on this fundamental shift in our regulatory approach and on any concerns HHAs may have regarding their ability, both operationally and financially, to undertake this new approach. We are especially interested in comments that address how HCFA could improve this approach, what additional flexibility could be provided, what (if any) process requirements that are critical to patient care and safety should be added, and how well HCFA's investment in the HHA's participation in a strong continuous quality assessment and performance improvement program of their own design will achieve our stated and intended goal of improving the efficiency, effectiveness and quality of patient outcomes and satisfaction. We are especially interested in comments that address how HCFA could improve this approach, what additional flexibility could be provided, what (if any) process requirements that are critical to patient care and safety should be added, and how well HCFA's investment in the HHA's participation in a strong continuous quality assessment and performance improvement program of its own design will achieve our stated and intended goal of improving the efficiency, effectiveness, and quality of patient outcomes and satisfaction.

For the reasons given above, we certify that the proposed rule will not have a significant effect on a substantial number of small entities and that a regulatory flexibility analysis is not needed.

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

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting comment on each of these issues for the proposed information collection requirements discussed below.

The title and description of the individual information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

As indicated earlier in this preamble, the current regulations dealing with the HHA conditions of participation are contained in part 484 of the Code of Federal Regulations. The information collection requirements for this part are currently approved under OMB approval number 0983–0365 with an expiration date of May 31, 1998. Since we are proposing to revise or delete many of the information collection

requirements in the existing HHA conditions of participation, we will be seeking OMB approval for all of the information collection requirements contained in the proposed part 484, including those that are currently approved under OMB approval number 0983–0365. Many of these requirements are performed only once by each HHA (such as the development of a standard patient's right disclosure) or would normally be performed by an HHA in the normal course of responsible business practices in the absence of these requirements (such as the maintenance of patient's records) and therefore represent a minimal, if any, burden on HHAs. Following is a list of the specific information collection requirements contained in the proposed 42 CFR Part 484.

Section 484.50 Patient's Rights

This section dealing with patient's rights mirrors those information collection requirements in section 4021 of OBRA '87, which specify the rights of patients receiving services from Medicare certified HHAs. These requirements are necessary to ensure compliance with statutory responsibilities at section 1891 of the Act. Current requirements at § 484.10 that are retained in the proposed rule include:

a. A HHA must provide the patient with a written notice of the patient's rights in advance of providing care and document that it has complied with this requirement.

b. The HHA must document the existence and resolution of complaints about care furnished by the HHA that were made by the patient, the patient's family or guardian.

c. The HHA must advise the patient in advance of the disciplines that will furnish the care, the plan of care, expected outcomes, barriers to treatment, and any changes in the care to be furnished.

d. The HHA must advise the patient of the HHA's policies and procedures regarding disclosure of patient records.

e. The HHA must advise the patient of his/her liability for payment.

f. The HHA must advise the patient of the number, purpose, and hours of operation of the State home health hotline.

Burden Estimate

We foresee that the HHAs will develop a standard notice of rights that will fulfill the requirements contained in this section. The standard notice will contain a checklist to be completed by the HHA in a manner appropriate to each patient being accepted. A carbon copy of the signed notice will serve as documentation of compliance. We estimate that the completion of this form will impose a burden of approximately 3 seconds per each current HHA patient for 1 year (3 seconds × 3.4 million patients) = 2,833 hours and each new admission in succeeding years (3 seconds × 800,000 (approximate admission in 1995) = 666 hours.

In the rare circumstances to which paragraph (b) applies, it is already common practice to have this information retained in the HHA's record. Therefore, this requirement imposes no burden.

Section 484.55 Comprehensive Assessment

This new section on comprehensive assessment of the patient would require HHAs to provide each patient with a comprehensive assessment (including drug regimen review) of his or her needs which would be used to develop expectations for treatment. We are proposing specific timeframes for the initial assessment visit and completion of the assessment of the patient because we believe that these requirements are predictive of good patient care and safety and as well as the prevention of harm to the patient. As many HHAs are already performing a standardized patient assessment within their own internal policies, we believe that these timeframes pose little or no burden since they would in all likelihood be performed in the absence of regulations. In addition, since HHAs already routinely obtain assessment information from patients upon initiation of care and on an ongoing basis during treatment, we believe this new requirement would not place an information collection or paperwork burden on HHAs. The proposed assessment timeframes serve as a strong performance expectation for HHAs.

It is important to note that this proposed rule does not include the requirement that HHAs participate in an external quality improvement process incorporating the core standard assessment data set. As discussed above, HCFA is proposing to require use of a core standard assessment data set, as discussed elsewhere in today's issue of the Federal Register. Reporting requirements associated with that proposal are discussed separately in that Federal Register notice.

Section 484.60 Care Planning and Coordination of Services

This new section reflects an interdisciplinary, coordinated approach to home health care delivery. The proposed new care planning and coordination of services section sets forth the requirement that each patient's written plan of care specifies the care and services necessary to meet the patient specific needs identified in the comprehensive assessment and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. This new section incorporates several of the existing requirements under current § 484.18. Section 484.18 consists of longstanding requirements which implement statutory provisions found in sections 1835 and 1814 of the Act, as well as section 1891(a) as amended by OBRA '87 for non-Medicare patients. In addition, HCFA Forms 485–488 are currently approved under OMB No. 0938–0357.

Burden Estimate

We believe that these requirements are commonly accepted as good medical practice. Therefore, they would impose little or no burden on HHAs as they would in all likelihood be performed even in the absence of these regulations. The only anticipated burden associated with this requirement concerns the possible establishment and periodic review of plans of care by doctors of osteopathy or podiatry. We estimate that this will affect approximately 3 percent of home health patients, resulting in a burden of 24,000 × 5 minutes = 2,000 hours for new admissions and 102,000 × 3 minutes = 5,100 hours for existing patients.

Section 484.65 Quality Assessment and Performance Improvement

This new section requires the HHA to develop, implement, maintain and evaluate an effective, data driven quality assessment and performance improvement program. Current requirements for HHAs do not provide for the operation of an internal quality assessment and performance improvement program, whereby the HHA examines its methods and practices of providing care, identifies the opportunities to improve its performance and then takes actions that result in higher quality of care for HHA patients. We have not prescribed the structures and methods for implementing this requirement and have focused the condition toward the expected results of the program. This provides flexibility to the HHA, as it is free to develop a creative program that meets the HHA's needs and reflects the scope of its services. This new provision would replace the current conditions at § 484.16 Group of professional

personnel and § 484.52 Evaluation of an agency's program.

Burden Estimate

We believe the writing of internal policies governing the HHA's approach to the development, implementation, maintenance, and evaluation of the quality assessment and performance improvement program will impose a burden. We want HHAs to utilize maximum flexibility in their approach to quality assessment and performance improvement programs. Flexibility is provided to HHAs to ensure that each program reflects the scope of its services. We believe that this requirement provides a performance expectation that HHAs will set their own goals and use the information to continuously strive to improve their performance over time. Given the variability across HHAs and the flexibility provided, we believe that the burden associated with writing the internal policies governing the approach to the development, implementation, and evaluation of the quality assessment and performance improvement program will reflect that diversity. Given the variability, it is difficult to predict an exact burden. We want to provide flexibility and do not want to be prescriptive in defining hourly parameters. However, we need to quantify the burden associated with this requirement. We estimate that the burden associated with writing the internal policies would be an average of 4 hours annually (although this figure may be much lower, since many HHAs have existing internal quality improvement programs). We estimate on average:

4 hours × 9,058 (total number of Medicare-certified HHAs in calendar year 1995) = 36,232 hours

4 hours × 1,145 (total number of newly certified HHAs in calendar year 1995) = 4,580 hours

Section 484.70 Skilled Professional Services

This new section would require skilled professionals who provide services to HHA patients as employees or under arrangement to participate in all aspects of care, including an ongoing interdisciplinary evaluation and development of the plan of care and be actively involved in the HHA's quality assessment and performance improvement program. In place of current provisions governing skilled nursing services § 484.30, therapy services § 484.32, and medical social services § 484.34 we would consolidate all new requirements under one new condition, Skilled professional services. We are broadly describing the expectations of skilled professionals who participate in the interdisciplinary approach to home health care delivery. The current requirements are commonly accepted as good medical practice and therefore impose little or no burden on the HHAs as they would in all likelihood be performed in the absence of Federal regulations.

We are proposing a new standard that the HHA must ensure that a majority of at least 50 percent of total skilled professional services are routinely provided directly. We are proposing to phase in this new approach over three years. In the first year, HHAs would be required to ensure at least 30 percent of the total skilled professional services are provided directly. In the second year, HHAs would be required to ensure at least 40 percent of the total skilled professional services are provided directly. In the third year, we would require at least 50 percent of the total skilled professional services are provided directly. The requirement that the HHAs determine compliance with this standard imposes a one-time annual burden of 2 minutes on existing HHAs and any newly certified HHAs to determine the total number of skilled professional visits that are provided directly. HHAs currently report employment data (full-time equivalents) on their cost reports (freestanding HHAs: Form HCFA–1728–S–3 currently approved under OMB number 0938–0022 and hospital based HHAs: Form HCFA–2552–H–S–4 currently approved under OMB number 0938–0050).

Burden Estimate

2 minutes × 9,058 existing HHAs = 302 hours

2 minutes × 1,145 newly certified HHAs = 39 hours

Section 484.75 Home Health Aide Services

This section governs the requirements for home health aide services. Many requirements in this section directly mirror the statutory requirements of section 4021 of OBRA '87. The requirements are longstanding and implement sections 1891 and 1861 of the Act: (1) The HHA must maintain sufficient documentation to demonstrate that training requirements are met; (2) The HHA's competency evaluation must address all required subjects; (3) The HHA must maintain documentation that demonstrates that requirements of competency evaluation are met; and (4) A registered nurse or appropriate skilled professional prepares written instructions for care to be provided by the home health aide.

In addition, this section requires the HHA to conduct criminal background checks of home health aides as a condition of employment.

Burden Estimate

The first requirement imposes no additional burden as this documentation will be included in personnel records. The second requirement will impose a one time burden (to develop competency evaluation) on all existing agencies and any newly certified agencies in the future. We estimate that it will require approximately 2 hours for each HHA to formulate this evaluation (although this figure may be much lower in practice if agencies chose to adopt standardized evaluation forms).

2 hours × 9,058 existing HHAs = 18,116 hours annually

2 hours × 1,145 newly certified HHAs each year = 2,290 hours annually

Maintaining documentation that demonstrates that each aide has met the evaluation requirements imposes no burden as this information will be retained in personnel records. The third requirement imposes a burden of approximately 3 minutes for each newly admitted patient that receives aide care, or 3 minutes × 260,000 (estimated number of patients receiving aide care) = 13,000 hours.

We are not able at this time to estimate the burden associated with the requirement that the HHA conduct criminal background checks of home health aides. We solicit comments on whether HHAs believe this requirement will impose an additional burden on them and what that burden would be.

Section 484.100 Compliance With Federal, State, and Local Laws

Under this section, the HHA must disclose to the State Survey Agency at the time of the HHA's initial request for certification the name and address of all persons with an ownership or control interest in the HHA, the name and address of all officers, directors, agents, and managers of the HHA, as well as the name and address of the corporation or association responsible for the management of the HHA and the chief executive and chairman of that corporation or association. This requirement directly implements section 4021 of OBRA '87.

Burden Estimate

This provision expands upon a similar requirement currently contained in § 405.1221(b). It imposes a minimal burden of adding the necessary additional information to the current disclosure used by existing HHAs and

the creation of a new disclosure of ownership for newly certified HHAs. The burden for supplementing the existing disclosure with the required additional information is estimated at—

5 minutes × 9,058 (total number of Medicare certified HHAs in 1995) = 755 hours

5 minutes × 1,145 (number of newly certified HHAs in 1995) = 95 hours

Section 484.105 Organization and Administration of Services

The revised organization and administration of services condition simplifies the structure of the current requirements and provides flexibility to the HHA by replacing the current focus on organizational structures with new performance expectations for the administration of the HHA as an organizational entity. In the proposed condition we revise the current standard on governing body § 484.14(b), retain with only minor editorial changes the current standard on services furnished § 484.12(a), retain with only minor editorial changes, the requirements with respect to services furnished under arrangements under existing § 484.14(h), delete the current standards on the administrator § 484.14(c), delete the current standards on supervising physician or registered nurse § 484.14(d), delete the current standards on personnel policies § 484.14(e), delete the current standards on institutional planning § 484.14(i), relocate current condition § 484.38 under this condition and relocate the current standard on laboratory services under the compliance with Federal, State and local laws condition.

The current institutional planning requirements under § 484.14(i) impose 5,474.5 hours of burden under the current HHA conditions of participation. We are proposing to delete that requirement from the HHA conditions of participation, therefore, reducing current burden associated with the institutional planning requirements.

Section 484.110 Clinical Records

A clinical record containing pertinent past and current findings is maintained for every patient receiving home health services. Clinical records are retained for 5 years after the month the cost report to which the records is filed with the intermediary. Written procedures govern the use and removal of records and conditions for release of information. This section contains longstanding provisions which are specifically required in section 1861(o) of the Act and are necessary to the preservation of the patient's privacy and the quality of care. There is no burden associated with the retention of patient records as this merely entails the filing of a copy of the record.

Total Burden Estimate

The total annual hourly burden for the information collection requirements under the revisions proposed to the HHA conditions of participation is estimated to be 86,008 hours. We estimate the annual hourly burden under the revised COPs to be 8.4 hours per Medicare-certified HHA (86,008 total hours/10,203 (total number of Medicare-certified HHAs and newly certified HHAs in calendar year 1995). The total annual hourly burden for the information collection requirements under OMB approval number 0938–0365 (current HHA conditions of participation) was estimated to be 7.7 hours per Medicare-certified HHA (69,499 total hours/9,009 (total number of Medicare-certified HHAs and newly certified HHAs as of November 1994).

Again, we welcome comments on all aspects of the above material. Written comments on these information collection and recordkeeping requirements should be mailed directly to the following:

Health Care Financing Administration, Office of Financial and Human Resources, Management Planning and Analysis Staff, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850; and 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.

Any comments submitted on these collection of information requirements must be received by these two offices on or before May 9, 1997, to enable OMB to act promptly on HCFA's information collection approval request.

VI. Crosswalk Current COPs/Revised COPs

Current COPs	Revised COPs
Patient Rights 484.10:	
484.10(a)	Intact 484.50(a).
484.10(b)	Revised 484.50(b).
484.10(c)	Revised 484.50(c).
484.10(d)	Revised 484.50(d).
484.10(e)	Intact 484.50(e).
484.10(f)	Intact 484.50(f).
Compliance with Federal, State and local laws, disclosure of ownership information 484.12:	
484.12(a)	Intact with minor revisions 484.100(a).
484.12(b)	Intact 484.100(b).
484.12(c)	Incorporated into QAPI 484.65.
Organization, Services and Administration 484.14:	
484.14(a)	Revised 484.105(e).
484.14(b)	Revised 484.105(a).
484.14(c)	Revised 484.105(a).
484.14(d)	Deleted.
484.14(e)	Incorporated into QAPI 484.65.
484.14(f)	Deleted.
484.14(g)	Revised 484.60(d).
484.14(h)	Revised 484.105(d).
484.14(i)	Deleted.
484.14(j)	Intact 484.100(d).
Group of Professional Personnel 484.16	Deleted—QAPI approach 484.65.
Acceptance of patients, plan of care and medical supervision 484.18:	
484.18(a)	Revised 484.60(a).
484.18(b)	Revised 484.60(b).
484.18(c)	Revised 484.60(c) and 484.55(a).

Current COPs	Revised COPs
Skilled Nursing Services 484.30	Deleted—combined aspects 484.70.
Therapy Services 484.32	Deleted—combined aspects 484.70.
Medical Social Services 484.34	Deleted—combined aspects 484.70.
Home Health Aide Services 484.36:	
484.36(a)	Intact 484.75(b).
484.36(a)(1)(i)	Revised 484.75(b)(1)(i).
484.36(a)(1) (ii)–(xii)	Intact 484.75(b)(1) (ii)–(xii).
484.36(a)(1)(xiii)	Revised 484.75(b)(1)(xiii).
484.36(a)(2)(i)	Intact 484.75(b)(2).
484.36(a)(2)(ii)	Revised 484.75(b)(3).
484.36(a)(3)	Revised 484.75(b)(4).
484.36(b)(1)	Revised 484.75(c)(1).
484.36(b)(2)(i)	Intact 484.75(c)(2).
484.36(b)(2)(ii)	Deleted.
484.36(b)(2)(iii)	Revised 484.75(d)(1).
484.36(b)(3)(i)	Revised 484.75 (c)(3) and (d)(2).
484.36(b)(3)(ii)	Revised 484.75(c)(4).
484.36(b)(3)(iii)	Revised 484.75(c)(2).
484.36(b)(4)(i)	Intact 484.75(c)(5).
484.36(b)(4)(ii)	Deleted.
484.36(b)(5)	Intact 484.75(c)(6).
484.36(b)(6)	Deleted.
484.36(c)	Revised 484.75(e).
484.36(d)	Revised 484.75(f).
484.36(e)	Intact 484.75(g).
Qualifying to furnish outpatient PT or Speech language pathology 484.38.	Intact 484.105(f).
Clinical Records 484.48	Revised 484.110.
Evaluation of Agency's Program 484.52	Deleted QAPI approach 484.65.
Definitions 484.2	Revised 484.2.
Personnel Qualifications 484.4	Revised Approach 484.115.

VII. 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, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

HCFA proposes to amend 42 CFR chapter IV as follows:

PART 484—CONDITIONS OF PARTICIPATION: HOME HEALTH AGENCIES

1. The authority citation for part 484 continues to read as follows:

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

2. Part 484 is revised to read as follows:

PART 484—CONDITIONS OF PARTICIPATION: HOME HEALTH AGENCIES

Subpart A—General Provisions

Sec.
484.1 Basis and scope.
484.2 Definitions.

Subpart B—Patient Care

484.50 Condition of participation: Patient rights.
484.55 Condition of participation: Comprehensive assessment of patients.
484.60 Condition of participation: Care planning and coordination of services.
484.65 Condition of participation: Quality assessment and performance improvement.
484.70 Condition of participation: Skilled professional services.
484.75 Condition of participation: Home health aide services.

Subpart C—Organizational Environment

484.100 Condition of participation: Compliance with Federal, State, and local laws.
484.105 Condition of participation: Organization and administration of services.
484.110 Condition of participation: Clinical records.
484.115 Condition of participation: Personnel qualifications for skilled professionals.

Subpart A—General Provisions

§ 484.1 Basis and scope.

(a) *Basis.* This part is based on sections 1861(o) and 1891 of the Act, which establish the conditions that an HHA must meet in order to participate in Medicare, and specify that the Secretary may impose additional requirements that are considered necessary to ensure the health and safety of patients.

(b) *Scope.* The provisions of this part serve as the basis for survey activities for the purpose of determining whether an agency meets the requirements for participation in Medicare.

§ 484.2 Definitions.

As used in this part—

Branch office means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Parent home health agency means the agency that develops and maintains administrative control of branches.

Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care that has been empirically shown to be predictive of access, care outcomes, or satisfaction.

Subpart B—Patient Care

§ 484.50 Condition of participation: Patient rights.

The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

(a) *Standard: Notice of rights.*

(1) The HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

(2) The HHA must maintain documentation showing that it has complied with the requirements of this section.

(b) *Standard: Exercise of rights and respect for property and person.*

(1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) The patient's family or guardian may exercise the patient's rights when the patient has been judged incompetent.

(3) The patient has the right to have his or her property treated with respect.

(4) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

(5) The HHA must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient or the patient's property by anyone furnishing services on behalf of the HHA, and must document both the existence of the complaint and the resolution of the complaint.

(c) *Standard: Right to be informed and to participate in planning care and treatment.*

(1) The patient has the right to be informed, in advance, about the care to be furnished, the plan of care, expected outcomes, barriers to treatment, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.

(2) The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(ii) The HHA must comply with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law.

(d) *Standard: Confidentiality of medical clinical records.* The patient has the right to confidentiality of the clinical records maintained by the HHA. The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records.

(e) *Standard: Patient liability for payment.*

(1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient. Before the plan of care is initiated, the HHA must inform the patient orally and in writing of:

(i) The extent to which payment may be expected from Medicare, Medicaid, or any other Federally funded or aided program known to the HHA;

(ii) The charges for services that will not be covered by Medicare; and

(iii) The charges that the individual may have to pay.

(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

(f) *Standard: Home health hotline.* The patient has the right to be advised of the availability of the toll-free home health hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs.

§ 484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs.

(a) *Standard: Drug regimen review.* The comprehensive assessment must include a review of the patient's drug regimen in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

(b) *Standard: Initial assessment visit.*

(1) Based on physician's orders, a registered nurse must perform an initial assessment visit to determine the immediate care and support needs of the patient. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or within 48 hours of the physician-ordered start of care date, if that is later.

(2) When rehabilitation therapy service (speech language pathology services, physical therapy, or occupational therapy) is the only service ordered by the physician, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

(c) *Standard: Timeframe for completion of the comprehensive assessment.* The HHA must complete the comprehensive assessment in a timely manner consistent with the patient's immediate needs, but no later than 5 working days after the start of care.

(d) *Standard: Update of comprehensive assessment.* The comprehensive assessment must include information on the patient's progress toward clinical outcomes, and must be updated and revised—

(1) As frequently as the condition of the patient requires, but not less frequently than every 62 days beginning with the start of care date;

(2) When the plan of care is revised for physician review; and

(3) At discharge.

§ 484.60 Condition of participation: Care planning and coordination of services.

Each patient must have a written plan of care that must specify the care and services necessary to meet the patient-specific needs identified by the physician or in the comprehensive assessment, or both, and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the

agency in the patient's place of residence.

(a) *Standard: Plan of care.* All home health services furnished to patients must follow a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric in accordance with § 409.42 of this chapter. All patient care orders must be included in the plan of care.

(b) *Standards: Review and revision of the plan of care.*

(1) The plan of care must be reviewed and revised by the physician and the HHA as frequently as the patient's condition requires, but no less frequently than once every 62 days, beginning with the date of start of care. The HHA must promptly alert the physician to any changes in the patient's condition that suggest a need to alter the plan of care or that suggest that measurable outcomes are not being achieved.

(2) A revised plan of care must include current information from the patient's comprehensive assessment and information concerning the patient's progress toward outcomes specified in the plan of care.

(c) *Standard: Conformance with physician orders.*

(1) Services and treatments must be administered by agency staff only as ordered by the physician.

(2) Oral orders must be accepted only by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies.

(3) When services are provided on the basis of a physician's oral orders, a registered nurse or qualified therapist responsible for furnishing or supervising the ordered services must put the orders in writing and sign and date the orders with the date of receipt. Oral orders must also be countersigned and dated by the physician.

(d) *Standard: Coordination of care.*

(l) The HHA must maintain a system of communication and integration of services, whether provided directly or under arrangement, that ensures the identification of patient needs and barriers to care, the ongoing liaison of all disciplines providing care, and the contact of the physician for relevant medical issues.

(2) The HHA identifies the level of coordination necessary to deliver care to the patient and involves the patient and care giver in coordination of care efforts.

§ 484.65 Condition of participation: Quality assessment and performance improvement.

The HHA must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program. The program must reflect the complexity of the HHA's organization and services (including those services provided directly or under arrangement). The HHA must take actions that result in improvements in the HHA's performance across the spectrum of care.

(a) *Standard: Components of quality assessment and performance improvement program.* The HHA's quality assessment and performance improvement program must include, but not be limited to, the use of objective measures to demonstrate improved performance with regard to:

(1) Quality indicator data (derived from patient assessments) to determine if individual and aggregate measurable outcomes are achieved compared to a specified previous time period.

(2) Current clinical practice guidelines and professional practice standards applicable to home care.

(3) Utilization data, as appropriate (for example, numbers of staff, types of visits, hours of services, etc.).

(4) Patient satisfaction measures.

(5) Effectiveness and safety of services (including complex high technology services, if provided), including competency of clinical staff, promptness of service delivery, and whether patients are achieving treatment goals and measurable outcomes.

(b) *Standard: Monitoring performance improvement.* The HHA must take actions that result in performance improvements and must track performance to assure that improvements are sustained over time.

(c) *Standard: Prioritizing improvement activities.* The HHA must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes. The HHA must immediately correct any identified problems that directly or potentially threaten the health and safety of patients.

(d) *Standard: External quality assessment and performance improvement program.* The HHA must meet periodic external quality assessment and performance improvement reporting requirements as specified by HCFA.

(e) *Standard: Infection control.* The HHA must maintain an effective infection control program in accordance with the policies and procedures of the HHA and Federal and State requirements.

§ 484.70 Condition of participation: Skilled professional services.

Skilled professionals who provide services to HHA patients directly or under arrangement must participate in all aspects of care, including an ongoing multidisciplinary evaluation and development of the plan of care, and be actively involved in the HHA's quality assessment and performance improvement program. For purposes of this section, skilled professional services include skilled nursing services, physical therapy, speech language pathology services, and occupational therapy as specified in § 409.44, and medical social worker and home health aide services as specified in § 409.45.

(a) *Standard: Services of skilled professionals.* Skilled professional services are authorized, delivered, and supervised (that is, given authoritative procedural guidance) only by health care professionals who meet the appropriate qualifications specified under § 484.115 and who practice under the HHA's policies and procedures.

(b) *Standard: Provision of services.* The HHA must ensure that a majority, at least 50 percent, of total skilled professional services are routinely provided directly by the HHA. An HHA may provide other skilled professional visits under arrangement as needed.

§ 484.75 Condition of participation: Home health aide services.

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

(a) *Standard: Home health aide qualifications.* A qualified home health aide is a person who—

(1) Has successfully completed a State-established or other training program that meets the requirements of paragraph (b) of this section and a competency evaluation program or State licensure program that meets the requirements of paragraph (c) of this section, or a competency evaluation program or State licensure program that meets the requirements of paragraph (c) of this section; or has completed a nurse aide training or competency evaluation program approved by the State as meeting the requirements of §§ 483.151 through 483.154 of this chapter and is currently listed in good standing on the State nurse aide registry;

(2) Under paragraph (a)(1) of this section, an individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a

continuous period of 24 consecutive months during none of which the individual furnished services described in § 409.40 of this chapter for compensation. If a 24-month lapse in furnishing services has occurred, the individual must complete another training and competency evaluation program or a competency evaluation program, as specified in paragraph (a)(1) of this section, before providing services.

(b) *Standard: Home health aide training.*—(l) *Content and duration of training.* The home health aide training must include classroom and supervised practical training that totals at least 75 hours. A minimum of 16 hours of classroom training must precede a minimum of l6 hours of supervised practical training. ''Supervised practical training'' means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse. The home health aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and make brief and accurate oral and written presentations to patients, care givers, and other HHA staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and knowledge of emergency procedures.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in personal hygiene and grooming that include—

(A) Bed bath.

(B) Sponge, tub, or shower bath.

(C) Hair shampoo (sink, tub, or bed).

(D) Nail and skin care.

(E) Oral hygiene.

(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

(xiii) Any other task that the HHA may choose to have the home health aide perform. The HHA is responsible for training the home health aide, as needed, for skills not covered in this basic checklist.

(2) *Conduct of training: Eligible training organizations.* A home health aide training program may be offered by any organization except an HHA that, within the previous 2 years, has been found——

(i) Out of compliance with the requirements of paragraphs (b) or (c) of this section;

(ii) To permit an individual that does not meet the definition of ''home health aide'' as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers);

(iii) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of HCFA or the State);

(iv) Has been assessed a civil monetary penalty of not less than $5,000 as an intermediate sanction;

(v) Has been found to have compliance deficiencies that endanger the health and safety of the HHA's patients and has had a temporary management appointed to oversee the management of the HHA;

(vi) Has had all or part of its Medicare payments suspended; or

(vii) Under any Federal or State law

(A) Has had its participation in the Medicare program terminated;

(B) Has been assessed a penalty of not less than $5,000 for deficiencies in Federal or State standards for HHAs;

(C) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;

(D) Had operated under a temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(E) Was closed or had its residents transferred by the State.

(3) *Conduct of training: Qualifications for instructors.* The training of home health aides must be performed by or under the supervision of a registered nurse. Other individuals may be used to provide instruction under the general supervision of the registered nurse.

(4) *Documentation of training.* The HHA must maintain documentation of the aide's successful completion of a home health aide training and competency evaluation program or competency evaluation program or State approved nurse aide training and competency evaluation to demonstrate that the requirements of this standard are met.

(c) *Standard: Competency evaluation.* An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.

(l) The HHA must ensure that all individuals who furnish home health aide services to patients meet the competency evaluation requirements of this section. Personal care aides who exclusively provide personal care services to Medicaid patients under a State Medicaid personal care benefit must meet the requirements specified in paragraph (g) of this section.

(2) The competency evaluation must address each of the subjects listed in paragraphs (b)(l)(ii) through (xiii) of this section. Subject areas specified under paragraphs (b)(l)(iii), (ix), (x), and (xi) of this section must be evaluated by observing the aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of the home health aide with a patient.

(3) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (b)(2) of this section.

(4) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

(5) A home health aide is not considered competent in any task for which he or she is evaluated as ''unsatisfactory.'' The aide must not perform that task without direct supervision by a licensed nurse until after he or she received training in the task for which he or she was evaluated as ''unsatisfactory'' and passes a subsequent evaluation with ''satisfactory.''

(6) The HHA must maintain documentation that demonstrates the requirements of this standard are met.

(d) *Standard: Inservice training.*

(l) The home health aide must receive at least l2 hours of inservice training in a l2-month period. During the first l2 months of employment, hours may be prorated based on the date of hire. The in-service training may occur while the aide is furnishing care to a patient.

(2) Inservice training may be offered by any organization except one that is excluded under paragraph (b)(2) of this section.

(3) The inservice training must be supervised by a registered nurse.

(e) *Standard: Home health aide assignments.*

(l) The home health aide is assigned to a specific patient by the registered nurse. Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate skilled professional (that is, physical therapist, speech language pathologist, or occupational therapist) who is responsible for the supervision of the home health aide as specified under paragraph (f) of this section.

(2) The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law. The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered.

(3) Home health aides must report changes in the patient's medical, nursing, rehabilitative, and social needs to the registered nurse or other appropriate skilled professional, and complete appropriate records in compliance with the HHA policies and procedures.

(f) *Supervision.*

(l) If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit required under paragraph (f)(2) of this section. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy, occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate skilled professional. Documentation of the supervisory visit must be made in the patient's record.

(2) The registered nurse (or another professional described in paragraph (f)(l) of this section) must make an onsite visit to the patient's home no less frequently than every 2 weeks.

(3) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech-language pathology services, the registered nurse must make a supervisory visit to the patient's home no less frequently than every 62 days. In these cases, each supervisory visit must occur while the home health aide is providing patient care to ensure that the aide is properly caring for the patient.

(4) If home health aide services are provided by an individual who is not employed directly by the HHA, the services of the home health aide must be provided under arrangement as defined in section l86l(w)(l) of the Act (42 U.S.C. 1395 x(w)). If the HHA chooses to provide home health aide services under arrangement with another organization, the HHA's responsibilities include, but are not limited to—

(i) Ensuring the overall quality of care provided by the aide;

(ii) Supervision of the aide's services as described in paragraphs (f)(l) and (2) of this section; and

(iii) Ensuring that home health aides providing services under arrangement have met the training or competency evaluation requirements, or both, of this condition.

(g) *Standard: Medicaid personal care aide services—Medicaid personal care benefit.*

(l) *Applicability.* This paragraph applies to individuals who are employed by HHAs exclusively to furnish personal care attendant services under a Medicaid personal care benefit.

(2) *Rule.* An individual may furnish personal care services, as defined in § 440.170 of this chapter, on behalf of an HHA after the individual has been found competent by the State to furnish those services for which a competency evaluation is required by this section and which the individual is required to perform. The individual need not be determined competent in those services listed in this section that the individual is not required to furnish.

Subpart C—Organizational Environment

§ 484.100 Condition of participation: Compliance with Federal, State, and local laws.

(a) *Standard: Compliance with Federal, State, and local laws and regulations.* The HHA and its staff must operate and furnish services in compliance with all Federal, State, and local laws and regulations applicable to HHAs. If a State has established licensing requirements for HHAs, all HHAs must be approved by the State licensing authority as meeting those requirements whether or not they are required to be licensed by the State.

(b) *Standard: Disclosure of ownership and management information.* The HHA must comply with the requirements of part 420, subpart C of this chapter. The HHA also must disclose the following information to the State survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(l) The name and address of all persons with an ownership or control interest in the HHA as defined in §§ 420.20l, 420.202, and 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in §§ 420.20l, 420.202, and 420.206 of this chapter.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(c) *Standard: Licensing.* The HHA and its branches must be licensed in accordance with State licensure laws, if applicable, prior to providing Medicare reimbursed services.

(d) *Standard: Laboratory services.*

(l) If the HHA engaged in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for the purpose by the Food and Drug Administration, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

§ 484.105 Condition of participation: Organization and administration of services.

The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity for each patient regarding medical, nursing, and rehabilitative needs as indicated by the plan of care.

(a) *Standard: Governing body.* A governing body (or designated persons so functioning) must assume full legal authority and responsibility for the management and provision of all home health services, fiscal operations, quality assessment and performance improvement, and appoints a qualified administrator who is responsible for the day-to-day operation designated persons to carry out these functions.

(b) *Standard: Primary HHA.* The HHA that accepts the patient becomes the primary HHA and assumes responsibility for the interdisciplinary coordination and provision of services ordered on the patient's plan of care, and continuity of care, whether the services are provided directly or under arrangement.

(c) *Standard: Parent-branch relationship.*

(1) The parent home health agency provides direct support and administrative control of its branches.

(2) The branch office is located sufficiently close to the parent home health agency to effectively share administration, supervision, and services in a manner that renders it unnecessary for the branch separately to meet the conditions of participation as an HHA.

(d) *Standard: Services under arrangement.*

(1) The HHA must ensure that all arranged services provided by other entities or individuals meet the requirements of this part and the requirements of section 1861(w) of the Act (42 U.S.C. 1395x(w)).

(2) An HHA that has a written agreement with another agency or organization to furnish services to the HHA's patients maintains overall responsibility for those services.

(e) *Standard: Services furnished.* Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the qualifying services directly, but may provide the second qualifying service and additional services under arrangement with another agency or organization.

(f) *Standard: Physical therapy or speech-language pathology services.* An HHA that furnishes outpatient physical therapy or speech language pathology services must meet all of the applicable conditions of this part and the additional health and safety requirements set forth in §§ 485.711, 485.713, 485.715, 485.719. 485.723, and 485.727 of this chapter.

§ 484.110 Condition of participation: Clinical records.

A clinical record containing past and current findings is maintained for every patient who is accepted by the HHA for home health service. Information contained in the clinical record must be accurate, available to the patient's physician and appropriate HHA staff, and may be maintained electronically.

(a) *Standard: Contents of clinical record.* The record must include:

(1) The patient's current comprehensive assessment, clinical/progress notes, and plan of care;

(2) Responses to medications, treatments and services;

(3) A description of measurable outcomes relative to goals in the patient's plan of care that have been achieved; and

(4) A discharge summary that is available to physicians upon request.

(b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated. Authentication must include signatures or a secured computer entry by a unique identifier of a primary author who has reviewed and approved the entry.

(c) *Standard: Retention of records.* Clinical records must be retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. The HHA's internal policies must provide for retention of the clinical records even if the HHA discontinues operations. If a patient is transferred to another health facility, a copy of the records or discharge summary must be sent with the patient.

(d) *Standard: Protection of records.* Patient information and the record must be safeguarded against loss or unauthorized use.

§ 484.115 Personnel qualifications for skilled professionals.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, all skilled professionals who provide services directly by or under arrangements with an HHA must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which he or she performs the functions or actions, and must act only within the scope of his or her State license or State certification or registration.

(b) *Exception for Federally defined qualifications.* The following Federally defined qualifications must be met:

(1) For physicians, the qualifications and conditions as defined in section 1861(r) of the Act and implemented at § 410.20 of this chapter).

(2) For speech language pathologists, the qualifications specified in section 1861(ll)(1) of the Act.

(3) For home health aides, the qualifications required by section 1891(a)(3) of the Act and implemented at § 484.75.

(c) *Exceptions when no State licensing laws or State certification or registration requirements exist.* If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met:

(1) The administrator of a home health agency must—

(i) Be a licensed physician; or

(ii) Hold an undergraduate degree and—

(A) Be a registered nurse; or

(B) Have education and experience in health service administration, with at least one year of supervisory or administrative experience in home health care or a related health care program, and in financial management.

(2) *An occupational therapist must*—

(i) Be a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(ii) Be eligible for the National Registration Examination of the American Occupational Therapy Association; or

(iii) Have 2 years of appropriate experience as an occupational therapist, and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

(3) *An occupational therapy assistant must*—

(i) Meet the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or

(ii) Have 2 years of appropriate experience as an occupational therapy assistant, and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

(4) *Physical therapist. A person who*—

(i) Has graduated from a physical therapy curriculum approved by—

(A) The American Physical Therapy Association;

(B) The Committee on Allied Health Education and Accreditation of the American Medical Association; or

(C) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or

(ii) Prior to January 1, 1966—

(A) Was admitted to membership by the American Physical Therapy Association;

(B) Was admitted to registration by the American Registry of Physical Therapist; or

(C) Has graduated from a physical therapy curriculum in a 4-year college

or university approved by a State department of education; or

(iii) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(iv) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(v) If trained outside the United States—

(A) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy;

(B) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy,

(5) *Physical therapist assistant.* A person who—

(i) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

(ii) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

(6) *Public health nurse.* A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content approved by the National League for Nursing for public health nursing preparation.

(7) *Registered nurse.* A graduate of a school of professional nursing.

(8) *Social work assistant.* A person who—

(i) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(ii) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

(9) *Social worker.* A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

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

Dated: July 15, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: August 16, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 97–5316 Filed 3–5–97; 9:45 am]

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42 CFR Part 484

[HSQ–238–P]

RIN 0938–AH74

Medicare and Medicaid Programs: Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would add additional requirements to the proposed revision to the conditions of participation for home health agencies (HHAs) which also appear in this issue of the Federal Register. Specifically, this proposed rule would require that HHAs use a standard core assessment data set, the ''Outcomes and Assessment Information Set'' (OASIS), when evaluating adult, non-maternity patients.

This proposed rule is an integral part of the Administration's 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 that focuses on stimulating measurable improved outcomes of care and patient satisfaction in the Medicare and Medicaid home health benefit while at the same time reducing burdens on providers.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on June 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: HSQ–238-P, P.O. Box 7518, 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 C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments may also be submitted electronically to the following e-mail address: hsq238phcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated into the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at the Independence Avenue address below.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ–238–P. Comments received timely will be available for pubic 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, D.C., on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone (202) 690–7890).

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

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 37194, Pittsburgh, PA 15250–7954.