DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 416, 482, 485, and 489

[HCFA–3745–P]

RIN 0938–AG79

Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The revised requirements focus on patient care and the outcomes of that care, reflect a cross-functional view of patient treatment, encourage flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are necessary to reflect advances in patient care delivery and quality assessment practices since the requirements were last revised in 1986. They are also 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. In addition, in an effort to increase the number of organ donations, we are proposing changes in the interaction between hospitals and organ procurement organizations. The proposed rule also would specify that HCFA may terminate the participation agreement of a hospital, skilled nursing facility, home health agency, or other provider if the provider refuses to allow access to its facilities, or examination of its operations or records, by or on behalf of HCFA, as necessary to verify that it is complying with the Medicare law and regulations and the terms of its provider agreement.

DATES: Comments will be considered if received at the appropriate address, as provided below, no later than 5 p.m. on February 17, 1998.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–3745–P, P.O. Box 7517, Baltimore, MD 21207–0517.

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, Central Building, 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 HCFA–3745–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, 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 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) 512–1530 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: Frank Emerson, (410) 786–4656, Doris Jackson, RN, (410) 786–0095, Rachael Weinstein, RN, (410) 786–6775.

SUPPLEMENTARY INFORMATION:

I. Introduction

As part of the President's and Vice President's regulatory reform initiative, the Health Care Financing Administration (HCFA) is committed to changing current regulations that focus largely on requirements for measuring procedural standards. One of HCFA's key initiatives in Reinventing Government (REGO) is to revise many of its conditions of participation (COPs) to focus on outcomes of care and to eliminate unnecessary procedural requirements. HCFA is working in partnership with the rest of the health care community to institute better, more commonsense ways of operating. On March 10, 1997 we published a proposed rule (62 FR 11004) that includes revisions for COPs for HHAs. Within the coming year, HCFA plans to propose revisions to the COPs for hospitals and end stage renal disease (ESRD) facilities and also to mount additional research in the area of ESRD to provide the basis for future changes.

What these efforts have in common is—

1. Reinventing Government (REGO) Initiative

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

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

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

2. Transitional Framework

The transitional framework for each set of COPs—

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

3. Structure

The basic structure of all of the COP follows the Joint Commission on Accreditation of Healthcare Organizations' (JCAHOs) ''Agenda for Change.'' This structure involves reducing the number of conditions; focusing on comprehensive assessment and patient outcomes; and deleting,

where possible, process requirements that are not specifically mandated by the statute or believed likely to produce outcomes vital to the protection of patient safety.

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

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

Each of the sets of COP requirements are tailored to specific statutory requirements, the historical context of the provider type, and the unique form of care delivery and patient case mix.

4. Professional Input

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

II. Background

A. Statutory Basis

Sections 1861(e) (1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established the requirements that a hospital must meet to participate in Medicare in regulations at 42 CFR Part 482, Conditions of Participation for Hospitals.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii), hospitals generally are required to meet the Medicare conditions of participation in order to participate in Medicaid.

The purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals. Surveyors use the conditions to determine whether a hospital qualifies for a provider agreement under Medicare and Medicaid. Under section 1865 of the Act and 42 CFR 488.5 of the regulations, hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are not routinely surveyed for compliance with the conditions but are deemed to meet most of the requirements in the hospital conditions of participation based on their accreditation. (See 42 CFR part 488, Survey and Certification Procedures.)

B. Why Revise the Conditions of Participation

The current conditions of participation (COPs) were adopted in 1986 and for the most part have not been revised since that time. They are organized according to the types of services a hospital may offer, and include specific, process-oriented requirements for each hospital service or department. Since the current conditions were developed, however, significant innovations in hospital patient care delivery systems and quality assessment practices have emerged, as evidenced by the JCAHO's recent revision of its accreditation standards and redesign of its survey process.

Moreover, as discussed above, the revision of the hospital 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. The existing hospital 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 no longer represents the best available method for assessing and improving hospital quality of care. Thus, we have concluded that significant revisions to the hospital conditions of participation are essential.

C. Transforming the Hospital Conditions of Participation

We are committed to working with affected parties to implement revised COPs that impose the minimum burden on hospitals and allow hospitals maximum flexibility in meeting the Federal requirements necessary to fulfill our quality of care responsibilities. Thus, in developing revised conditions, we have solicited suggestions from organizations representing hospitals, practitioners, patients, and States, including distributing an informal, preliminary draft of the proposed hospital COPs to approximately 70 groups for comment. We have used those comments in the development of the revised COPs contained in this proposed rule.

The fundamental principles that guided the development of the proposed COPs were the need to:

- Focus on the continuous, integrated care process that a patient experiences across all aspects of hospital services, centered around patient assessment, care planning, service delivery, and quality assessment and performance improvement.
- Adopt a patient-centered approach that recognizes the contributions of various skilled professionals and how they interact with each other to meet the patient's needs. 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 an overarching requirement that each hospital participate in its own quality assessment and performance improvement program.
- Facilitate flexibility in how a hospital meets our performance expectations, and eliminate process requirements unless there is consensus or evidence that they are predictive of desired outcomes for patients.
- Require that patient rights are assured.

Based on these principles, we are proposing new hospital conditions of participation that revise or eliminate many existing requirements and incorporate critical requirements into four ''core conditions.'' These four COPs—Patient Rights; Patient Admission, Assessment, and Plan of Care; Patient Care; 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 hospital as an organization, and the impact of the treatment furnished by the hospital on the health status of its patients. The first, Patient Rights, emphasizes a hospital's responsibility to respect and promote the rights of each hospital patient. The second proposed core COP, Patient Admission, Assessment, and Plan of Care, reflects the critical nature of a comprehensive assessment and a resulting plan of care in determining appropriate treatments and accomplishing desired health outcomes. It also would incorporate the need for a coordinated, team approach to planning care. The third proposed core COP, Patient Care, focuses on the actual delivery of care. Finally, the proposed Quality Assessment and Performance Improvement COP would charge each hospital 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 patients.

In the revised COPs, we are proposing to include process-oriented requirements only where we believe they remain highly predictive of ensuring desired outcomes or are necessary to deter or prevent fraud and abuse (for example, the requirement for error-free medication administration under the pharmaceutical services COP). 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 as part of the hospital's overall quality assessment and performance improvement responsibilities. For example, we would no longer specify that a hospital must make available to medical staff a written description of its laboratory services. However, we would continue to require that a hospital provide laboratory services needed to meet its patients' needs and would specify under the proposed quality assessment and performance improvement condition that a hospital's assessment and performance improvement program must include evaluation of its diagnostic services. The practical effect of this approach would be to stimulate the hospital 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 their patients. The proposed COPs invest hospitals 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 focus more resources on joining with hospitals (in this case, principally non-accredited hospitals) in partnerships for improvement. It should result in fewer compliance surveys and the reduced need to threaten or take adverse actions that could jeopardize a hospital's reputation, financial viability, 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 hospital's capacity to provide needed care and services to patients. Under the current regulations, termination actions are initiated based on the evidence found during the survey. We foresee no changes in that regard in applying the new COPs.

Thus, as with the current COPs, the enforceability of the proposed COPs will be rooted in the evidence found during the onsite survey when poor performance is identified and corrective action is not taken. We believe that if there is a need to seek a provider agreement termination based on the proposed COP, although a hospital may argue that its performance met the regulatory standards, HCFA will be successful at arguing that based on the evidence found during a survey the requirements of the regulation were not met. In fact, we believe the enforceability is strengthened by standards that establish outcome-oriented performance expectations. When poor performance is documented from the evidence found during a survey and compared to the performance expectations embodied in these patient-centered, outcome-oriented COPs, we believe the contrast between the poor performance identified and the performance expectation of the COP will be clear.

We recognize that an important part of the successful implementation of these proposed regulations will depend on how effectively State and Federal surveyors are able to learn and internalize this patient-centered, outcome-oriented approach and incorporate it into the survey process. The proposed approach embodied in these regulations, in fact, parallels the approach that we have taken in survey and certification, beginning as early as 1985 (for intermediate care facilities for the mentally retarded) and 1986 (for 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 what the patients actually experience. For example, for nearly a decade, nursing home 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 almost exclusively on record reviews and observing care processes and organizational structures.

These proposed regulations contain two critical improvements that support and extend the change to 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 receive the care her or his assessed needs show is necessary, rather than requiring that certain services and processes be in place. Also, the addition of a strong, quality assessment and performance improvement requirement not only stimulates the provider to continuously monitor its performance and to find opportunities for improvement, it affords the surveyor the opportunity to assess how effectively the provider has pursued a continuous quality improvement agenda. All of these changes are directed toward improving outcomes of care and satisfaction for patients.

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 become available, we will be helping State survey agencies to learn how to use

these data effectively to target scarce survey resources and to identify and implement opportunities for improvement (e.g., reduction in falls or in nosocomial infection rates).

The proposed COPs are designed to decrease the regulatory burden on hospitals 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 hospitals in terms of achieving needed and desired outcomes for patients and increasing patient satisfaction with services provided. We invite public comment on this fundamental shift in our regulatory approach. We are especially interested in comments that address how HCFA could improve this approach, what additional flexibility could be provided, what process requirements are critical to patient care and safety and how well HCFA's investment in the hospital's participation in a strong continuous quality assessment and performance improvement program of their own design will achieve our intended goal of improving the efficiency, effectiveness and quality of patient outcomes and satisfaction.

D. Development of National Outcome-Based Performance Measures for Hospitals

Before proceeding to a detailed discussion of the proposed requirements, we want to touch briefly on the prospects for standard outcome-based performance measures for hospital services. As mentioned above, HCFA is committed, through its Strategic Plan, to increasing the amount and quality of information about health care to beneficiaries, providers, plans, and the public at large. The purpose of this effort is to improve the ability of:

- Beneficiaries to make informed choices about their health care;
- Providers to improve the effectiveness and efficiency of their services, improve the outcomes of care they provide, and increase beneficiary satisfaction with their services;
- Organizations such as health maintenance organizations and insurance companies to choose providers, and evaluate and improve the performance of providers with which they contract; and
- The public to know more about the availability and quality of health care services in their communities.

Through various initiatives, such as the Consumer Information Program's mammography screening initiative, HCFA is implementing its broad-based information strategy. A strong quality assessment and performance improvement (QAPI) requirement in the proposed hospital conditions of participation, as well as similar requirements in proposed HHA, hospice, and ESRD conditions, is intended to stimulate providers to develop and use a wide variety of information and data, from internal and external sources, to inform their improvement efforts. We go into more detail on this and industry efforts to implement QAPI later in the discussion on the QAPI conditions in section II.B.5 of the preamble.

We have proposed requiring that HHAS and we are contemplating requiring that ESRD facilities report certain standard core data to HCFA to serve as the basis of a national performance measures data base, which could then be used for provider improvement, consumer information and other purposes. We are able to suggest this for HHAs and ESRD facilities because extensive work has been done on performance measures in both areas. However, with hospitals the challenge is greater and sufficient similar work has not been done on hospital measures, as described later in section II.B.5 of this preamble (§ 482.25), that could produce common agreement on measures that would be acceptable for use on a national basis.

Therefore, we have decided not to include in the hospital COPs any requirement for hospitals to collect and report certain standard data items (for example, nosocomial infection rates, medication errors, reports of falls and other injuries, restraint use, various patient characteristic data elements, etc.) that could produce quality of care predictors in the future. Although we eventually intend to move in that direction in hospitals, we do not believe it is reasonable to establish any related requirements at this time, in view of the lack of any current consensus or science that could establish a reliable and valid set of measures.

However, we invite comments from the public in response to the following questions:

1. Should HCFA (either separately or in a public/private partnership of some sort) assume a leadership role in developing and implementing hospital-based performance measures that would serve as the basis of a national quality assessment and performance improvement data base?

2. If so, how should HCFA proceed to develop and implement this system?

3. If HCFA does not assume a leadership role in this area, individual hospitals invest in the development of multiple systems, and those systems are later superseded by a single required system, would the overall burden be greater than if a single system had been imposed at the outset?

4. If HCFA does not assume a leadership role in this area and individual hospitals adopt multiple systems that produce nonstandardized data, to what extent would it be difficult or impossible to use these data to make comparisons between hospitals?

5. Should HCFA require or encourage hospitals to use the standardized measures that some accredited hospitals are using? The advantage would be that hospitals using such standardized choices would not have to develop their own measures and their results could be compared to other hospitals with similar characteristics. Examples include: (1) Number of days from initial surgery to discharge for patients undergoing isolated coronary artery bypass graft procedures; and (2) time from the emergency department arrival to procedure for trauma patients undergoing specified abdominal surgical procedures.

6. Would it be appropriate for HCFA to include any ''placeholder'' language in the revised COPs concerning the eventual need for hospitals to report relevant data, or is this premature?

7. If HCFA should include placeholder language, what changes should we make to these proposed requirements to set the stage for the development and implementation of such a system?

Even without a performance measure-based national system, we expect hospitals to develop and use their own measures and other available external information to inform their own quality assessment and improvement programs, and to participate in any external quality improvement programs (such as a national program to reduce the use of inappropriate psychoactive medications in hospitals) as the Secretary may direct.

II. Provisions of the Proposed Rule

A. Overview

Under our proposal, the hospital conditions of participation would continue to be set forth in regulations under 42 CFR part 482. However, since the majority of the existing requirements in part 482 would be revised, consolidated with other requirements, or eliminated, we are proposing a complete overhaul of the organizational scheme. The most significant change would be our proposal to group together all COPs directly related to patient care in Subpart B, Patient Care Activities. Then, in Subpart C, Organizational

Environment, we would group together those organizational activities the hospital must perform to support the delivery of patient care. We believe that this proposed format would embody the patient-centered focus of our proposed changes, emphasizing the continuous, integrated care processes that a patient experiences across all aspects of the hospital environment. Also, because functions and processes for delivering patient care often require interdisciplinary teamwork involving many hospital departments and services, the proposed regulations would incorporate a functional framework for the COPs rather than maintaining a stovepipe approach that gives the appearance that patient care activities can occur in isolation.

The complete proposed new organizational format for part 482 is as follows:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

Subpart A—General Provisions

482.5 Basis and scope.
482.10 Condition of participation: Patient rights.

Subpart B—Patient Care Activities

482.15 Condition of participation: Patient admission, assessment, and plan of care.
482.20 Condition of participation: Patient care.
482.25 Condition of participation: Quality assessment and performance improvement.
482.30 Condition of participation: Diagnostic and therapeutic services or rehabilitative services.
482.35 Condition of participation: Pharmaceutical services.
482.40 Condition of participation: Nutritional services.
482.45 Condition of participation: Surgical and anesthesia services.
482.50 Condition of participation: Emergency services.
482.55 Condition of participation: Discharge planning.

Subpart C—Organizational Environment

482.110 Condition of participation: Administration of organizational environment.
482.115 Condition of participation: Infection control.
482.120 Condition of participation: Information management.
482.125 Condition of participation: Human resources.
482.130 Condition of participation: Physical environment.
482.135 Condition of participation: Life safety from fire.
482.140 Condition of participation: Blood and blood product transfusions.
482.145 Condition of participation: Potentially infectious blood and blood products.
482.150 Condition of participation: Utilization review.

Subpart D—Requirements for Specialty Hospitals

482.155 Special provisions applying to psychiatric hospitals.
482.160 Condition of participation: Special medical record requirement for psychiatric hospitals.
482.165 Condition of participation: Special staff requirements for psychiatric hospitals.
482.170 Special requirements for hospital providers of long-term care services (''swing-beds'').

We note that although we are proposing no changes to the requirements for specialty hospitals, the existing requirements would be redesignated numerically to accommodate the proposed changes to the preceding COPs.

B. Discussion of Proposed Conditions

1. Basis and Scope (§ 482.1)

We are proposing to add a new paragraph (a)(6) to the statutory basis section for part 482 that sets forth, under section 1138 of the Act, requirements for hospital protocols for organ procurement and standards for organ procurement agencies' agreements with hospitals for organ procurements. This provision will further the authority governing organ procurements.

2. Patient Rights (§ 482.10)

Under section 1861(e)(9) of the Act, an institution may be recognized by Medicare as a hospital only if, in addition to meeting the specific requirements in the preceding sections of that provision, it meets such other requirements as the Secretary finds necessary in the interest of patient health and safety. In our view, patient health and safety cannot be protected simply by avoiding obvious risk factors such as poor infection control practices or inadequate nurse staffing (as documented in recent literature on the effects of Nursing on patient outcomes such as morbidity, mortality, length of stay, and cost—see Keeler, E., *et al.*, ''Hospital Characteristics and Quality of Care,'' *JAMA* 268 (1992): 1709–1714.; and Krakauer, H., *et al.*, ''Evaluation of the HCFA for the Analysis of Mortality Following Hospitalization,'' Health Services Research 27 (1992): 317–335). Patient rights dealing with freedom from physical or verbal abuse, harassment, or inappropriate restraints are examples of direct protections of patients' physical and emotional health and safety. In addition, patients' successful recoveries from illness or injury depend on many factors related to their psychological and emotional health, including their general feeling of well-being. Because of the importance of these psychological and emotional factors, we believe patient health and safety can be protected adequately only if patient care is delivered in an atmosphere of respect for the individual patient's comfort, dignity, and privacy.

This view is shared by other parties involved in the development of these conditions of participation, many of whom expressed strong support for the inclusion of specific provisions addressing patient rights. Therefore, we propose to set forth a new condition of participation that would recognize explicitly that a hospital must protect and promote certain patient rights.

The proposed condition is composed of five standards. The first proposed standard would require that a hospital inform each patient of his or her rights in advance of furnishing care. It also would require that a hospital have a grievance process and must indicate who a patient should contact if he or she desires to express a grievance. We are not proposing a specific method as to how a hospital should notify each patient of his or her rights, or establishing structural or procedural expectations about how a hospital's patient grievance process should be set up. Instead, we believe each hospital should implement a patient rights policy that reflects its specific manner of operations and minimizes administrative burden, as long as the hospital meets the underlying expectation that it informs patients about their rights and about whom to contact when patients believe these rights have been violated.

The remaining four proposed standards under the patient rights condition would establish a minimum set of required patient rights. In developing these provisions, we closely examined the regulations concerning patient rights for other provider types, such as nursing homes and HHAs. Because the nature of patient care varies among provider types, we are proposing only those patient rights that we believe are appropriate and necessary in the hospital setting. Based on the strong support from all parties involved in the development of these proposed hospital conditions, we are proposing that a patient should have the following rights:

- The right to be informed of his or her rights, to participate in the development and implementation of the individual's plan of care, and to make decisions regarding that care.

- The right to formulate advance directives and to have those directives followed.
- The right to privacy and to receive care in a safe setting.
- The right to be free from verbal or physical abuse or harassment.
- The right to confidentiality of his or her clinical records.
- The right to access information contained in his or her clinical records within a reasonable time.
- The right to be free from the use of seclusion and restraints as a means of coercion, convenience, or retaliation by staff. If seclusion or restraints are used (including psychopharmacological drugs used as restraints) they must be used in accordance with a patient's plan of care and may be used only as a last resort and in the least restrictive manner possible, to protect the patient or others from harm. Restraints must be removed or seclusion ended at the earliest possible time.

We believe these proposed patient rights are clearly necessary in the interest of patient health and safety and are for the most part self-explanatory. We note that the rights concerning advance directives are tied directly to the statute (section 1866(f) of the Act), and the hospital's responsibilities in these areas are more fully described in other sections of the regulations (see existing § 489.102). However, we believe it is appropriate to reference advance directives in the proposed patient rights section, consistent with the reference to advance directives in the patient rights sections of the existing regulations for both nursing homes and HHAs.

We considered proposing a specific time period within which a hospital would be required to provide access to requested medical records under proposed § 482.10(d)(2), but concluded that the proposed requirement that a hospital provide access to such information within a ''reasonable'' time is more feasible. If a former patient requests access to 3-year-old closed medical records, which could be in storage, a ''reasonable'' time to retrieve them likely would be longer than if the spouse (with appropriate power of attorney) of an inpatient requests to see the medical records of her or his spouse who is still in the hospital. In the former case, a ''reasonable'' time might be measured in days, whereas it could be hours in the latter example. Thus, we believe that ''reasonable'' must be defined in terms of the individual circumstances. Most important, we believe that ''reasonable'' means that the hospital will not frustrate the legitimate efforts of individuals to gain access to their own medical records and will actively seek to meet those requests as quickly as its recordkeeping system permits. If a hospital receives complaints from patients or their legal representatives about delays in gaining access to properly requested records, we would expect that the hospital would both respond quickly to resolve the complaints and consider the complaints as an opportunity for improvement as part of its quality assessment and performance improvement program. In summary, we believe that the use of the word ''reasonable'' sets the proper performance standard for the hospital without imposing an arbitrary burden, while at the same time enabling surveyors to take action if a hospital is systematically frustrating legitimate efforts to gain access to medical records. We welcome comments on the appropriateness of our decision not to propose any specific timeframe for providing access to a patient's records.

We also strongly considered expanding the proposed patient rights provisions (or establishing separate requirements) to provide further detail related to a patient's right to be free from seclusion or restraints. We recognize that the use of restraints or seclusion has the potential to produce serious consequences for a patient's health and safety, such as physical and psychological harm, loss of dignity, violation of civil rights, and even death. Thus, our expectation is that a hospital would impose restraints or seclusion only when absolutely necessary to prevent immediate injury to the patient or others and when no alternative means are sufficient to accomplish this purpose. We also expect that when restraints or seclusion are used, the plan of care should address how and when such practices are to be employed, and patients placed under restraints or in seclusion would be released as soon as they no longer pose an immediate threat of injury to themselves or others. Although we have built these expectations into the proposed patient rights provisions, the question remains whether it would be advisable to add further, more prescriptive requirements concerning the use of seclusion or restraints. One possibility would be to incorporate into the regulations a series of specific requirements governing the use of restraints and seclusion, as detailed below:

- Seclusion or restraints may only be used to the extent authorized by the signed order of a physician. Written authorization must include the date and time of the order, and the reason for seclusion or restraint. For restraint, the order must include the type of restraint(s) and the number of restraint points.
- Each order for seclusion or restraints must be in writing, must be time-limited and specify start and end times. Implementing a time-limited order does not require applying the intervention for the entire period if the patient demonstrates a reduction or change in the behavior that led to being placed in restraint or seclusion.
- A renewal order may be issued if the physician clinically assesses the patient face to face and determines that seclusion or restraint continues to be necessary to prevent injury to self or others, and there is no less restrictive method of preventing the injurious behavior.
- Orders for seclusion or restraint must never be written on a standing or as needed basis.
- Written orders for restraint and seclusion for adults must be valid for no more than 6 hours; written orders for restraint and seclusion for children and adolescents must be valid for no more than 2 hours.
- A patient in seclusion or restraint must be checked by a person trained in the use of restraints and seclusion at least every 15 minutes for comfort, body alignment, circulation, hydration, feeding, and toilet needs. A patient in seclusion or restraint must have vital signs checked a minimum of every 2 hours. Written documentation of checks must include, at a minimum, the name of the person doing the check, the date and time of the check, and the patient's condition.

For purposes of this proposed rule, we have opted not to set forth these kinds of detailed requirements in the regulations but instead to require that a hospital achieve the intended outcome that restraints or seclusion are never imposed inappropriately, without limiting a hospital's flexibility in how it meets this requirement. However, we welcome comments on the prevalence of the use of restraints and seclusion in the hospital setting and whether the above standards, or alternative requirements, are needed to ensure patient health and safety.

Subpart B—Patient Care Activities

3. Patient Admission, Assessment, and Plan of Care (§ 482.15)

The first proposed condition under proposed Subpart B, Patient Care Activities, would combine the requirements for patient admission, assessment, and care plan development in a single condition, which would be followed by a separate condition on patient care. We believe this

organization is in keeping with the patient centered orientation of these regulations and would help illustrate our view that patient assessment and planning is a prerequisite for the delivery of high quality care.

The underlying requirements of this COP would be first that a hospital ensure that each patient receives a comprehensive assessment of his or her care needs, including an initial estimate of posthospital needs, if any, and then that the hospital establish a coordinated plan for how all relevant hospital disciplines will meet those needs. A comprehensive assessment of patient care needs is critical for planning patient care and achieving desired health care outcomes. Because patient assessment activities are performed by various disciplines within the hospital setting, coordination of the information obtained during patient assessment activities is vital to assuring a well-developed plan for meeting the patient's identified care needs. Moreover, a coordinated plan for care delivery is increasingly important in a health care environment where payment incentives encourage shorter hospital stays. We note for an assessment to be truly ''comprehensive,'' it must address all of a patient's anticipated care needs; thus, we believe it is appropriate to include a reference to posthospital needs under the proposed assessment COP. The inclusion of posthospital needs in a comprehensive assessment does not constitute an added burden on hospitals but simply reflects current, accepted practice in patient assessment activities. For example, in conducting a comprehensive assessment on a 17-year-old male with no history of medical problems who will undergo surgery to repair a fractured femur resulting from a football injury, it would be appropriate to gather information on who will be available to assist the patient at home, who is available to take the patient to follow-up medical appointments, and necessary instructions for posthospital needs (e.g., crutch walking, body positioning, medication administration, etc). (We note that, in accordance with section 1861(ee) of the Act, the proposed COPs would continue to address separately the formal discharge planning procedures required to ensure that patients receive appropriate posthospital care and services. As explained in further detail later in this preamble, we are proposing to retain the existing discharge planning COP (now codified at § 482.43) and redesignate it as proposed § 482.55.)

Under the first proposed standard, ''Admission and comprehensive assessment'' (proposed § 482.15(a)), we propose to retain the current flexible requirement (at existing § 482.12(c)(2)) under which patients can be admitted to the hospital by any licensed practitioner allowed by the State to do so. Then, with respect to assessment, we would revise the requirement under existing § 482.22(c)(5) that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission. Instead, we propose to require that each patient receive a comprehensive assessment that identifies the patient's condition and care needs as well as an initial estimate of posthospital needs, if any, at the time of admission and is placed in the patient's medical record within 24 hours of admission.

We propose to provide the hospital and medical staff the flexibility to define the content and activities of the comprehensive patient assessment. We recognize that to require, for example, that every patient have an evaluation of rehabilitation potential or nutritional status, is not necessarily appropriate. The information to be included in the comprehensive assessment would be determined by the hospital based on the characteristics and needs of the specific patient. For example, when the patient's condition or symptoms indicate possible alcohol or drug abuse, an alcohol or drug abuse assessment should be performed as part of a mental status assessment. Again, the performance expectation is that a hospital would ensure that each patient's assessment is comprehensive relative to the reason the patient is in the hospital. We do not believe it is appropriate to prescribe how a hospital meets this responsibility.

We are proposing that the comprehensive assessment must be completed in a timely manner consistent with the patient's immediate needs and placed into a patient's medical record within 24 hours of admission. We believe that this proposed requirement sets a clear expectation for a close, effective relationship between assessment and care planning, a relationship that is essential to achieving desired health care outcomes. We view the maximum 24-hour timeframe for completion of the assessment as essential for adequate patient care and safety, since by definition a patient being admitted to a hospital is at a point of immediate need. The 24-hour timeframe should pose no burden for the well-managed hospital, since in all likelihood it would already be performing assessments within this timeframe for initial care planning and decision making purposes.

We are also proposing a 12-hour timeframe for placement into the patient's medical record of any assessment information collected before admission to the hospital. For example, a patient may have had a health history and physical examination completed in the physician's office before admission. Allowing a copy of a previously completed health history and physical examination to be placed in the hospital records would eliminate duplication in the creation of these records, especially if the findings during the physician office visit were the basis of the admission to the hospital. Unlike under existing regulations, which permit use of a physical examination or medical history done within 7 days of a patient's admission, the proposed requirements would not establish an arbitrary limit on the use of such information. Instead, we would require that any comprehensive assessment information recorded before admission be updated to reflect the patient's condition on admission. That is, a hospital would be expected to reassess the necessity of the patient's admission to the hospital and document, as appropriate, any changes in the patient's condition at the time of admission. We believe this requirement would reduce the hospital's information collection burden without compromising patient health and safety. Because, in such a case, the history taking and physical examination activities essentially are completed before admission, we believe that 12 hours is a reasonable timeframe for placement of that assessment information into the medical record. That is, it should take the hospital less time to update the assessment information than the proposed 24-hour timeframe for a comprehensive assessment performed after admission.

The second standard under this COP, proposed § 482.15(b)(1), would require that each patient have an initial written plan of care that meets the needs identified in the comprehensive assessment and that the plan of care must be placed in the medical record within 24 hours of admission. Thus, each patient would be assured of having a comprehensive assessment and an initial care plan within 24 hours of admission to the hospital. We believe that this 24-hour timeframe for care planning is both reasonable and necessary, given the continuing decreases in average lengths of stay in hospitals.

Presently, responsibility for a patient's plan of care is addressed under various separate COPs, including governing body, medical staff, and nursing services. In place of this

fragmented approach, we would focus on the need for coordination in care planning for hospital patients by requiring that the plan include care to be delivered by all disciplines. We would not specify which disciplines must be involved in care planning; instead, the hospital would have the flexibility to determine which disciplines should be involved based on the nature of a patient's illness or injury. Similarly, we are not proposing to require that a hospital have a single care plan that documents interdisciplinary care planning needs, but only that care planning by all relevant disciplines be included in the medical record using whatever organizational structure or format the hospital believes is appropriate.

Under proposed § 482.15(b)(2), we would require that the patient's plan of care be modified to meet any changes in the patient's condition that affects the patient's needs. We believe this requirement is preferable to a mandate that reassessments be conducted at specified time intervals on all patients. Instead, each practitioner involved in a patient's care may perform reassessments and modify the plan of care, as needed.

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.

4. Patient Care (§ 482.20)

Patient care activities occur in all areas and departments of a hospital. These activities are carried out by a variety of staff and licensed practitioners from the medical, nursing, pharmacy, dietetics, rehabilitation, and other departments and services. Rather than describing distinct patient care responsibilities for each service or department, we have organized these regulations to reflect the integrated way in which a patient experiences care, by establishing a single, unified patient care condition. Thus, by consolidating patient care activities into one COP, the proposed regulations would no longer support a ''stovepipe'' approach to patient care and instead foster a hospital's efforts to integrate, coordinate, and evaluate patient care in the same way as the patient experiences care in a contemporary hospital setting.

Overall, the proposed patient care COP would require that each Medicare patient be under the care of an appropriately qualified practitioner, and that the care provided to each patient be coordinated and based on the plan of care required under proposed § 482.15. The first standard under the proposed patient care COP (§ 482.20(a)) concerns the assignment of a practitioner responsible for each Medicare patient's care. Under this standard, we would retain, with only minor editorial changes and one substantive change (discussed below) the current requirements in § 482.12(c)(1), (3), and (4). These requirements, while specific and detailed, are needed to implement section 1861(e)(1) of the Act, which defines a hospital as an institution that provides services by or under the supervision of physicians, and section 1861(e)(4) of the Act, which requires that every Medicare patient be under the care of a physician. It is necessary to implement the latter requirement in a way that recognizes the many types of practitioners who are authorized by State scope of practice laws and hospital staff bylaws to treat patients in hospitals.

Within this standard, the only substantive change from current requirements appears at proposed § 482.20(a)(1)(vi), which would permit a clinical psychologist to admit and treat patients receiving qualified psychologist services (as defined in section 1861(ii) of the Act), to the extent this is permitted under State law. This change is needed to implement a change in section 1861(e)(4) of the Act that was made by section 104 of Public Law 103–432, the Social Security Act Amendments of 1994.

Proposed paragraphs (a)(2) and (3) of this standard restate current requirements under § 482.12(c)(3) and (4) concerning the presence of doctors and their responsibilities toward patients.

The second proposed standard, delivery of patient care (§ 482.20(b)), would require that each patient be provided care and treatment interventions that are coordinated by all relevant disciplines and conform to the plan of care. We then would require a hospital to evaluate the patient's progress and adjust care when appropriate progress is not being achieved. That is, in keeping with the requirement under proposed § 482.15(b)(2) that the plan of care be modified as needed, we believe it is essential to include under this COP the companion requirement that actual care provided also be changed as needed, thus establishing the essential linkage between evaluation of treatment results and care plan modification.

We also propose that patient care services are provided only on the order of qualified practitioners with delineated clinical privileges. This proposed provision is in keeping with the overall approach of the patient care COP, that is, the focus on the integration and coordination of hospital services rather than the former ''stovepipe'' approach. Thus, rather than specifying under the nutrition services COP that therapeutic diets must be prescribed by the responsible practitioner (now required under § 482.28(b)(1)), we intend that such department-specific requirements would be encompassed within the hospital's overall responsibility to ensure that all patient care services be provided in accordance with the orders of qualified practitioners. So, if a surveyor finds evidence that therapeutic diets were prescribed inappropriately, the hospital could then be cited for a deficiency under this standard and, if applicable, under proposed § 482.40 (Nutrition services) if the outcome of this problem was that patients' nutritional needs were not met.

Finally, if a hospital provides care to outpatients, it would be responsible for ensuring that outpatient care meets the same quality of care requirements as inpatient care and that inpatient and outpatient services are coordinated to promote continuity of care for patients who move between levels of care. Inpatient and outpatient care should be coordinated, so that a patient does not experience any disruption of care or duplication of services simply because of a change from inpatient to outpatient status, or vice versa. We recognize that some procedures can appropriately be done only on an inpatient basis, and we do not intend to require that every service be available on either an inpatient or outpatient basis. The intent of this proposed provision is to ensure that if a service is provided in both the inpatient and outpatient settings, the level of quality in each setting is the same, so that there is a uniform level of care throughout the hospital. For example, infection control procedures and practices should be followed uniformly throughout the hospital, not merely in inpatient areas, and we would expect a hospital to investigate adverse outcomes among outpatients as thoroughly as those among inpatients. Thus, as noted below, we would expect a hospital's quality assessment and performance improvement program to encompass outpatient services, if the hospital provides those services.

5. Quality Assessment and Performance Improvement (§ 482.25)

The current quality assurance condition of participation (§ 482.21)

relies on a problem-focused approach to identify and correct problems in patient care delivery. During the last decade, the health care industry has moved beyond the problem-focused approach of quality assurance in favor of focusing on systemic quality improvements, as evidenced by the JCAHO's overhaul of its accreditation standards over the last few years. We propose to follow suit by requiring a Medicare-participating hospital to participate in a continuous effort to improve its performance, incorporating to the greatest extent possible an approach that focuses on the hospital's performance in improving patient outcomes and satisfaction. Specifically, we are proposing a new COP that would require that each hospital develop, implement, maintain, and evaluate an effective data-driven quality assessment and performance improvement program.

We do not propose to prescribe specific methodologies to achieve this objective, with the exception of retaining the current rule on autopsies (see below). Instead, we would specify that a hospital's quality assessment and performance improvement program should reflect the complexity of the hospital's organization and services. Thus, each hospital would be free to pursue quality improvement in a manner best suited to its individual characteristics and resources. However, every hospital would be responsible for implementing actions that result in performance improvements across the full range of the hospital's services to patients. Also, we would require that a hospital's quality assessment and performance improvement program must use objective measures that make it possible to track performance to ensure that improvements are sustained over time.

The proposed quality assessment and performance improvement condition (§ 482.25) contains three standards, the first addressing the scope and direction of the performance improvement program, the second on responsibility for the program, and the third on autopsies. The first proposed standard would require that a hospital's quality assessment and performance improvement program include the use of objective measures to evaluate performance changes and would delineate the minimum items that must be included in the hospital's program. Specifically, we would require that a hospital objectively evaluate the following areas that we believe are critical to hospital performance: Access to care; patient satisfaction; staff, administrative, and practitioner performance; complaints and grievances; diagnostic and therapeutic services provided; medication error incidents, achievement of drug therapy goals, and incidents of adverse drug effects; nutritional services, including, if applicable, patient's responses to therapeutic diets and parenteral nutrition; surgery and anesthesia services; safety issues, including infection control and physical environment; emergency services (if provided); discharge planning activities; and the results of autopsies. We included the first 11 items as the minimum elements of the performance improvement program because we believe they comprise the fundamental building blocks of a well-managed hospital, whose primary business is achieving desired outcomes for patients and ensuring their satisfaction. We are proposing the twelfth item, ''results of autopsies,'' because we believe that autopsies can be an important source of information to both individual practitioners and hospitals that can point to opportunities for improvement in both practitioner and hospital performance. We are asking for comments on the minimum content of the Quality Assessment and Improvement Program as well as the twelve elements that are part of the Whole Quality Assessment standard.

The next standard (proposed § 482.25(a)(2)) would then state that for each of the areas listed above, and any others the hospital includes, the hospital must measure, analyze, and track quality indicators or other aspects of performance that the hospital adopts or develops that reflect processes of care and hospital operations. These measures must be shown to be predictive of desired outcomes or be the outcomes themselves. As explained below, we also would require a hospital to use hospital-specific data, as well as Peer Review Organization (PRO) and other relevant data, in its quality assessment and performance improvement strategy.

Again, when we use the word ''measure,'' we mean that the hospital must use objective means of tracking performance that enable a hospital (and a surveyor) to identify the differences in performance between two points in time. For example, we would not consider a hospital's subjective statement that it is ''doing better'' in a given performance area as a result of an improvement process to be an acceptable measure. 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 projects, but they must at least identify a start point and end point stated in objective terms, most often, numbers, that actually relate directly to the objectives and expected/desired outcomes of the improvement project.

We do not believe it is feasible at this time to propose that a specific set of quality indicators or objective performance measures be used. However, systematic collection and analysis of quality indicators or performance measures that each hospital identifies should foster the eventual development of a data-driven system of hospital indicators. Many hospitals are already very active in this area. We recognize that collection and analysis of clinical outcome data may represent an increased burden on some hospitals, particularly on the subset of hospitals that are routinely subject to HCFA's survey process. These non-accredited hospitals typically are smaller than JCAHO-accredited hospitals, are located in more sparsely populated areas, and may not have the resources for extensive data gathering and reporting. However, rather than mandating specific performance measures, we would allow each hospital the flexibility to identify its own measures of performance for the activities it identifies as priorities in its quality assessment and performance improvement strategy. With this in mind, we believe the proposed quality assessment and performance improvement condition would lay the foundation for specific hospital quality indicators that might be developed by consensus in the future.

We anticipate that hospitals, both large and small, rural and urban, will or already use a variety of performance measures to inform their internal quality assessment and performance improvement programs. Some of these measures may be designed by the hospital itself, while others will be developed through research or by consensus groups or other sources outside the hospital. Regardless, HCFA intends, through its survey process, to assess the hospital's success in using performance measures principally in terms of whether the hospital can demonstrate with objective data that sustained improvements have taken place in: (1) Actual care outcomes, patient satisfaction levels, or other performance data, and/or (2) processes of care and hospital operations that are predictive of improved outcomes of care and satisfaction for patients. HCFA does not intend and would not be in a position to judge the measures themselves; instead, we would assess

their utility for the hospital in its own efforts to improve its performance.

While we recognize that there is no single system available for the measurement of a hospital performance, we are also aware of efforts in the hospital industry to find ways to increase the use of intra- and inter-hospital performance measurement systems. For example, under programs called ORYX and ORYX PLUS JCAHO plans to require hospitals to use a defined number of performance measures that evaluate care to a percentage of patients in an initiative to integrate performance measures with the accreditation process. Initially, we understand these programs set forth an initial framework for evaluating a wide range of performance measurement systems. The specific attributes of the measurement systems that will be evaluated include: the performance measures and data elements (how they focus on processes and/or outcomes related to patient care and organizational performance); the construction of the database; the quality of the database; the extent of risk adjustment/stratification for patient factors; performance-related feedback; and the relevance of the performance measurement system for accreditation.

Under this proposed rule, we would require a hospital to engage in a quality assessment and performance improvement program that uses objective measures, but we are not proposing that a hospital be required to participate in a system of performance measurement with other hospitals. However, we intend to develop such a requirement for inclusion in our final rule, and welcome public comments addressing the appropriateness of such a requirement or how it could best be structured. For example, one possibility is that the final rule would set forth the requirement as suggested above, and would include the evaluation criteria for the system or systems the hospitals might use. We do not envision that we would require the use of a specific system. Again, we are not proposing any specific provisions at this time, but we invite comment on whether HCFA should require non-accredited hospitals to participate in one or more performance measurement systems as part of their overall quality assessment and performance improvement program (both internally and externally).

Example of a quality improvement project. HCFA wants to assure hospitals, particularly smaller, more rural hospitals, that our expectations for the use of performance measures are commensurate with the size and resources available to the hospital. Powerful improvement programs can be and are often premised on simple, straightforward designs, using measures that are direct and uncomplicated. For example, a hospital might collect information on a routine, sampled basis about the rate of utilization of psychoactive medications that are initiated during a hospital stay, when none were used by the patient prior to hospitalization. This data collection could be a part of the hospital's quality assessment and performance improvement program associated with the proposed drug management requirements (proposed § 482.35(b)). The data could be collected manually or electronically and could be analyzed by case mix, age, physician specific prescribing patterns, the shift most likely to request medication orders, etc. This data would fulfill our requirement that it be an ''objective measure'' because the unit of measure in this example is the number of patients for whom psychoactive medications are prescribed after admission. If this data is taken for 1 month as a start period, and taken again 6 months later as an end period, the differences in the number of patients for whom psychoactive medications were prescribed after admission (both increase and decrease) would inform the hospital staff responsible for this project how well (or poorly) their intervention plan worked.

The hospital's quality assessment and performance improvement team could then use that data to design a specific improvement project, implement it, and continue to collect data to demonstrate, in a nonstatistical way change over time (for example, a steady reduction in orders for psychoactive medications during a hospital stay). The performance measures for a project like this are immediate and simple to collect, and well within the reach of any hospital. Hospitals that have more resources could be expected to produce more sophisticated measures that involve more complicated issues, but the key expectation of these requirements is that the hospital make an aggressive and continuous effort to improve its performance across the board. HCFA is more interested in the outcomes of such an effort than in the specific processes the hospital uses to achieve the performance improvements. We recognize that: (1) There is not yet a wide menu of available performance measures that have been shown to be reliable and valid that could be offered to a hospital to use to meet these requirements; (2) a hospital cannot control many related nonpatient care outcomes (such as substance abuse practices of the patient, or lack of adequate support systems to ensure lasting positive outcomes from the hospital stay, etc.); and (3) many hospitals will need more experience with data collection methods and in the design implementation and monitoring of improvement projects. However, experience in many hospitals, other health care providers, and business and industry in general has shown convincingly that creating an expectation for continuous improvement is a far more powerful performance incentive than maintaining a set of process and structural requirements.

Therefore, we want to stress that our emphasis at this time is on the improvement of processes. The process of improvement entails: (1) Identification of an organization's critical patient care and services components; (2) application of performance measures that are predictive of quality outcomes that would result from delivery of the patient care and services; and (3) continuous use of a method of data collection and evaluation that identifies or triggers further opportunities for improvement. We do not intend for hospitals to collect data from performance measures for the sake of meeting a regulatory requirement. The hospital must have the flexibility to identify the processes targeted for improvement based on the unique needs and priorities of the facility and its patients. Moreover, we would expect the processes targeted for improvement to change over time as the hospital makes the necessary improvement efforts.

As stated by W. Edwards Deming, the late quality management expert, ''* * * quality comes from * * * improvement of process(es)'' and the degree to which improvement occurs is measured through analysis of collected data. (Katz, Jacqueline, Managing Quality, St. Louis: Mosby Year Book, 1992, p. 122). Likewise, the intent of this requirement is that each hospital will engage in improvement activities, based on its own analysis of data, that improve care outcomes and patient satisfaction and lead to greater efficiency and economy of operation.

How to Measure Hospital Quality Improvement Efforts—Options for Establishing a Required Minimum Level of Improvement Projects Per Year. As the preceding discussion illustrates, even small, rural hospitals and those without sophisticated ''research'' capabilities can develop and manage effective quality assessment and

improvement programs that demonstrate sustained improvement over time. However, we are concerned that some hospitals may make token efforts to meet this requirement, efforts that are aimed primarily at avoiding adverse enforcement action resulting from a survey, rather than at improving processes and outcomes of care and satisfaction for patients. Thus, depending on the comments we receive, we intend to develop for the final regulation a requirement that a hospital engage in a minimum number of improvement projects that are based upon the hospital's own quality assessments of its performance and that show measured, sustained results that actually benefit patients.

We are not proposing specific language in the regulation text at this time because we recognize there are many ways in which a minimum level of effort can be set.

We are inviting comment not only on the advisability and necessity of such a requirement, but also on the best approaches to achieve this minimum level of effort. At a minimum, we would require under the quality assessment and performance improvement condition of participation that the number of distinct successful improvement activities to be conducted annually must be proportional to the scope and complexity of the hospital's program. The success of the activity would be measured in terms of demonstrated sustained improvement over time. We intend to then supplement this underlying requirement with a more precise explanation of what would be expected of each hospital. Among the possible alternatives that we are considering are the following:

(1) Require the hospital to engage in a specific number of improvement projects equal to not less than 1 project per 1,000 patient discharges.

(2) Require a minimum set number of projects (e.g., five) that are hospital-wide and most broadly affect patient outcomes and satisfaction.

(3) Require a minimum set number of projects (e.g., five) that are not hospital-wide, but that are developed and implemented in various areas of the hospital's range of care and services (e.g., one project might reduce waiting time in the emergency room, another might focus on improving the accuracy of medication administration, etc.).

(4) Require a minimum number of projects based on bed-size, rather than discharges (e.g., 8 projects in a 600-bed hospital, 2 in a 50-bed hospital).

(5) Rather than requiring a minimum number of projects, require the hospital to demonstrate (e.g., to the PRO and/or survey agency) what projects they are doing and what progress is being achieved.

(6) Again, rather than specifying minimum number of projects, establish a minimum set of types of projects that must be done (e.g., hospital operational processes that are predictive of positive outcomes, such as infection control measures, or condition-specific projects that improve certain clinical outcomes, such as emergency room responses to heart attack patients).

We are certain there are many other ways to approach the ''minimum effort'' discussion. The examples noted above illustrate some of the possible approaches to ensuring that hospitals invest substantial efforts in quality assessment and improvement. The purpose of these examples is to elicit comment and suggestions in this regard, and we welcome alternative approaches. We note that although our intention is to specify in the final rule a minimum level of effort, it is also possible that after reviewing all the comments we may conclude that it is neither feasible nor desirable to do so.

Other Elements of the Proposed Quality Assessment and Performance Improvement Condition. We propose a new requirement at § 482.25(a)(3) that a hospital must use hospital-specific as well as PRO data and any other available relevant data, as an integral part of its quality assessment and performance improvement strategy, to develop its improvement plans and projects. However, if a hospital elects not to participate in an improvement project with its PRO, we propose at § 482.25(a)(4) that it must be able to demonstrate a level of achievement through its own quality assessment and performance improvement strategy comparable to or better than that to be expected from such participation. Thus, we intend that each hospital have the responsibility to engage in improvement projects that are vigorous and needed to improve performance across the range of hospital activities that affect patient outcomes. For example, if a PRO proposes a cooperative project to improve the outcomes for Medicare patients with pneumonia, and the hospital chooses not to participate, HCFA surveyors would expect to find that projects that the hospital designed and implemented on its own (e.g., an improvement project to reduce the use of psychoactive medications and physical restraints as patient management tools) achieved improvements that were demonstrably as important as the expected outcomes that would have been expected from the pneumonia study had the hospital chosen to participate in that cooperative study. (In assessing the comparability of a hospital project with a PRO project, we would consider the number of patients affected, the projected magnitude of the benefit to individual patients, and the actual changes achieved by the project to the changes achieved by participants in the PRO project.)

We also would require that a hospital set priorities for performance improvement, based on the prevalence and severity of identified problems. Of course, we expect that a hospital will immediately correct problems that are identified through its quality assessment and performance improvement program that actually or potentially affect the health and safety of patients. For example, if a hospital's quality assessment and performance improvement process identifies problems with accuracy of medication administration, it is not enough for the hospital to consider this area a candidate for an improvement program that may or may not be chosen from a priority list of potential projects. Rather, since accuracy of medication administration is critical to the health and safety of patients, the hospital must intervene with a correction and improvement program immediately. Overall, a hospital would be expected to give priority to improvement activities that most affect clinical outcomes.

As noted above, perhaps the most fundamental change proposed in the new quality assessment and performance COP in comparison to the present condition on quality assurance is the focus on taking action to correct problems identified through the hospital's quality assessment and performance improvement program. This change is reemphasized in the proposed requirement at § 482.25(a)(6) that a hospital must take actions based on measurement and tracking that result in demonstrable, sustained improvements. We envision a hospital meeting this requirement by conducting a systems/process analysis when adverse outcomes are identified and then taking action to afford long-term correction and improvement of the identified problems, as illustrated in the above example concerning medication administration.

The second proposed standard under this COP, proposed § 482.25(b), basically builds on the current requirement under § 482.21 that the hospital's governing body ensures that there is an effective, hospital-wide quality assessment and performance improvement program, as well as on the current requirements concerning

medical staff responsibilities under § 482.22(b) and (c). Under the new proposed standard, we would state that the hospital governing body, medical staff, and administration officials are responsible for ensuring that the hospital-wide quality assessment and performance improvement efforts address identified priorities in the hospital and for implementing and evaluating improvement actions. We would, however, eliminate several procedural requirements under the current medical staffing provisions, such as those concerning the organization of the medical staff.

Finally, in keeping with the cross-cutting, hospital-wide approach to quality improvement that we believe represents current best practices, the standard includes a requirement that all programs, departments, and functions be involved in the hospital's quality assessment and performance improvement program. This would include services that are carried out under contract or by arrangement.

Under the third standard in this COP, we would retain the current requirement on autopsies (existing § 482.22(d)). Under this requirement a hospital's medical staff must attempt to secure autopsies in cases of unusual deaths or of medical, legal, or educational interest. Although this requirement is somewhat prescriptive, we believe it is necessary because autopsies are a valuable educational tool that contribute to the quality of care in a hospital and, as we stated above, can be used by the hospital to improve its performance.

6. Diagnostic and Therapeutic Services or Rehabilitative Services (§ 482.30)

We are proposing to restate and consolidate current standards from several COPs that relate to required and optional diagnostic and therapeutic services into one COP. The condition would have four standards. The first standard would require that a hospital be primarily engaged in providing, by or under the supervision of one of the practitioners described in 42 CFR 410.20(b) (which specifies by whom physician services must be furnished to be eligible for Medicare Part B payment), either diagnostic and therapeutic services to inpatients, or rehabilitative services to inpatients. This standard would implement the statutory requirement at section 1861(e)(1) of the Act. If a hospital does not meet this standard, it would be found out of compliance and would risk termination of its participation in the Medicare program.

The second standard of this condition at proposed § 482.30(b) would require that a hospital furnish diagnostic radiology services, as required under existing § 482.26. We would expect a patient's initial needs for radiology services would be identified in the comprehensive assessment performed at admission. In addition we are proposing that a hospital that furnishes emergency services on a full-time basis must provide diagnostic radiology services on a full-time basis.

Separate mention is not made in this condition of the personnel, safety, and record standards that are now found under § 482.26(b), (c), and (d). As discussed earlier in this preamble, under our proposed reorganization of these COPS, we try to deal with such common elements in one place instead of repeating them for each condition. Therefore, the personnel and safety standards accompanying these conditions are now encompassed in the proposed Human Resources and Physical Environment conditions, respectively.

In the next standard, proposed § 482.30(c), we would require hospitals to furnish laboratory services, including 24 hour-a-day emergency laboratory services, as presently required under existing regulations (see § 482.27). We are also proposing to retain the current requirement at § 482.27(a) that laboratory services provided to patients in the hospital must meet the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as codified in 42 CFR part 493. We propose to delete the requirements of existing § 482.27(b)(2), (3) and (4). Section 482.27(b)(3) requires the hospital laboratory to make provisions for the proper receipt and reporting of specimens the laboratory handles. Since this requirement is covered under CLIA provisions, it would be redundant to place it in the proposed hospital COP. We are requesting comment on our proposal to eliminate the current requirements at § 482.27(b)(2) which requires that a written description of laboratory services be available to the medical staff and at § 482.27(b)(4) which requires the medical staff and a pathologist to determine which tissue specimens require a microscopic and/or macroscopic examination. We recognize that it is essential for practitioners to know what laboratory services are available for diagnosing and delivering care. However, we believe that hospitals make their services known to their practitioners, and we are not convinced that a regulation is necessary to assure that this process occurs. In addition, although microscopic and macroscopic examination of tissue specimens may provide valuable information, we are requesting comment on whether it is necessary to have a regulation which states who can determine what tissue specimens require these examinations.

The fourth proposed standard at § 482.30(d) would state that a hospital may elect to offer services in addition to these required diagnostic and therapeutic services, such as nuclear medicine, ultra sound, rehabilitation medicine services, psychology services, respiratory care services, speech and language pathology services, audiology services, social work and vocational rehabilitation services, to name a few. This listing illustrates but does not limit the range of diagnostic and therapeutic services a hospital may provide. If the hospital elects to offer such additional optional services, those services must be delivered in accordance with the requirements of part 482.

7. Pharmaceutical Services (§ 482.35)

Overview. Under the proposed condition on pharmaceutical services, which would replace current § 482.25, we would require the hospital to provide needed medication therapy through a safe, accurate, and effective system that minimizes adverse drug events and evaluates the patient's response to the therapy.

In general, we propose to adopt requirements that integrate drug therapy services and support a coordination of services by the various disciplines that provide them (medicine, nursing, and pharmacy). This integration of services is intended to protect patients by establishing a four-layer ''safety net'' to prevent adverse drug events (including medication errors). It is intended also to detect system errors that result from the multiple nodes in the drug distribution process: Ordering, transcription, dispensing, and administration.

The first layer of this safety net is a peer review activity for the identification of events that are predictive of adverse drug events (see § 482.35(a)(1)). The second layer is the detection of medication errors (see § 482.35(a) (2) and (3)). This layer focuses on the more objective errors of transcription, dispensing, and administration, and leaves the more subjective drug error issues to peer review and nurse review mechanisms. The third layer of the net is the comprehensive drug information resource, which endeavors to provide vital drug and patient information at keys points in the drug distribution process (see § 482.35(b)(4)). The fourth layer of the net relies on nursing personnel to review drug orders for

accuracy of the entire system before drugs are administered (see § 482.35(b)(5)).

As a consequence, we are proposing to delete a number of narrowly focused, structure and process-oriented requirements, as follows:

In existing § 482.25(a)—

(1) Requiring a full-time, part-time or consultant pharmacist.

(2) Requiring the pharmaceutical service to have adequate personnel.

In existing § 482.25(b)—

(1) All compounding, packaging, and supervision of drugs must be under the supervision of a pharmacist.

(2) All drugs must be kept in a locked storage area. (Note: Locked storage of only controlled drugs is proposed at § 482.35(b)(1).)

(3) Outdated, mislabeled or otherwise unusable drugs are not available for patient use.

(4) When the pharmacist is not available, drugs and biologicals may only be removed from the pharmacy or drug storage area by a designated person.

(6) Drug administration errors, adverse drug reactions and incompatibilities are immediately reported to the attending physician and the quality assurance program.

(9) A drug formulary system must be established by the medical staff to assure quality pharmaceuticals at a reasonable cost.

A drug formulary is a system for determining the best quality and least expensive drugs, listing them in a formulary, and restricting the medical staff to the drugs listed in the formulary. This is a vastly different document than the ''comprehensive drug information resource'' referred to under § 482.25(b)(4) of this proposed rule. A drug formulary is a cost control and quality mechanism. We do not think it would be a wise investment of survey agency time to pursue this cost control mechanism through enforcement of the COPs, since current efforts at cost controls and an emphasis on managed care will probably be far more effective at constraining drug costs in hospitals.

Finally, we plan to eliminate the explicit, process-oriented requirements for administration of drugs, and acceptance of telephone and other oral orders for drugs, that are now set forth in our nursing services requirements at § 482.23(c)(2).

Description of Standards. The first proposed standard has to do with monitoring of adverse drug events (ADEs) and with eliminating or minimizing medication errors. We believe a separate standard covering ADE monitoring is needed because of its importance to patient care quality and patient health and safety. This standard is based on Journal of the American Medical Association (JAMA) papers on adverse drug events (see Bates, D. W., *et al.*, ''Incidence of Adverse Drug Events and Potential Adverse Drug Events,'' *JAMA*, 274 (1995): 29–34, and Leape, L. L., *et al.*, ''Systems Analysis of Adverse Drug Events,'' *JAMA*, 274 (1995): 35–43).

These papers make the following salient points:

- Forty-two percent of serious and life-threatening ADEs were preventable (Bates, page 33).
- Adverse drug events have multiple etiologies, but the lack of readily accessible and current drug information along with patient care information is a significant part of the problem with adverse drug events (Leape, page 40).
- Computerized detection programs that search for events likely to be associated with an ADE (e.g., naloxone, an opiate antagonist), supplemented by spontaneous reporting using the computerized information system and a dedicated person or group with responsibility for evaluating these events have been found to represent an effective, relatively inexpensive method for identifying ADEs and will probably be the strategy of the future (Bates, page 33).
- The most common defects were in systems to disseminate knowledge about drugs and to make drug and patient information readily accessible at the time it is needed. System changes to improve dissemination and display of drugs and patient data should make errors in the use of drugs less likely (Leape, page 35).

We have endeavored to implement the principles established in these papers in the first standard, ''Adverse Drug Monitoring.'' First we propose that the facility must establish a system of evaluation of ADEs by searching current clinical records for events that are predictive of an ADE and reporting them to the quality assessment and performance program for action. We have not proposed to require that a computerized system be used by all hospitals since these regulations primarily will affect small, rural, nonaccredited hospitals who may not have the resources to develop such a computer system.

The second and third parts of the ADE standard deal with medication errors. A longstanding body of research exists concerning medication errors in hospitals. In a paper by Allan and Barker (Allan, Elizabeth L. and Barker, Kenneth N., ''Fundamentals of Medication Error Research,'' American Journal of Hospital Pharmacy, 47 (1990): 555–71), the authors documented medication error studies in approximately 40 hospitals and nursing homes in the United States and Canada. These studies covered a period of time from 1962 to 1987. The hospitals' medication error rates ranged from a high of 20.6 percent to a low of 1.6 percent when wrong timing errors were excluded. When wrong timing errors were included, the range was 42.9 percent to 4.4 percent.

This proposal would permit an overall medication error rate in a hospital of no greater than 2 percent and require zero tolerance for significant medication errors. Significant medication errors are defined as errors that jeopardize or cause serious potential for jeopardizing the health and safety of the patient. HCFA has used this concept for many years in long-term care facilities, and has considerable experience at defining what would constitute a significant medication error. The overall error rate would include significant as well as nonsignificant (e.g., wrong timing) errors and would result in a deficiency citation. Setting an overall limit on medication errors, including significant errors, does not mean significant errors are tolerated if they remain below 2 percent. Rather, even though the regulation provides zero tolerance for significant errors, if significant errors do occur, and they are added to the nonsignificant errors, a deficiency occurs where the result is greater than 2 percent. This deficiency is in addition to the separate deficiency for the significant errors. We are proposing the 2-percent standard because research and expert opinion has determined that this is a reasonable medication error rate to achieve, given modern drug packaging and drug information systems. (See Barker, Kenneth N., *et al.*, ''Consultant Evaluation of a Hospital Medication System: Analysis of the Existing System,'' American Journal of Hospital Pharmacy, 41 (1984): 2013).

In the Bates, et al, paper, adverse drug events are categorized as follows: Ordering, Transcription, Dispensing and Administration. It is important to point out that the medication error regulation proposal would examine all these categories except ADEs occurring from physician ordering questions. For this issue we would rely on the licensed nurse (that is, a registered nurse (RN), licensed practical nurse (LPN), or licensed vocational nurse (LVN)) review, as proposed under § 482.35(b)(5). This is necessary because physician ordering questions dealing with the drug, the dose, the route of

administration, etc., frequently require consultation before a positive determination about the occurrence of an ADE.

The second standard, ''Drug Management Procedures,'' has seven parts. The first one requires that drugs and biologicals be kept in secure areas; however, those drugs that are ''controlled'' must be stored in locked areas as required by the Comprehensive Drug Abuse Prevention and Control Act. (We are not requiring that biologicals be stored in locked areas because this Act does not include ''biologicals'' in its provisions.) We are not requiring that the areas where the controlled drugs are stored be double locked, since what is usually found in most facilities is an individual with a ring of keys containing both keys to the double locked compartment. In this case ''double locked'' is hardly an added security feature. The key to the locked compartment should be restricted strictly to individuals who have an identified need to access these drugs.

The requirement for the facility to maintain a record of receipt and disposition of controlled drugs may be met in ways other than the use of proof of use sheets for each controlled drug. For example, the facility may use existing patient records such as the medication administration record as a record of disposition of controlled drugs. If the facility wishes to maintain records of receipt and disposition of controlled drugs by using existing patient care records, it will reduce its paperwork burden considerably.

Proposed § 482.35(b)(3) requires that discrepancies in the record of controlled drugs be reported to the individual responsible for pharmaceutical services and to the hospital administrator. Discrepancies in these records indicate that controlled drugs are being used for unauthorized purposes. Proposed § 482.35(b)(3) would require that these discrepancies be reported to responsible individuals in the hospital, who will then decide whether the local police or the Drug Enforcement Agency should be involved.

The fourth part of the Drug Management Procedures standard would require the hospital to establish a computerized or hard copy ability to merge patient information with current comprehensive drug information at the points of drug ordering, dispensing, and administration. This system would promote the development of information systems that bring patient information and drug information together at critical junctures in the drug ordering and distribution process. Comprehensive drug information resources would include the United States Pharmacopoeia-Drug Information, American Medical Association Drug Evaluations, and the American Hospital Formulary Service—Drug Information. (These drug information resources are those used to establish Medicaid drug use review under the provisions of section 1927(g)(1)(B) of the Social Security Act. Drug information resources would not include the Physician Desk Reference since this reference is not considered comprehensive and was not listed in the statute.)

The fifth part of this standard would require that before medications are administered, a licensed nurse, or a physician if he or she is personally administering the drug, review the patient's information and the drug order. (The comprehensive drug information would also be available for review if there was a need for this information.) The purpose of this proposal is to support the established practice of nursing personnel questioning the drug order from the standpoint of the correctness of the order itself in relation to specific patient and drug information that must be readily available before or at the point of drug administration. In reviewing this information to prevent drug errors, a nurse would be acting only within the scope of her or his State licensure. The expectation is that the nurse would report any potential errors in drug prescribing to the physician, so the physician could determine whether the order needed to be changed. This proposed requirement is consistent with current research. Leape identified a total of 334 adverse drug events that were identified by review of all admissions in 11 medical and surgical units in 2 tertiary hospitals for a period of 6 months. Of the 334 adverse drug events, 91 or 27 percent were intercepted (prevented). Of these 91 prevented adverse drug events, 86 percent were prevented by nurses and 12 percent by pharmacists. This proposed regulation is intended to strengthen the potential for nurses and pharmacists to intercept adverse drug events of all kinds by providing them with readily available information necessary to prevent these events.

The sixth part of the Drug Management Procedures standard deals with positive identification of medication. The current regulations do not contain a requirement for positively identifying drugs brought to the facility by the patient and then obtaining physician orders before they can be administered. We are proposing such a requirement here because when an individual is hospitalized it indicates a considerable change in their status. ''Positively identified'' in the context of this proposed rule means that a pharmacist or someone with similar drug identification skills must make sure that the drugs brought to the facility are in fact the same drugs that the label represents. This is necessary because patients often mix drugs within one container, or they separate drugs from their proper labeling. The drugs that the individual was taking prior to this hospitalization should be reviewed by competent medical personnel to determine if these drugs are still necessary, or if they may interfere with other therapies that are underway in the hospital.

Unlike current regulations, this proposed rule would make it clear that self-administration of drugs is permitted, but only under orders and hospital policy. This proposed rule is important for patients being prepared for discharge. These patients should become familiar with self-administration of drugs (especially eye drops, inhalers, intramuscular injections), so they become well-practiced with this task while still under competent supervision.

Regarding our seventh proposal, existing § 482.25(b)(5) requires that orders for drugs and biologicals be automatically stopped after a reasonable period of time as predetermined by the medical staff. This proposed rule endeavors to achieve the same objective as the current rule, that is, the cessation of drug therapy when it is no longer necessary. However, our proposal would not limit the hospital to the option of automatic stop orders, which discontinue drug therapy (especially on holidays and weekends) by administrative fiat without any medical assessment as to whether the drug therapy has achieved its therapeutic objectives. The proposed rule allows the hospital to develop its own approaches for achieving this objective.

The last standard of the Pharmaceutical Services COP (proposed § 482.35(c)) deals with discharge orders for psychopharmacological drugs. Under this standard, we would require that orders for psychopharmacological drugs be discontinued upon the patient's discharge unless the patient has been diagnosed (using standard criteria for such diagnoses) with a mental illness. This will prevent the use of these drugs (which may be temporarily necessary during a hospitalization) from becoming routine after discharge unless a valid reason for their use is established. This is particularly necessary in patients

transferred to long-term care facilities, who can suffer considerable adverse effects from long-term use of antipsychotic and antianxiety drugs that may have been started in the hospital for very valid reasons but that may no longer be valid after discharge. A study by Garrard (Garrard, Judith, *et al.*, ''Evaluation of neuroleptic drug use by nursing home elderly under proposed Medicare and Medicaid regulations,'' *JAMA*, 265 (1991): 463–467) showed that the rate of use of neuroleptic (antipsychotic) drugs among nursing home admissions was: 16 percent when admitted from hospitals, 18 percent from the community, and 21 percent from other nursing homes. Regulation of the use of these drugs (in the absence of proper differential diagnoses) in nursing homes have been in effect since 1990 (see 42 CFR 483.25), and we have been criticized because similar rules were not imposed on hospital and community practice (Thurston, Ronald G., Letters, *JAMA*, 265 (1991): 2962). We believe this proposed requirement represents a fair way to address this issue, but invite public comment on alternatives for achieving the same objective.

8. Nutritional Services (§ 482.40)

Currently, the food and dietetic services requirements that a hospital must meet are found at § 482.28. These requirements emphasize the organizational aspects of a hospital's food and dietetic services program, including provisions that specify allowable contractual arrangements, employee qualifications, and other process-oriented details.

We are proposing extensive revisions to these provisions under a new nutritional services condition of participation. In keeping with the principles discussed above, the new condition of participation would promote a patient-centered approach to nutrition. Thus, the introductory language for these proposed requirements states explicitly that each patient must receive adequate nutrition, including therapeutic diets or parenteral nutrition if needed.

The proposed condition includes only two standards. The first standard, ''Sanitary conditions,'' requires that food provided to patients be obtained, stored, prepared, distributed and served under sanitary conditions. (Note that the term ''food'' is intended to include all forms of nutrition, liquid or solid, provided to patients.) Although this requirement is not contained in the current hospital conditions of participation, we believe that it clearly is an underlying necessity for any acceptable nutritional services program. Thus, we are proposing to include it explicitly under the nutritional services condition. The only other standard would require that menus be prepared in advance and meet the nutritional needs of patients based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. We believe the Board's guidelines can appropriately be used here because they represent accepted best practices and are already in widespread use among hospitals.

In developing the proposed requirements, we have attempted to incorporate straightforward statements of a hospital's responsibilities, while eliminating procedural requirements and avoiding unnecessary details of how the hospital should carry out its nutritional services function. We believe that the requirements largely incorporate current best practices in hospital nutrition services, while eliminating several burdensome process requirements that are not central to meeting the patient's dietary needs (such as the requirement under current § 482.28(b)(3) that a current therapeutic diet manual approved by the dietitian and medical staff be readily available to all medical, nursing, and food service personnel.) We considered supplementing the requirements with additional provisions concerning staffing requirements or qualifications. Instead, however, we decided that the staffing requirements set forth under the proposed human resources condition of participation are sufficiently broad to ensure that a hospital has adequate qualified staff to carry out its nutritional services function. Rather than prescribing how a hospital should organize itself to meet its nutritional services responsibilities, we prefer to allow each hospital as much flexibility as possible in this regard, so that it can focus on incorporating its nutritional services program into a cross-cutting approach toward achieving optimal patient outcomes. Finally, as discussed above in section II.B.4 of this preamble, we note that the existing requirement under § 482.28(b)(1) that a therapeutic diet be prescribed by the responsible practitioner would now be encompassed within the hospital's responsibility under proposed § 482.20(b) to ensure that all patient care services be provided in accordance with the orders of qualified practitioners.

9. Surgical and Anesthesia Services (§ 482.45)

The proposed condition on surgical and anesthesia services would replace the existing regulations at § 482.51 (Condition of participation: Surgical services) and § 482.52 (Condition of participation: Anesthesia services). We have decided to address both areas under a single condition in order to simplify the organization of part 482, and to emphasize the close relationship between surgery and anesthesia.

In the new condition, we would delete current process-oriented standards having to do with the organization and staffing of the hospital's surgical and anesthesia departments or services (existing § 482.51(a) and § 482.52(a)), and with hospital policies governing surgical and anesthesia care (existing § 482.51(b) and § 482.52(b)). In particular, we propose to delete the current specific requirements regarding the types of personnel who can serve as scrub nurses or perform circulating duties in the operating room. We also would eliminate current rules on which practitioners can administer anesthesia, and what level of supervision must be provided to them. We also propose to delete current prescriptive requirements specifying the types of equipment that must be maintained in operating suites (existing § 482.51(b)(3)). We believe those requirements should be eliminated in favor of those that focus more directly on outcomes.

In place of the current requirements, we propose two basic rules on staffing. We would require that surgical procedures be performed only by practitioners with appropriate clinical privileges, and that anesthesia be administered only by a licensed practitioner permitted by the State to administer anesthetics.

One effect of our proposed staffing and equipment requirement would be to allow more flexibility to certified registered nurse anesthetists (CRNAs) to practice without oversight by another practitioner. Currently, the anesthesia condition (§ 482.52(a)(4)) requires that a CRNA administer anesthesia only under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed. To allow greater flexibility to hospitals and practitioners and to give deference to State scope of practice law, we propose to delete this supervision requirement and allow the CRNA to function without supervision by another practitioner, where this is in accordance with State law. We emphasize that CRNAs are allowed to practice in this way only where doing so is consistent with State law. If State law establishes a more stringent rule, the hospitals (42 CFR 482.110) would be required to furnish care in a way that is consistent with that rule.

To ensure that our requirements are consistent across the settings in which surgery may be performed, we propose also to eliminate the supervision requirement for CRNAs in ambulatory surgical centers (ASCs) (42 CFR 416.42) and in critical access hospitals (CAHs) (formerly rural primary care hospitals) (RPCHs) (42 CFR 485.639) and allow the CRNA to function without supervision by another practitioner, where this is in accordance with State law. In addition, if State law establishes a more stringent rule, the ambulatory surgical centers (42 CFR 416.40) and critical access hospitals (42 CFR 485.608) would be required to furnish care in a way that is consistent with that rule.

We believe it is critical to the health and safety of surgical patients to have accurate information on each patient's condition before anesthesia is administered and a surgical procedure is undertaken. Therefore, we would require under proposed § 482.45(b) that a comprehensive assessment be performed before surgery (with a modified assessment being permitted in emergency cases) and that a preanesthesia evaluation be done by an individual qualified to administer anesthesia. We also would require that a postanesthesia evaluation for proper recovery be done by an individual qualified to administer anesthesia. We propose to delete the current prescriptive rule under which the postanesthesia evaluation must be done by the same individual who administered the anesthesia.

In the standard on documentation of care, we have included requirements for entry of specified information in the medical record. The information that would be required includes a report of the comprehensive or modified pre-surgical assessment, a properly executed informed consent form, an operative report describing complications, reactions, length of time, techniques, findings, tissues removed or altered, a record of intraoperative anesthesia, and a report of the postanesthesia evaluation. By ''properly executed informed consent,'' we mean only that the patient understands the information the hospital wishes to convey. The pre-surgical assessment and informed consent form would have to be entered in the record before surgery except in emergency cases, while the operative report, intraoperative anesthesia record, and a report of the postanesthesia evaluation would have to be entered in the record promptly following surgery. (The postanesthesia evaluation report combines the current requirements for an inpatient postanesthesia followup report (§ 482.52(b)(3)), and for an outpatient postanesthesia evaluation (§ 482.52(b)(4)) into a single new requirement.) The hospital also would be required to maintain a complete, up-to-date operating room register. We recognize that our proposal for the documentation requirements for the surgical and anesthesia services COP is more extensive and specific than many other requirements in these proposals. However, such documentation is common to current practice and imposes no additional burden to hospitals as these documentation requirements are part of the existing COPs.

10. Emergency Services (§ 482.50)

We propose to delete the existing regulations at § 482.2 (Condition of participation: Provision of emergency services by nonparticipating hospitals), and to add a single new emergency services condition that would replace both current § 482.12(f) (Condition of participation: Governing body; Standard: Emergency services) and current § 482.55 (Condition of participation: Emergency services). We believe § 482.2 need not be retained since the regulations at 42 CFR 424.101 set forth a definition of ''hospital'' that is used for purposes of payment for services to Medicare patients that are furnished on an emergency basis by a hospital that does not participate in the program. By addressing the two latter areas under a single regulation, we hope to simplify the organization of the regulations and eliminate the need for the user of the regulations to refer to separate sections to review the rules on closely related services. For the reasons explained below, we also are proposing to add a separate standard for hospitals that offer emergency services on less than a full-time basis.

In the standard on hospitals providing full-time emergency services, we have emphasized requirements that most directly affect the safety of patients. These are the requirements regarding the personnel who furnish the services, the appropriateness of the services to patient needs, and the integration of emergency services with those of other hospital departments. Regarding the proposed requirement for sufficient numbers of personnel, we note that some hospitals may choose to meet patient needs by using a comparatively smaller, but more highly trained and skilled staff. In assessing compliance with this requirement, our primary concern will be to determine whether emergency service staffing is adequate to produce good treatment outcomes.

We are proposing the second standard, which is applicable only to hospitals providing part-time emergency services, in order to allow more flexibility to hospitals that find it necessary, because of staffing limitations, low emergency room volumes, or other factors, to limit the times during which emergency services can be offered. Because of the nature of emergency services, it clearly would be desirable to have them available on a 24-hour per day, 7-day per week basis. However, many hospitals, particularly those that are small and are located in remote rural areas, find it difficult to recruit and pay staff to furnish emergency services on this schedule. To avoid a situation in which these hospitals find it necessary to terminate emergency services altogether, we propose that hospitals that are located in rural areas and have fewer than 100 beds may offer emergency services on a part-time basis. We propose to use the definition of ''rural area'' now set forth in our regulations at 42 CFR 412.62(f)(1)(ii). Under that definition, an area is considered ''rural'' if it is located outside any Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), and outside specified New England counties.

We emphasize that this flexibility is not intended to foster development of dual standards of care—during its stated hours of operation, a hospital emergency department or service must meet exactly the same standards as full-time departments or services. However, at the times when it chooses not to offer emergency services, the hospital would be required to meet only the standard for hospitals that do not offer emergency care.

Section 1867 of the Act (Examination and Treatment of Emergency Medical Conditions and Women in Labor) imposes certain obligations on Medicare-participating hospitals that have emergency departments. If an individual comes to the hospital's emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition, the hospital must provide, within the capability of its emergency department, an appropriate medical screening examination and, if necessary, either stabilizing treatment or an appropriate transfer. Section 1867 of the Act does not deal explicitly with the situation of a hospital that opens its emergency department on only a part-time basis. However, it is our policy that a hospital that offers emergency services on a regular, part-time basis is not considered to have an emergency department under section 1867 at the scheduled times when emergency

services are not available. At those times only, the hospital is not subject to the requirements of section 1867 of the Act. The hospital would remain obligated at those times to meet the requirements of proposed § 482.50(c) for appraisals of emergency cases, initial treatment, and referral when appropriate. At all other times (that is, when emergency care is offered), the hospital is fully responsible for compliance with the statute (and with the implementing regulations at 42 CFR 489.24) and also would be obligated to meet the emergency services requirements set forth in proposed § 482.50(a) and (b).

We expect that a hospital offering part-time emergency services will do so in good faith, and not ''open'' and ''close'' its emergency department selectively, in an attempt to avoid meeting its statutory obligations to some patients based on their perceived inability to pay. We will continue to investigate all allegations we receive of violations of section 1867 of the Act and will not hesitate to initiate termination proceedings, or to refer cases to the Office of Inspector General, if it is clear that a violation has occurred. We welcome comments on this proposal.

The third proposed standard deals with hospitals not offering emergency services. We propose to continue to require such a hospital to provide for appraisal of emergencies, initial treatment, and referral of patients when appropriate. However, we propose to delete current process-oriented requirements having to do with the organization of the hospital's emergency services (§ 482.55(a)(1)) and with policies and procedures for the medical care provided in the emergency department (§ 482.55(a)(3)). We believe those requirements should be eliminated in favor of those that focus on activities more directly related to outcomes.

11. Discharge Planning (§ 482.55)

Section 1861(e)(6) of the Act requires that a hospital have in place a discharge planning process that meets the requirements of section 1861(ee) of the Act. Under section 1861(ee), a discharge planning process must apply to services furnished by the hospital to Medicare beneficiaries, and meet the guidelines and standards established by the Secretary of HHS to ensure a timely and smooth transition to the most appropriate type of setting for posthospital or rehabilitative care. Section 1861(ee)(2) further requires that the Secretary's standards and guidelines include seven specific elements, as listed in that provision. On December 13, 1994, we published a final rule to implement the requirements of sections 1861(e)(6) and 1861(ee) of the Act by adding new § 482.43 (Condition of participation: Discharge planning) (59 FR 64141). For the reasons explained in the preamble to that final rule, we elected under the authority in section 1861(e) of the Act to require a discharge planning process that applies to all patients, not just to Medicare beneficiaries.

On October 31, 1994, Congress enacted Public Law 103-432, the Social Security Act Amendments of 1994 (SSAA'94). Section 107 of that legislation amended section 1861(ee)(2) effective November 1, 1995, to require that a discharge planning evaluation for a Medicare patient include an evaluation of the need for hospice care as well as other posthospital care.

Congress included in the Balanced Budget Act of 1997 (BBA '97), Public Law 105–33, enacted August 5, 1997, several amendments to section 1861(ee)(2) to address concerns about reports of some hospitals referring patients only to HHAs with which they have financial ties. Subsection 4321(a) of that legislation, effective November 3, 1997, amended the discharge planning evaluation requirements in section 1861(ee)(2)(D) and added a subparagraph (H) to section 1861(ee)(2). These changes are consistent with patient rights, the first core condition of patient-centered care in this regulation. As a result of these changes a Medicare participating hospital now must: (1) Include in a patients's discharge planning evaluation the availability of home health services through Medicare participating HHAs which serve the patient's geographic area and which request the hospital to be listed; and (2) ensure that a patient's discharge plan does not specify or otherwise limit the qualified participating HHAs and identify any HHA with which the hospital has a ''disclosable financial interest'' if the patient is referred to such entities.

We propose to redesignate § 482.43 as new § 482.55, and to republish it with only the changes discussed below. In keeping with the shift in focus of these regulations from process to outcome, we propose to delete the requirement that a hospital's discharge planning policies and procedures be specified in writing, and to add the requirement that the discharge planning process assure that appropriate posthospital services are obtained for each patient, as necessary.

To implement section 107 of SSAA'94, we would specify under proposed § 482.55(b)(3) that hospitals must evaluate the need for hospice as well as other posthospital care. To implement section 4321(a) of the BBA '97 we would specify under proposed 482.55(b)(7) that the discharge planning evaluation must include a list of home health agencies that participate in the Medicare program and whose services are available to the patient, serve the area in which the patient resides, and request to be listed. Since, section 4321(a) requires listing the availability of individuals and entities, we have been questioned as to who those individuals and entities are. We have determined that since section 1861(m) of the Act identifies home health services as items or services furnished by a home health agency, or by others under arrangement with the agency, section 4321(a) is referring to Medicare participating home health agencies. Also in § 482.55(b)(7), we have proposed that the HHA should determine the geographic area in which the patient resides. We believe the HHA should determine the geographic area because the HHA is in the best position to know its service area and presumably, would not misrepresent its services by requesting to be listed for an area it does not serve. Discharge planning is effective if there are resources available to the patients at discharge. A hospital's ability to provide patients with outside resources for posthospital care are essential to allow many patients to stay at home which is a much less expensive alternative than institutionalization.

Under proposed 482.55(c)(6), we propose to require that the hospital tailor the plan, where possible, to the preferences of the patient and family. Specifically, we would state that the discharge plan must inform the patient (or patient's family) of their freedom to choose among available Medicare-participating providers that are capable of furnishing the needed services (such as SNF or HHA services) and must, if possible, respect the patient's or family expressed preference. Also, the discharge plan shall not specify or otherwise limit the qualified providers that are available to the patient. The intent of this change is to provide the patient with the freedom of choice to determine which HHA will provide care in accordance with Section 1802 of the Act, which states that beneficiaries may obtain health services from any Medicare participating provider. As written, section 1861 (ee) of the Act requires Medicare participating hospitals, as part of their discharge evaluation, to provide patients with a list of Medicare-certified home health agencies that serve a patient's

geographic area and request to be listed by the hospital.

Hospitals and managed care organizations (MCO) have expressed concern as to whether the BBA'97 change was intended to apply to patients in managed care plans. MCO members are limited as to what services they may obtain from sources other than through the MCO. Therefore, providing members with a standardized list of all HHAs in the area can be misleading and potentially, financially harmful since MCO enrollees may be liable for services that they obtain from sources other than the MCO, and patients may interpret a list of HHAs that are not available to them under their health plan to mean that they are authorized by the MCO. This does not mean that Medicare MCO members in particular are denied the freedom of choice they are entitled to under section 1802 of the Act. Medicare beneficiaries exercise their freedom of choice when they voluntarily enrolle in the MCO and agree to adhere to the plans provisions on coverage.

To alleviate the confusion, hospitals can provide MCO patients with a list of available and accessible HHAs approved by the MCO. Another option is, when discussing discharge planning with patients, hospitals can determine whether the beneficiary has made any prior commitments through enrollment in a managed care organization. Where this is the case, the patient should be informed of the potential consequences of going outside the plan for services. The discharge planning process is initiated when a patient is admitted to the hospital. The collection of data includes verifying the patient's health insurance. At this time, the hospital personnel responsible for discharge planning activities can retrieve this information and initiate communication with the MCO to coordinate available and accessible posthospital care. We solicit the public for comments on this issue.

HCFA has received a number of questions concerning section 4321(a). These questions include: How does the hospital compile the list of agencies? What is the hospital's responsibility and liability for providing a list? Is there a form for home health agencies to complete to request placement on a hospital's list? We welcome public comments on these questions and we will take these comments into consideration when developing the final rule.

The process of making a choice includes being provided options to make an informed and confident decision. Hospital providing a list of available Medicare-certified home health agencies will assist patients in making such decisions. Although a hospital is free to design the list's format, the list is neither a recommendation nor endorsement by the hospital of any particular home health agency's quality of care. If HHAs do not meet all criteria, the hospitals are under no obligation to place that HHA on the list. The list should be legible and should not be used to specify or limit the choice of a HHA.

Under proposed § 482.55(c)(7), we would state that the discharge plan must identify those entities to whom the patient is referred in which the hospital has a disclosable financial interest or those entities which have a financial interest in the hospital. ''Disclosable financial interest'' will be defined in the rule-making process which implements section 1866(a)(1)(S) of the Act. In the interim, we suggest that hospitals reference the Disclosure of Ownership and Control provisions of 42 CFR 420 subpart C, which sets forth requirements for providers to disclose ownership and control information and identities of managing employees. If a hospital refers patients about to be discharged and in need of services, only to entities it owns or controls, then the hospital is infringing on the rights of the patient to choose the facility they would like to go to for services. The proposed disclosable financial interest requirement is an effort to increase the beneficiary's awareness of the actual or potential financial incentive a hospital may receive as a result of the referral. This regulation supports and extends our focus on patient-centered outcomes of care. We invite comments on this proposed requirement and other concerns hospitals may have regarding their ability both operationally and financially to undertake this approach.

In proposed § 482.55(e), we propose to add the requirement that the hospital's discharge planning process be an integral part of the hospital's quality assessment and performance improvement program. We believe this change is needed to enhance the effectiveness of the hospital's discharge planning program and to emphasize the important role of discharge planning in contributing to overall quality of care in a hospital.

We are not proposing any other changes in the current discharge planning COP. In view of the specificity of section 1861(ee) of the Act and the relatively recent implementation of that legislation through notice and comment rulemaking, we do not believe there is any further benefit to the public to be obtained by again requesting public comment on the parts of the regulation that we are republishing without change. Thus, with the exception discussed below, we are soliciting comments only on the proposed changes to the discharge planning requirements, rather than on the entire discharge planning COP.

Proposed § 482.55(b) (5) and (6) require that hospital personnel must complete the required discharge planning evaluation on a timely basis and include it in the medical record, thus ensuring that appropriate arrangements for posthospital care are made before discharge and avoiding unnecessary delays in discharge. We believe these requirements, which has been carried over without change from existing § 482.43(b) (5) and (6), are useful because they emphasize the need for prompt action to assess and act on the discharge planning needs of patients. We note that we considered including under proposed § 482.55(c) similar requirements about the discharge plan itself; however, we decided not to do so because we believe the existing requirements will ensure that a discharge plan is completed and available far enough in advance of discharge to allow it to be put into practice. Nevertheless, it is conceivable that some may interpret the absence of an explicit rule on the timing of the plan as an indication that it would be acceptable to have only a partial or incomplete plan at the time of discharge, or even to develop an after-the-fact ''plan'' that does not anticipate needs and try to meet them, but instead merely records and attempts to rationalize the postdischarge care already received. We welcome comments on whether the possibility of a misunderstanding of this point is strong enough to warrant adding, in the final rule, an explicit requirement that the discharge plan itself must be completed on a timely basis and entered into the medical record. We will consider the comments received on this issue, and may add an explicit requirement on this point to the final rule.

Possible Use of the Uniform Needs Assessment Instrument. In 1986, Congress directed the Secretary to develop a uniform needs assessment instrument (UNAI), or instruments, to serve primarily as a standardized means of evaluating an individual's needs for posthospital or supportive care. Congress also envisioned the possibility of the UNAI being used for determining whether individuals should receive services provided under publicly funded programs (that is, linking the individual's health status per the UNAI

to decisions regarding the scope and duration of services to be covered). In addition, the UNAI was envisioned as a vehicle for tracking individual patients across different Medicare service providers (primarily HHAs and SNFs). Although Congress directed the Secretary to produce the UNAI, there was no direction concerning its implementation. Thus, there is no statutory obligation to use the UNAI in practice.

The Secretary appointed a panel of experts, with HCFA providing the staff support services, to develop the UNAI. The expert panel was successful in devising a consensus tool that was brief, described the patient's functional status, nursing and other care requirements, and available family/care giver supports. The UNAI was seen as having content validity and clinical utility as judged by the comments of a group of experts and a stratified random sample of providers. The final UNAI and a comprehensive report about its development were submitted to the Congress in 1992. While the panel was enthusiastic about the potential for the UNAI as a posthospital discharge planning tool and a means of tracking a patient across provider types, the panel did not believe the UNAI could be used to evaluate an individual's eligibility for posthospital services under the current Medicare benefit structure.

The UNAI and the Report to Congress have been widely disseminated, and many hospitals have chosen to begin using the tool because it provides a useful method to organize their discharge planning processes. Currently, HCFA is preparing to field test the UNAI in hospitals, HHAs, and SNFs. The field test will rely on provider staff to complete the UNAI, and will provide information on the UNAI's reliability, validity, and administrative feasibility. HCFA's contractor for the field test, Research Triangle Institute, is also developing a ''high risk screener,'' which will be used to identify those Medicare patients in need of an intensive discharge planning evaluation and thereby reduce the number of patients who would be subject to the UNAI. For example, a Medicare patient who has a minor operation and will return to the home with support from an able spouse and adult children nearby likely would pass the screener and not receive the UNAI as part of the hospital's discharge planning effort for that patient. However, an elderly beneficiary who suffers a severe stroke, and has a spouse in frail health and no children nearby would certainly fail the screener and would receive the UNAI as part of the hospital's discharge planning for that patient.

In the preamble to our December 13, 1994 final rule on discharge planning (59 FR 64141), we discussed our work on the UNAI, but we did not establish a requirement for its use. Now, with a comprehensive effort to change the hospital conditions of participation to a more patient-centered, outcome-oriented approach, and a strong emphasis on quality assessment and performance improvement, coupled with HCFA's intention to use data—particularly functional assessment data—more widely in care giving, quality improvement, and consumer information, we are considering requiring hospitals to use the UNAI to assess Medicare patients who are at-risk of needing posthospital services. The purposes of imposing the UNAI as a standard hospital discharge planning tool for Medicare patients would be to: (1) Ensure that all relevant factors are considered in evaluating an individual's needs for continuing care; (2) foster more uniform decisionmaking about the need for posthospital care services; (3) direct those patients to the most effective and efficient approach to posthospital care services; (4) provide posthospital care service providers with more complete and consistent baseline information about the patient in order to facilitate continuity of care and early assessment and care planning by the posthospital provider; and (5) enable managed care organizations and HCFA to track the course of outcomes of individual patients across provider types within the same health care episode. One primary benefit of standardizing the needs assessment process is that the use of common language and definitions enables the type of quality monitoring and improvement efforts that depend on consistent data and health status/outcome measures.

The establishment of common data elements will also allow the same types of measures to be used across care settings. Another advantage associated with using the UNAI across provider types is that we intend that it ''map'' to other assessment tools, such as the Minimum Data Set in SNFs and the standard core assessment data set we plan to propose shortly for use in HHAs. Thus, if a UNAI accompanies a patient to an HHA, the HHA can use most of the information on the UNAI to complete a number of items on the HHA standard assessment data set. This ultimately would decrease provider burden by streamlining the assessment processes and eliminating the need for assessing and reporting redundant information. It also would enable providers and managed care entities to track and understand care outcomes more fully.

The UNAI is not a comprehensive assessment tool, nor is it adequate for comprehensive care planning. Rather, it gives a snapshot view of the patient's functional status and support systems in the home and community to help caregivers direct the patient to the next source of care and to give the continuing care provider baseline information to make initial assessment, care planning, and service delivery more efficient and individualized.

Although we are not now formally proposing to require use of the UNAI, we invite comment from the hospital community, especially discharge planners, as well as from SNFs, HHAs, and others, about the desirability of having a standard approach to posthospital discharge planning for Medicare patients who fail the high-risk screener. We invite comment on the following questions, as well as any other related comments:

(1) Would the use of a standard posthospital discharge planning tool for Medicare patients be helpful to the hospital, the patients, and the posthospital care providers in their efforts to ensure the patient receives the most effective, efficient, and desirable posthospital services necessary to address the patients' continuing care needs? If so, why, and if not, why not?

(2) Would a proposal that limits the required use of the UNAI to Medicare patients only (the States could impose it separately if they wished for Medicaid patients) create duplicate or multiple systems within a hospital and create more problems than benefits? Should the UNAI be used for every patient over a certain age (e.g., 50) for whom discharge planning is necessary? How would other payers (e.g., fee-for-service or managed care plans) be affected by a Federal requirement to use the UNAI?

Subpart C—Organizational Environment

12. Administration of Organizational Environment (§ 482.110)

The proposed condition on administration of organizational environment would replace the existing regulations at § 482.11 (Condition of participation: Compliance with Federal, State, and local laws) and § 482.12 (Condition of participation: Governing body). Combining these provisions would simplify the structure of the regulations. In addition, it would emphasize that if State or local law provides for the licensing of hospitals, and an institution in the State wishes to

participate in Medicare as a separate hospital (rather than as an organizational unit of another provider), that institution must also show that it is regarded as a separate entity by the State for licensure purposes.

In developing the proposed new condition, we have relocated three of the standards previously in the current governing body COP. These are the standard on medical staff (§ 482.12(a)), the standard on care of patients (§ 482.12(c)), and the standard on emergency services (§ 482.12(f)). Under the cross-functional approach we are following in these proposed rules, medical staff issues would be covered by the proposed new condition on human resources (§ 482.125), and patient care issues would be covered in the new COP that includes patient care (§ 482.20). As discussed above, we propose to create a new condition on emergency services which would include the rules now stated under § 482.12(f) with respect to appraisal, initial treatment, and referral of emergency patients by hospitals that do not provide emergency services.

The primary requirement under the proposed governing body COP is that a hospital's governing body, other organized group, or an individual (hereafter ''governing body'') is legally responsible for the management and provision of all care furnished to hospital patients, including the structure needed to administer the hospital effectively. Thus, the governing body must create an environment that helps ensure the provision of high quality care that is consistent with patient needs and the effective administration of the hospital. In the proposed new condition, we emphasize the responsibility of the hospital governing body for the entire operation of the hospital, including care furnished under contracts and arrangements, the appointment of an administrator, the appointment of the medical staff and its bylaws, and the implementation of effective budgeting, accounting, and quality control programs. Although these requirements necessitate the use of certain processes, they are essential to ensuring that the entity with which the Secretary has entered into a participation agreement is in fact able to ensure patient health and safety. To help ensure this accountability, we have specified the responsibility of the governing body for the hospital's compliance with all applicable conditions of participation and standards. In addition, performance of these basic organizational functions is, in our view, a minimum condition for the creation of an environment in which appropriate patient-centered activity can occur.

We are proposing that a hospital must notify HCFA or the State survey agency whenever the hospital adds a new service category to the list of services it offers (proposed § 482.110(b)(2)(i)). We believe this is necessary so that the State survey agency may determine whether an onsite survey of the new service is necessary and to ensure that the survey team may have the correct number and type of qualified members when it next visits the hospital. This should then improve the speed and efficiency with which the hospital's certification process can be accomplished.

In addition, we are proposing to require that a hospital notify HCFA (through its regional offices) whenever it adds a new service site (proposed § 482.110(b)(2)(ii)). For example, a hospital would need to notify us if it were to acquire a physician's office and consider it an offsite hospital outpatient clinic. We believe this is necessary so that we may decide whether an onsite survey is necessary to assure that the addition does not alter the previous certification decision regarding the hospital. Further, HCFA would need to review the new service site to assure that it meets the level of integration required for inclusion of the new site as a part of the provider. This will ensure that appropriate payment is made. We have issued instructions outlining the criteria that must be met in order to demonstrate integration inherent in classification of an offsite service as part of the hospital in Program Memorandum A–96–7.

Proposed § 482.110(b)(3) and (4) restate with only minor editorial changes current requirements concerning the governing body's responsibilities for an institutional plan and budget, as well as the medical staff's bylaws. We propose to retain these requirements, in accordance with section 1861(e) of the Act.

Under proposed § 482.110(c), we would redesignate, with changes, the requirements under existing § 482.12(c)(5) concerning a hospital's responsibility to identify potential organ donors. We recognize that these provisions, in particular the requirement that a hospital have written protocols addressing various aspects of its organ procurement responsibilities, are more prescriptive and process-oriented than other parts of these proposed rules. However, we believe it is necessary to retain these regulations in their existing form to implement section 1138 of the Act, which specifically requires written hospital protocols for organ procurement. The changes to this section are discussed below.

We are revising § 482.110(c)(ii) (formerly § 482.12(c)(5)(i)(A)) and adding new requirements under § 482.110(c)(1)(iv) concerning organ procurement organizations (OPOs) and hospitals. The development of these requirements is in response to issues raised during public hearings held by the Department on December 11 through 13, 1996, to examine the allocation policies for liver transplantation and to receive comments regarding methods to increase organ donation. During those hearings, it became abundantly clear that there is a critical shortage of organs available for lifesaving transplantation. While the science of transplantation has made progress over the last two decades, lives that could be saved continue to be lost because of an inadequate supply of donor organs. For example, an estimated 12,000 to 15,000 deaths occur in the United States each year that could yield suitable donor organs, yet in 1996 no more than 5,400 resulted in donations. In April 1997, approximately 52,000 Americans were waiting for organ transplants. Therefore, we believe it is appropriate to propose revisions to the current hospital conditions relating to organ donation because we expect these revisions will result in a significant number of lives being saved.

The existing regulations merely repeat the language in section 1138 of the Social Security Act which requires hospitals to assure that families are advised of the right to donate or not donate organs, encourage discretion and sensitivity to family values, and notify an OPO of potential donors. We are proposing to revise the hospital conditions of participation regarding organ donation to emphasize the role and relationship of the OPO in the process. Although the proposed changes increase the importance of the OPO, our aim is that they will result in a more collaborative organ donation process which achieves positive results. That is, we hope hospitals and OPOs will work together in dealing with their individual and unique circumstances and, using the best available practices, achieve significant increases in the rate of organ donations.

Specifically, we are proposing to specify that the hospital must ensure that the family is advised, in collaboration with the OPO with which the hospital has an agreement, of their right to donate or decline to donate (§ 482.110(c)(1)(ii)). This proposal is based on research in the field of organ donation that indicates that consent to donation is highest when the request is

made by the staff of the OPO rather than the hospital. OPO staff are specialty trained medical personnel. They have training in bereavement counseling and extensive experience in dealing with families undergoing the loss of a loved one. They have knowledge of brain death and are particularly skilled in making complicated medical terminology understandable to a grieving family. Most importantly, organ donation is their principal field, whereas hospital staff have numerous other responsibilities. Further, donor consent rates tend to be higher when there is a time lapse between the hospital notifying the family of a death and the request for organ donation.

In proposing this change, we considered the possibility that we might be viewed as holding hospitals responsible for ensuring that a function, such as advising a family of their organ donation rights, be performed without providing them with the ability to control the situation. That is, the hospital cannot control the OPO and may consider that it may be a victim of poor OPO performance. However, the conditions of coverage for OPOs include performance standards that hold OPOs accountable for achieving a specified number of donors and organs based on the size of the population it serves. We believe these performance standards will motivate OPOs to provide satisfactory service to hospitals. Moreover, we note that the proposed hospital conditions hold hospitals accountable for ensuring that they have written protocols and do the following:

- Identify potential organ donors as defined by the OPO with which the hospital has an agreement;
- Notify the OPO of such potential donors;
- Assure, in collaboration with the OPO with which the hospital has an agreement, that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to donate;
- Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors; and
- Ensure that the hospital works cooperatively with the OPO with which the hospital has an agreement, in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs take place.

We expect that if the hospitals and OPOs are not achieving the desired results the hospitals would reevaluate and revise their protocols. Hospitals would not be cited for a deficiency of this standard if the hospital has appropriate protocols, regardless of the success of OPO staff in acquiring donors.

We also are proposing to revise an existing requirement that specifies that the hospital must notify OPOs of potential organ donors. There is a good deal of variability among hospitals in referral patterns. Some hospitals do not call the OPO unless they have determined that the patient is medically suited to be a donor and the family has consented. On the other hand, some hospitals refer all deaths to the OPO. Most hospitals have established criteria, such as age or absence of systemic disease, to determine if a potential donor should be referred to the OPO.

In evaluating the organ donor shortage and the actions that hospitals may take with regard to donor referral, we considered the following options:

- Maintain the current requirement which provides hospitals with the flexibility to determine appropriate referrals through their written protocols;
- Require mandatory reporting of all death of patients under age 75 to the OPOs; and
- Require mandatory reporting of deaths to OPOs using protocols defined by the OPOs.

During our analysis, we identified a number of advantages and disadvantages to each of these alternatives before we concluded with the proposal to require mandatory reporting of deaths to OPOs using protocols defined by the OPO as discussed below. However, we are specifically soliciting comments on the advantages and disadvantages of the various options, and inviting identification of additional alternatives and empirical data supporting various opinions, during the public comment period.

The advantages of the current requirement, which specifies that hospitals have a protocol for referring potential donors, are that it provides hospitals with desired flexibility and it reiterates the language of the statute. However, there are significant disadvantages to this approach. The primary concern is that many hospitals have never referred a potential donor. As noted above, we believe that there has been a large number of potential donors that have been missed; that is, we believe the number of potential donors is double to triple the number of current donors. We are concerned that this flexibility has resulted in a significant number of hospitals failing to refer all potential donors and some hospitals not referring any donors. Some hospitals view as potential donors only those in whom consent to donate has already been obtained and do not even attempt to ask other families about the possibility of donating; others refer only when they consider the deceased to be a good candidate or when they believe the family may consent to the donation. This leads to a loss of opportunity for families for whom the gift of a loved one's organ may be the first step in the healing process as well as the loss of a substantial number of life-saving organs.

We also considered the alternative of requiring referrals of all deaths to the OPO. The State of Pennsylvania has implemented this practice. The resulting increase in donation in Eastern Pennsylvania has been at least 10-percent. We believe telecommunication technology currently exists to permit low-cost and efficient implementation of a policy requiring referrals of all deaths. OPOs that have implemented such programs indicate that reporting of an individual's death and relevant medical information takes only 5 to 10 minutes of time by hospital staff. Under such a system of mandatory death reporting, it is reasonable to assume that no potential donor will go unidentified and few, if any, families of potential donors will go without being given the opportunity to donate. This system also has the advantage of relieving hospital staff of the burden of making any assessment of donor suitability or the families' willingness to donate. Finally, as more families are educated about organ donation, even if they decide not to donate, myths that inhibit organ donation may be dispelled.

Despite the major advantages to this alternative, there are potential problems. There is clearly a significant cost involved in providing and interpreting information on over 1 million deaths annually. Conservative implementation estimates of this alternative are about $4 million annually (1 million deaths times 5 minutes of hospital and OPO time at an assumed average salary cost of $50,000), and may be as great as $8 to $10 million. Arguably, the saving of even a single statistical life would justify such a cost, using standard benefit-cost analysis assumptions. Nonetheless, we recognize that these costs should not be imposed if less costly approaches can also achieve increased organ donation. In discussing this alternative with the OPO industry, we have been advised by some OPOs that they are concerned about implementing such a system because they would have to handle a large number of unproductive referrals. That is, of the approximately 1 million deaths

annually, only about 12,000 to 15,000 are potential organ donors.

This proposed regulation includes the requirement that hospitals report all potential donors using protocols as defined by the OPO. This alternative has the advantage of providing support for OPOs in dealing with low referral hospitals, while providing a great deal of flexibility for OPOs to respond to local community situations and resource limitations. As noted above, we solicit comments on alternatives that could be more responsive to the national organ shortage. We are also considering whether to propose in the OPO conditions of coverage a performance standard that could be used to determine the extent of organ donations. In principle, procedural standards related to organ procurement could be replaced by an outcome standard related to organ recovery. However, since we are not clear as to how to design or implement the most cost-effective, low-cost standard we would welcome public comment.

We are aware that this proposal, by giving the OPO responsibility for defining potential organ donors and the protocol for referring such donors to the OPO, raises questions about the impact that it will have on the donation and retrieval of a variety of tissues that are also used in patient care. Tissue transplants also are important procedures that improve, and sometimes save, the lives of recipients. It is our expectation that hospitals, OPOs, eye, and tissue banks will work cooperatively and effectively to facilitate and enhance both organ and tissue donation. We recognize that there is considerable local variation in how these arrangements are currently carried out and how they might be done under our proposed changes. We will appreciate receiving comments on how these proposed changes are likely to impact on tissue donation, as well as suggestions on what measures we could appropriately take to maximize both tissue and organ donation.

Finally, we are proposing to add a new requirement that specifies that hospitals work cooperatively with the designated OPO in educating hospital staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining patients while necessary testing and placement of potential donor organs take place (proposed § 482.110(c)(1)(iv)). We do not believe this requirement is unduly burdensome on hospitals since all reasonable hospital costs incurred with respect to any organ procurement effort are paid. To further the cooperative efforts between hospitals and OPOs, we are also proposing to add a requirement that hospitals must provide requested data related to patients eligible for transplantation either directly to the Department or through the Organ Procurement or Transplantation Network. This requirement is explained further in § 482.120 ''Information Management''. We invite comments on the content of this new requirement.

13. Infection Control (§ 482.115)

The present requirements on infection control (§ 482.42) were promulgated as a separate COP largely due to the seriousness of the problem of Nosocomial infections. Nosocomial infections subject patients to significant additional pain and risk, prolong hospital stays, and lead to significant additional costs in health care spending.

We propose to maintain a separate COP on infection control because we believe it is vital for protecting patient health and safety. We propose to retain most of the standards under the current COP, but we would strengthen its focus by requiring hospitals to take appropriate actions that result in improvement when problems are identified in their infection control programs. This is in concert with the proposed quality assessment and performance improvement COP, of which infection control must be an integral part.

The proposed infection control condition places accountability on hospitals to prevent, control, and investigate infections and communicable diseases, and take actions that result in improvements. However, the proposed condition allows flexibility for hospitals to determine how to meet these objectives. This includes the flexibility to determine how much training in infection control is necessary for the hospital's personnel.

We propose to delete the present requirement that the hospital maintain a log of incidents related to infections and communicable diseases. In keeping with the outcome-oriented approach of this rule, we propose that the hospital must have a method of identifying problems in its infection control program and take appropriate actions that result in improvement. Although use of a log may be one method to identify problems, we do not intend to prescribe how a hospital should identify problems.

We considered requiring hospitals to meet Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA) standards for providing an environment to avoid sources of infections and communicable diseases. However, such a requirement would raise questions as to which CDC or OSHA standards must be met. Moreover, where alternative sets of professionally recognized standards exist, we do not wish to restrict hospital flexibility by mandating compliance with a particular body of standards. Therefore, we are not mandating that hospitals follow any specific set of infection control guidelines; however, such guidelines are published by CDC, the Association of Practitioners in Infection Control (APIC), the American Hospital Association (AHA), and the JCAHO and are available as resources on infection control practices.

We also considered including specific requirements concerning employee health status issues. However, we believe the hospital's obligation to protect patients from employees with communicable diseases is covered in the proposed language that states that the hospital maintains an effective infection control program that protects patients and hospital staff by preventing and controlling infections and communicable diseases. Adequate assessments of employee health status fall under this language as part of the protective responsibilities of the hospital.

14. Information Management (§ 482.120)

We propose to consolidate current § 482.24 ''Condition of participation: Medical record services'', and record requirements in several other COPs into a new ''Information management'' COP which would reflect the increasing automation and integration of patient care data. This new COP would require that a hospital maintain an information system to record, communicate, and measure hospital performance in order to assure that patient needs are documented and met. The information system is also needed to support the hospital's quality assessment and performance improvement program.

The condition consists of two standards. In both standards, we have not retained many current process-oriented requirements concerning how a hospital must maintain its medical records; instead, we have kept only those requirements needed for accurate documentation of a patient stay and for quality assessment and performance improvement purposes. These requirements should help ensure that orders are communicated and documented accurately, thus reducing the risk of errors that could jeopardize patients' health and safety.

The first standard, ''Health Information System'', focuses on patient

care and outcomes. First, we would require the hospital to maintain clinical records on all patients. This requirement not only implements a specific statutory requirement (section 1861(e)(2) of the Act), but also provides a basis for the quality assessment and performance improvement activities that we expect will lead to a high standard of care for all patients. We have retained the current record retention requirement of 5 years because we believe access to records during this period is essential to protect the health and safety of current patients, since clinicians may well need the details of prior treatment to assess and treat current conditions. Five years has been the minimum requirement since 1986 and it has proved to be a clear, workable, and not overly burdensome standard.

One part of this standard on which we especially seek comment concerns the authentication of record entries. Under proposed § 482.120(a)(5), we would consolidate the present requirements at § 482.24(c)(1)(i) and (ii) regarding authentication of entries in the medical record to state that all entries must be legible, dated, and authenticated in written or electronic form by whomever is responsible for ordering or providing the service. We are proposing to delete the current requirement at § 482.23(c)(2)(ii) on verbal orders because we believe our proposed requirement at § 482.120(a)(5) would cover authentication of verbal orders. The present requirement at § 482.24(c)(1)(ii), which states that authentication may include signatures, written initials or computer entry, would also be deleted. Although these are accepted standards of practice, we do not believe it is necessary that the regulations include this level of prescriptive detail.

We are seeking comment from as broad a range of interests as possible on the issue of authentication of medical record entries. We recognize that there is a strong interest in the hospital industry in modifying, if not eliminating, the requirement for authentication, because of questions about whether authentication adds value to the quality of the medical record, especially when the countersignature comes after the service has been delivered to the patient. However, others believe that absence of authentication leads to questions of accountability. Therefore, we request comment and suggested language, as appropriate, on this issue.

Regarding the issue of verbal orders, the present requirement at § 482.23(c)(2)(ii) states that verbal orders must be signed or initialed by the prescribing practitioner as soon as possible. We invite comment on the issue of whether a timeframe should be specified for signing verbal orders. We believe that many States have laws governing timeframes in which verbal orders must be signed; therefore a Federal specification may not be necessary.

Currently, transplant centers report data to the Organ Procurement and Transplantation Network, the Scientific Registry, and organ procurement organizations regarding the disposition of organs made available for transplant. These data include information regarding patients waiting for transplants, information on those who have received a transplant, follow-up data on patients who have received a transplant, and information on those offered an organ for transplant but declining to use the organ at the time. Moreover, the information submission is voluntary on the part of the transplant centers.

For the most part, this system of information exchange has worked very well. However, from time to time, some concerns have arisen regarding the voluntary nature of the data submission, ownership of the data, and public access of the information. In an effort to overcome any confusion surrounding this information system and to assure that all facilities submit appropriate data timely, we are proposing to include a provision in section 482.120, information management, related to transplantation data.

Specifically, we are proposing to add a requirement that hospitals that perform transplants, whether they are approved by Medicare for coverage of the transplant or not, must provide requested data related to patients eligible for transplantation either directly to the Department or through the Organ Procurement and Transplantation Network. The proposal clarifies that data submission is no longer voluntary, but is a requirement for the hospital's participation in the Medicare program.

We believe there is authority in both section 1861(e)(9) and section 1138 of the Act for this requirement. First, section 1861(e)(9) provides that the Secretary may require hospitals participating in the Medicare program ''to meet such other requirements that the Secretary finds necessary in the interests of the health and safety of individuals who are furnished services in the institution.'' When we determine whether hospitals are fit for inclusion (or continued inclusion) in the Medicare program, we have an interest in knowing how well the hospital is performing the full range of services it provides to its patients. A hospital's history with respect to the transplant services it provides is one area, among many, that helps tell us whether the institution is providing high quality services in the safe and healthful environment the statute requires, and we believe that reviewing data from this area of operation is no less useful for this purpose than evaluating other surgical or care areas of the hospital. Second, section 1138 requires hospitals to abide by the rules and requirements of the Organ Procurement and Transplantation Networks (OPTNs). Where OPTNs require hospitals to furnish the kind of data addressed in this proposed rule, hospitals would be obligated to provide it.

The second standard in the Information Management COP, ''Management of the Information Systems'', contains requirements on the integrity, effectiveness, confidentiality, and security of the hospital's data systems that are similar to current requirements shorn of their process-oriented details. We are also proposing in this standard to expand the current requirement in § 482.25(b)(8), which discusses the dissemination of a patient's drug profile to the hospital's professional staff. We propose building on this to require that all medical information on a patient be available to all authorized professional staff who provide medical care to the patient. This is consistent with the emphasis on an interdisciplinary plan of care for each patient, and an integrated approach towards a patient's needs, both of which depend on practitioners having accurate and current information to deliver appropriate and necessary care.

15. Human Resources (§ 482.125)

Current regulations, which are organized on a department-by-department basis, contain scattered requirements concerning the qualifications and numerical staffing standards for nursing and other hospital staff, and for doctors of medicine or osteopathy and other practitioners with privileges to treat hospital patients. For example, there is a separate condition on medical staff at § 482.22, and several COPs, including nursing services (§ 482.23), medical record services (§ 482.24), pharmaceutical services (§ 482.25), and others, contain requirements for screening and credentialling of medical staff members and for employment of (or contracting with) adequate numbers of qualified nursing and other nonphysician staff.

Under the integrated, interdisciplinary approach inherent to these proposed regulations, we are consolidating these scattered references into a single condition of participation on human resources. The overall goal of the new proposed COP would be to ensure that all hospital areas are staffed with sufficient qualified personnel to meet the needs of the hospital's patients. We also propose to eliminate many process-oriented requirements, in particular those currently set forth in §§ 482.12(a) and 482.22, relating to the composition, organization, and conduct of a hospital's medical staff. Although a process-oriented requirement, we have retained the current requirement that the medical staff operate under bylaws because section 1861(e)(3) of the Act explicitly requires them.

In proposing these changes to the current medical staff requirements, we do not intend to discount the value to a hospital of having a carefully selected and well-organized medical staff. On the contrary, we believe it is self-evident that the medical staff has a critical role in ensuring that high quality care is delivered consistently and that any hazards to patients are promptly detected and eliminated. However, individual hospitals, their employees or contractors, and the professionals who have been granted practice privileges may choose to have medical staff functions performed in a variety of appropriate ways, and we do not believe it is necessary to prescribe to a hospital what the composition or organization of its medical staff should be. For example, existing § 482.12(a)(7) has been interpreted by some to prohibit hospitals from requiring specialty board certification or eligibility as a necessary condition for medical staff membership. However, there is considerable disagreement between hospitals and physicians as to whether board certification or eligibility is an important indicator of professional competence. In view of this diversity of opinion and absent any indication that the quality of care would decline if the current requirement were deleted, we are proposing to eliminate the current requirement and to allow each hospital to determine, in consultation with its medical staff, whether requiring certification, fellowship, or membership in a specialty body or society would enhance the quality of care for the hospital's patients.

The proposed new condition consists of three standards that support the COP's aim that the hospital be staffed with sufficient qualified personnel. The first of these has to do with the qualifications of those individuals who furnish health care services to patients of the hospital. We wish to emphasize that the requirement would apply to all such persons, whether or not they are employed or compensated by the hospital and, if they are compensated, without regard to whether they are salaried employees or contractors. The standard also applies to those separately licensed practitioners, such as doctors of medicine or osteopathy, who typically practice independently and bill patients or their insurers, rather than the hospital, for their services.

This proposed standard reflects our view that the conditions of participation should not prescribe specific Federal personnel qualification requirements for nonphysician personnel, or attempt to limit or specify the functions they may perform, unless the Medicare statute requires us to do so. We believe this is the best course of action for several reasons. First, most States have in effect laws and regulations governing licensure and scope of practice for health care workers. We believe individual hospitals and their medical staffs, working within the context of applicable State law and regulations, are best able to determine which personnel to use and how to use them. Moreover, the emphasis of the proposed requirements in this area, as in other areas affected by these regulations, is not on whether staff have specific credentials or were selected under formalized procedures, but on whether the outcome of the hospital's staffing practices is the delivery of safe, high quality care.

We recognize that there may be some cases in which the absence of any State requirements for a category of hospital worker in a particular State may mean that no specific credential is required for performance of the function in that State. However, the hospital would remain obligated under proposed § 482.125(a) to ensure that personnel are qualified to provide or supervise services, and would be fully accountable under this section as well as under other relevant parts of the regulations (such as § 482.20, Patient Care) for the quality of care provided. Individual hospitals are free to develop their own specific credential requirements if they believe that doing so is in the best interest of their patients.

In addition, we note that among the resources a hospital has in acquiring and maintaining qualified staff is the National Practitioner Data Bank, which was authorized by the Health Care Quality Improvement Act (HCQIA) of 1986 (Pub. L. 99–660). The HCQIA requires that hospitals request information from the National Practitioner Data Bank at the time a physician, dentist, or other health care practitioner applies for a position on its medical staff (courtesy or otherwise) or for clinical privileges at the hospital; and every 2 years (biennially) on all physicians, dentists, and other health practitioners who are on its medical staff (courtesy or otherwise) who have clinical privileges at the hospital.

The HCQIA requires that hospitals report to the National Practitioner Data Bank all professional review actions, based on reasons related to professional competence or conduct, adversely affecting clinical privileges of physicians and dentists for a period longer than 30 days; or voluntary surrender or restriction of clinical privileges for physicians and dentists while under, or to avoid, investigation.

We recognize that some may ask whether the hospital's responsibility to use qualified personnel is sufficient to assure that qualified staff are used in States with weak licensure programs and, in such States, whether Medicare should impose additional requirements or undertake a larger role. Therefore, we specifically invite public comments on this issue especially with regards to specific examples where States have weak or no licensure requirements for hospital health professions. We hope that commenters who believe Medicare should issue additional requirements would offer specific suggestions and any available empirical data to support such suggestions.

The second proposed standard, ''Staffing (§ 482.125(b)), retains all of the nurse staffing requirements in current regulations at § 482.23(b) that are essential to the professional role and importance of nurses in a hospital. Of the six requirements in this standard, the first two are general in nature and the remaining four deal with specific nursing needs. Under the first requirement a hospital's staffing must reflect the volume of patients, patient acuity, and intensity of the services provided to ensure desirable patient care outcomes. To enforce this requirement, and because we are concerned about an apparent trend in the country toward reductions in hospital nurse staffing, we also propose as a second requirement that a hospital must develop and use consistently an explicit process to determine on an ongoing basis the level of nursing staff (including registered nurses, licensed practical nurses, and nursing assistants) needed to effectively implement the general requirement for appropriate staffing. This methodology and evidence of its use in meeting the nursing staffing needs of the patients must be available

for public inspection. We are interested in receiving comments on this proposal, specifically:

(1) Is this process-oriented requirement needed and is it strongly predictive of the desired quality outcomes one would associate with the proposed staffing requirement at § 482.125(b)(1)?

(2) If not, are there other requirements (such as specific numerical ratios) that would better achieve the desired outcomes?

The third requirement under the staffing standard is that a hospital maintain 24-hour registered nurse coverage if it does not have a waiver in effect under 42 CFR 405.1910(c). Twenty-four hour nursing coverage is required under section 1861(e)(5) of the Act, and thus we are continuing to include this requirement. The remaining three requirements under this staffing standard discuss the availability of registered nurses for bedside care, the responsibility of a registered nurse for managing nursing care for patients, adherence of nurses to hospital policies and procedures, and hospital management of nonemployee nursing personnel. We recognize that some of the other nurse staffing requirements are prescriptive and process-oriented, but we believe that they help ensure adequate staffing levels in hospitals. We welcome comments on how these requirements could be revised or simplified without jeopardizing attainment of this goal.

The third proposed standard is ''Education, Training and Performance Evaluation'' (§ 482.125(d)). The education and training sections are intended to ensure that hospital staff are aware of their job responsibilities and capable of meeting them, and that reassigned personnel receive the orientation or training needed to help them adapt to new or additional job demands. We emphasize that under this standard the hospital would be responsible only for ensuring that the individual adequately knows the nature of his or her specific job duties in the hospital. The individual would continue to be responsible for his or her own basic professional education, and for any continuing education needed to retain licensure or professional certification, unless the hospital chooses to assume this responsibility as part of a compensation or incentive arrangement.

The second part of this standard requires that all personnel who furnish health care services in the hospital demonstrate in practice the skills and techniques necessary to perform their assigned duties and responsibilities. While we believe that process requirements that focus on providing training and education to those who provide care and services in the hospital are predictive of positive outcomes and satisfaction for patients (and protection from negative outcomes), we also believe that the real outcome expectation of the requirements is reflected in the demonstrated skills and techniques staff actually use on a routine basis. This is why we are proposing that all personnel furnishing health care services (which would include hospital employees, contractors, and individuals working under arrangements) demonstrate in routine practice the skills and techniques necessary to perform their jobs.

Such a requirement closes the training and education loop. It is not enough for the hospital to demonstrate that individuals have received training, or how much training has been offered and provided. For effective patient care, it is critical that when the staff perform their duties, they actually use the necessary skills and techniques they have been taught to do their jobs correctly. For example, every hospital employee who comes into contact with patients is taught infection control techniques, one of which is hand washing in between patient contacts. If a surveyor observes staff who do not wash their hands between patient contacts, it is of little value that the hospital can show that staff were taught to wash their hands. One of the tasks of the survey process will be to determine if a lapse in performance is simply an isolated failure of one employee (although that can be so serious as to pose a threat to patient health and safety) or if it represents a systemic failure posing a widespread danger. Regardless, this requirement poses no extraordinary burden on the hospital, since the performance expectation of all staff—especially those who directly or indirectly serve patient needs—is that they perform their duties competently and efficiently. This outcome-oriented requirement simply makes explicit this expectation.

16. Physical Environment (§ 482.130)

We propose to replace the requirements on physical environment now at § 482.41 with a new physical environment COP that would require in general that a hospital maintain a physical environment that is free of hazards for patients. The current requirements consist of three safety standards containing separate requirements for buildings, life safety from fire, and facilities. Each of these standards contains requirements on the process of implementing safety standards as well as the physical structures and property that must be available in the hospital.

Based on our experience with applying these current requirements and suggestions from the parties involved in the development of these proposed hospital conditions, we are proposing to reorganize these requirements into two physical environment standards and a separate COP for life safety issues, as discussed below. We believe this reorganization emphasizes the role of physical structures and property in ensuring the delivery of high quality care.

In the first proposed standard, ''Safety management'' (§ 482.130(a)), we have set forth four requirements that we believe are fundamental to effective management of a hospital's physical environment. These include preventing, reporting, and correcting threatening situations, equipment failures, and actual incidents that involve injury to patients or that involve damage to property. Also, we believe proper safety management should include a requirement that a hospital must have an emergency preparedness system to respond to power failures, natural disasters, or other emergencies that disrupt the hospital's ability to provide care. We have chosen not to prescribe the frequency of reporting safety initiatives, such as quarterly reports to the governing body, because we believe the wide range of hospital structures and property requires each hospital to define its own internal reporting practices. We considered specifying which personnel should be responsible for safety management initiatives, but we believe no staff should be exempt from ensuring that the hospital environment is free of hazards. We also believe hospitals commonly employ safety engineers and others who contact all types of personnel when designing and managing safety initiatives.

The second proposed standard, ''Physical Plant and Equipment'' (§ 482.130(b)), combines three current general requirements for a hospital's physical structures and property, but does not include the level of detail in current regulations. (For example, a requirement concerning the location of diagnostic and therapeutic facilities has been deleted.) The requirements simply state that there must be proper storage and disposal of trash and medical waste, proper temperature control, light and ventilation throughout the hospital, adequate power, light, gas and water for patient care during emergencies, and that equipment used for patient care services must be properly maintained.

The inclusion of medical waste and air exchanges is new. These items reflect health and safety concerns in recent years over unsafe medical waste disposal, the proper care of tuberculosis patients, and the prevention of airborne particles and bacteria in hospitals, concerns which led to the publication of CDC guidelines on the disposal of medical waste and the prevention of transmission of mycobacterium tuberculosis (see Occupational Exposure to Bloodborne Pathogens, 56 FR 64004, December 6, 1991 (Final Rule), and Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities, 59 FR 54242, October 28, 1994 (Notice). The requirement on maintaining equipment is a consolidation of several references in the current regulations.

17. Life Safety From Fire (§ 482.135)

The Life Safety Code (LSC) developed by the National Fire Protection Association serves as the basis for many Federal, State, and local fire safety regulations, including those contained in the Medicare conditions of participation for hospitals. The LSC is a nationally recognized standard that includes fire protection requirements necessary to protect patients and residents in health care facilities. Designed to provide a reasonable degree of safety from fire and similar emergencies, the LSC covers construction, fire protection, and occupancy features needed to minimize danger to life from fire, smoke, and fumes. The code may be applied to both new and existing buildings. The National Fire Protection Association revises the LSC periodically to reflect advancements in fire protection.

In the current hospital COPs, the physical environment COP includes a standard, ''Life safety from fire,'' that requires that hospitals comply with the 1985 edition of the Life Safety Code (§ 482.41(b)(1)). Section 482.41(b)(1)(i) then sets forth a ''grandfather'' clause specifying that, under certain circumstances, a hospital that originally complied with the 1967 or 1981 edition of the LSC hospitals may be considered to be in compliance with the life safety standard. The existing regulations also provide that HCFA may waive specific provisions of the LSC that would result in unreasonable hardship upon a facility, as long as the waiver has no adverse effect on patient health and safety. In addition, the regulations permit a hospital to meet a fire and safety code imposed by State law if HCFA finds that the State-imposed code adequately protects patients in hospitals.

In the proposed hospital COPs, we would continue to incorporate the LSC by reference. However, in order to stress the importance of fire safety standards for patient health and safety, we propose to establish a separate condition, ''Life safety from fire,'' at proposed § 482.135. We also propose to update this requirement to specify that hospitals must meet the 1994 edition of the LSC, with no ''grandfathering'' under any of the earlier codes. However, we are also currently considering adoption of the later 1997 edition of the LSC instead of the 1994 edition. We welcome comments on the proposed adoption of the 1997 edition also and will address this issue in the final rule for this proposed rule.

We consider compliance with the LSC to be essential to the safety of patients. As noted above, however, compliance with the LSC currently is a standard within the existing Physical Environment condition of participation. The surveyor that inspects a hospital for LSC purposes often works separately from the team that conducts the rest of the hospital survey, including those portions of the survey that involve other physical environment issues. When the LSC surveyor determines that the LSC is not met, the entire Physical Environment COP is found to be out of compliance. In practice then, the LSC standard essentially is treated as a condition level requirement. Therefore, we believe that establishing a separate COP for the Life Safety Code would accurately reflect its importance for patient health and safety.

We are proposing to adopt the 1994 edition of the LSC because we believe that it provides the highest available level of protection for patients and staff in hospitals, with little or no additional burden to providers in existing facilities and at a lower cost in new construction. The 1994 edition of the LSC contains distinct sets of requirements for new construction and existing facilities. Newly constructed health care facilities must have automatic sprinklers throughout, allowing them to meet somewhat less rigorous standards in other areas. For example, under the 1994 LSC, exits may be 150 feet apart rather than 100 feet, interior finish may be Class C rather than Class B. Thus, it may actually cost less to construct a new building in conformance with the 1994 LSC than under the 1985 LSC.

The 1994 LSC does not impose any additional requirements for existing buildings beyond those specified in the 1985 LSC. Thus, an existing hospital that is in compliance with the 1985 LSC would not have to make any changes to come into compliance with the 1994 LSC. Only hospitals that still comply only with the 1967 LSC may require some additional features to achieve compliance with the 1994 LSC. For such hospitals, we believe it is inappropriate to require compliance with a code that relies on outmoded fire protection methods. We note that we are proposing to retain both the waiver provision from the existing regulations and the provision permitting use of a State code if HCFA finds that it adequately protects patients, which should ensure that hospitals that can demonstrate an ability to protect patient health and safety are not faced with unreasonable burdens to comply with the LSC requirements.

18. Blood and Blood Product Transfusions (§ 482.140)

We propose establishing this requirement as a separate COP because of its importance for patient health and safety. The transfusion of blood and blood products requires a high degree of coordination between medical and nursing staff. Therefore, it is critical that a hospital demonstrate practices that ensure safe and accurate transfusions with a minimum of transfusion-related reactions.

Currently, specific, process-oriented requirements for pre-transfusion testing of blood and blood products are set forth at 42 CFR Part 493 (§§ 493.1271, 493.1273, 493.1275, 493.1277, 493.1279, 493.1283, and 493.1285). We considered proposing to include all these CLIA requirements in the hospital COPs as well as requirements for transfusions, maintaining the same degree of prescriptiveness. However, we believe that the transfusion COP should incorporate the same approach used in the rest of the proposed rule, that is, a balanced approach that combines HCFA's and the hospital's responsibility to ensure that essential health and safety standards are met. Moreover, many of the requirements set forth under part 493 are already stated broadly in the proposed hospital COPs. For example, the requirement that transfusion facilities are administered only by qualified personnel already appears in general terms in the proposed rule at § 482.125, Human Resources. Likewise, the requirement that blood and blood products be stored under appropriate conditions, including proper temperature, is implicit in § 482.130, Physical Environment.

Therefore, we are proposing under § 482.140 a new COP on blood transfusions that would require that hospitals—

(1) Have procedures for averting, responding promptly to, investigating, tracking, and reporting blood

transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities; and

(2) Take appropriate measures to ensure the positive identification of the blood or blood product and the recipient, that blood and blood products are stored at the appropriate conditions, including temperature, to prevent deterioration, and that blood and blood products are readily accessible to the appropriate medical and nursing staff.

As noted above, we have included these requirements because they are essential to patient safety.

19. Infectious Blood and Blood Products (§ 482.145)

This condition specifies the steps hospitals must take when they become aware that they have administered potentially HIV (human immunodeficiency virus)-positive blood or blood products to a patient. These requirements restate without change the requirements in existing § 482.27(c), Potentially infectious blood and blood products, which were set forth in our September 9, 1996 final rule (61 FR 47423). Because these requirements were so recently established through notice and comment rulemaking, and would merely be redesignated under this proposed rule, we are not accepting comments on this section.

20. Utilization Review (§ 482.150)

We propose to maintain the present utilization review (UR) COP as presently set forth in § 482.30. We believe this is appropriate because when the current UR COP was revised in 1986 (51 FR 22010), we strove to delete overly burdensome requirements and reflect only the statutory obligations of hospitals for utilization review. These obligations have not changed since that time.

Since all Medicare-participating hospitals must have an agreement with the Utilization and Quality Control Peer Review Organization (PRO) in the State in which the hospital is located as a condition of payment in accordance with the regulations at § 466.86(b), PRO review activities fulfill the UR requirements for hospitals. Therefore, the UR COP has limited applicability in the survey process. However, in unusual cases where a PRO does not in fact perform review provided for in its contract with the hospital, these regulations would ensure that the provisions of sections 1861(e)(6) and (k) of the Act concerning utilization review can be applied.

21. Provider Agreement—Surveyor Access to Provider Records (§ 489.53)

In addition to the changes described elsewhere in this document, which would affect only hospitals, we propose to add a new provision that would apply to all providers participating in Medicare. Under this new provision, which would amend our provider agreement regulations at 42 CFR 489.53, HCFA would be authorized to terminate a provider's participation in Medicare if the provider refused to allow access to its facilities, or examination of its operations or records, by or on behalf of HCFA, as necessary to verify that it is complying with the provisions of title XVIII and the applicable regulations of Chapter IV of Title 42 of the Code of Federal Regulations, or with the provisions of its provider agreement.

Under Medicare, the surveys needed to verify compliance with health and safety requirements or other Medicare rules are not mere paperwork reviews, but instead require State surveyors or HCFA personnel to perform firsthand observations of facilities and operations as well as to review relevant records. The great majority of hospitals and other providers recognize the need for these surveys and cooperate willingly with them. However, in rare cases a provider may attempt to thwart the survey process by refusing to allow access to its facilities, operations, or medical or other records. Without this access, it may be difficult or impossible to document provider noncompliance with applicable conditions of participation or other requirements.

We believe that a provider that has agreed to participate in Medicare and accept payment for treating Medicare patients has an inherent obligation to allow access to its facilities, operations, and records to the extent that access is needed to verify that the provider is complying with all applicable Medicare requirements. If this access were denied, we would be unable to carry out our obligations to administer the Medicare program. In addition, the health and safety of both Medicare and other patients might be jeopardized, since we would not be able to detect unsafe practices and identify them for corrective action. However, our current regulations do not make this longstanding obligation explicit. The proposed rule would correct this problem by adding new § 489.53(a)(6) to specify that HCFA may terminate a provider agreement if the provider refuses to allow access to its facilities, or examination of its operations or records, to verify compliance with applicable Federal law and regulations.

The specific statutory basis for the proposed rule is section 1871(a)(1) of the Act, which authorizes the Secretary to prescribe such regulations as may be necessary to carry out the administration of the Medicare program. However, we emphasize that this provision does not create a new obligation for providers, but merely codifies an existing obligation. For this reason, the proposed rule would not increase the compliance burden for facilities. Existing limits on the types of information requested and the uses to which it can be put would be maintained. For example, as part of the review of the hospital's quality assessment and performance improvement program, we would expect to have access to hospital incident reports only as a nonpunitive review function to determine how the hospital analyzes and tracks these data and incorporates the data into its quality assessment and performance improvement program.

III. 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 non-profit hospitals and other hospitals with revenues of $5 million or less annually 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. 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 most hospitals. However, to the extent that our proposals may have significant effects on providers or beneficiaries, or be viewed as controversial, 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 hospital conditions of participation that revise or

eliminate many existing requirements and incorporate critical requirements into four ''core conditions.'' These four COPs—Patient Rights; Patient Admission, Assessment, and Plan of Care; Patient Care; 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 hospital as an organization, and the impact of the treatment furnished by the hospital on the health status of its patients. 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, requiring error free medication administration). More often though, we have eliminated structural or process-oriented requirements that we no longer believe are necessary (such as the prescriptive details concerning bylaws, medical staff composition, medical record services, etc.), in favor of an approach that, through the proposed core COP on quality assessment and performance improvement, invests hospitals with internal responsibility for improving their performance. This approach is intended to incorporate into our regulations current best practices in well-managed hospitals, relying on the hospital 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 hospitals to comply with detailed Federal requirements, thus reducing the costs incurred by the typical hospital 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 hospitals that would be associated with this proposed rule.) Instead, the proposed COPs would provide hospitals with much more flexibility to determine how best to pursue our shared quality of care objectives in the most cost-effective manner. We expect hospitals 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 uncertain readiness of some individual hospitals to comply with performance expectations under the proposed COPs, quantitative analysis of the effects of these proposed changes is not possible. Hospitals with quality assessment and performance improvement programs already in place that meet these proposed requirements may see a reduction in administrative burden because they would no longer have to comply with many of the process-oriented requirements of the current COPs. Other hospitals that do not currently meet the proposed requirements for quality assessment and performance improvement may encounter an increased burden in the short term because resources would have to be devoted to the development of a quality assessment and performance improvement program that covers the complexity and scope of the particular hospital's services. However, even in situations where the proposed requirements could result in some immediate costs to an individual hospital, we believe that the changes that the hospital would make would produce real but difficult to estimate long-term economic benefits to the hospital (such as cost-effective performance practices or higher patient satisfaction that could lead to increased business for the hospital).

We are considering strengthening organ procurement standards and we welcome suggestions for an outcome standard. However, with or without such a standard, we believe the resource implications of the proposed changes are minimal and may even reduce hospital costs. When hospitals use organ procurement organization staff to make the required requests to the families of potential donors, it is OPO staff rather than the hospital staff that must spend time with the family. As to the option of reporting all or most deaths to OPOs, this relieves the hospital of making the suitability decision. Fewer than 400 patients a year die in an average hospital. Assuming five minutes a telephone call, only a few person-days would be needed to report all such deaths.

For the reasons explained above, the Secretary certifies that this proposed rule will not have a significant economic impact on a substantial number of small providers, and that preparation of an Initial Regulatory Flexibility Analysis is not required.

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

IV. Information Collection and Recordkeeping 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 3505(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.

This proposed rule contains information collection requirements that are subject to OMB review under the Paperwork Reduction Act of 1995. These information collection requirements are discussed below.

This proposed rule revises the hospital conditions of participation contained in existing 42 CFR part 482 (§§ 482.1 through 482.66) that are applicable under the Medicare and Medicaid programs. The information collection requirements contained in these existing regulations are approved by OMB under approval number 0938–0328, which expires on July 31, 2000 (§§ 482.12, 482.21, 482.22, 482.27, 482.30, 482.41, 482.43, 482.53, 482.56, 482.57, 482.60, and 482.62) and 0938–0698, which expires on January 31, 2000 (§ 482.27(c)). For the most part, these requirements have been in effect for over 9 years. In this proposed rule, we would delete some of these requirements, retain others, and add some new ones. On balance, the proposed regulations would result in a significantly smaller information collection burden on hospitals.

A. Proposed Deleted Requirements

The existing information collection requirements that we propose to delete are:

- § 482.12(e)(2)—The requirement that a hospital maintain a list of all contracted services.
- § 482.12(f)(2)—The requirement that the governing body ensure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referrals when appropriate.
- § 482.22(c)—The requirement that a hospital must have written bylaws for medical staff.
- § 482.27(a)(2)—The requirement that a hospital must have written description of laboratory services.

• § 482.41(b)—The requirement that a hospital use the applicable provisions of the Life Safety Code of the National Fire Protection Association. (We are including application of a later edition of the Code in proposed § 482.140.)

• § 482.53(d)—The requirement that a hospital maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures. (We proposed to delete the requirement specific to nuclear medicine records, but expand recordkeeping requirements to apply to all services under a new information management requirement in proposed § 482.120.)

B. Proposed Retained Requirements

The existing information collection requirements that we propose to retain are:

• § 482.12(c)(5)(i)—The requirement that a hospital must have written protocols related to the identification of potential organ donors (proposed § 482.110(c)).

• § 482.12(d)(1), (2), and (4)—The requirement that a hospital must have an institutional plan and budget (proposed § 482.110(b)(3)).

• § 482.27—The requirement that a hospital undertake certain activities when it learns that it has received blood and blood products that are at increased risk of transmitting HIV, including the requirement that the hospital have specified notifications procedures in place and retain certain documentation in the medical record (proposed § 482.145).

• § 482.30(c)(1) and (d)(3)—The requirement that a hospital must have in effect a utilization review plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs (proposed § 482.150).

For those information collection requirements for which we have current OMB approvals that will expire sometime in the future (as specified earlier under this section), we are asking for public comments only as they pertain to the overall requirements under the new proposed structure of these regulations.

C. Standard Industry Practice

Under 5 CFR 1320.3(b)(2), the burden associated with the time, effort, and financial resources that would be necessary to comply with a collection of information that would be incurred by persons in the normal course of business will be excluded from an information collection that is subject to OMB approval. The burden in connection with these types of collection activities can be disregarded if an agency can demonstrate that the collection activities are usual and customary. The collection requirements referenced below are usual and customary in the conduct of hospital business. Thus, they fall under this exclusion:

• § 482.15(a)—The requirement that a hospital must ensure that each patient receives a comprehensive assessment that identifies the patient's condition and care needs at the time of admission as well as an initial estimate of posthospital needs, if any. Should the needs of a patient change, the assessment must be updated to reflect these changes.

• § 482.15(b)—The requirement that a hospital must create a plan of care for all newly admitted patients. The initial plan of care must be placed in the medical record within 24 hours of admission and must include, although not necessarily in one location in the medical record, care to be delivered by all relevant disciplines. This plan must be modified to meet any changes in the patient's condition that affect the patient's needs.

• § 482.43—The requirement that a hospital must have in effect a discharge planning process, with written policies and procedures (proposed § 482.55).

• § 482.110(c)(1)(ii)—The requirement that a hospital must assure, through the OPO with which the hospital has an agreement, that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to donate.

• § 482.120—The requirement that a hospital must maintain information systems to record, communicate, and measure hospital performance. The information systems may include manual systems, automated systems, or both, depending on the complexity of the hospital, to record and maintain the clinical and operations data necessary for patient care.

• § 482.140—The requirement that a hospital must administer blood and blood product transfusions according to approved medical staff and nursing policies and procedures, and ensure the safety of individuals being transfused within the facility.

D. New Information Collection Requirements

The proposed regulations allow hospitals greater flexibility in the utilization of their staff and resources while strengthening quality control requirements to assure patient health and safety. The new proposed information collection requirements that are subject to OMB approval represent minimal, if any, burden on hospitals.

As we have discussed earlier in this preamble, in order to participate in Medicare and Medicaid, hospitals must be certified as meeting the conditions of participation (and hence the information collection requirements contained in the conditions). There are approximately 6,700 hospitals that participate in Medicare or Medicaid. Approximately 5,200 of these hospitals are accredited by JCAHO or AOA. HCFA deems these JCAHO and AOA accredited hospitals to meet the conditions of participation, except for utilization review requirements. The remaining 1,500 non-accredited hospitals must be surveyed to ensure compliance with the conditions of participation. Therefore, only those hospitals that are not accredited by JCAHO or AOA would incur burden from the new information collection requirements listed below. The hospitals that would be subject to the information collection requirements would include new hospitals (approximately 2 per year) and current ones undergoing a recertification (currently a hospital is resurveyed approximately every 5 years, so an average of 20 percent of the 1,500 hospitals (300) are resurveyed each year). However, we believe that, of the 302 hospitals subject to a survey each year, the actual number surveyed would only be 250. We reached this conclusion because at least 52 of the hospitals are already implementing these three new requirements and would incur no additional burden.

Included in the estimate of burden for the new information requirements listed below is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

1. § 482.10(a)—Standard: Notice of Rights

a. Requirement: This section requires a hospital to have in effect a grievance process for patients to follow if they want to file a grievance. The hospital must also indicate who the patient should contact to express a grievance.

b. Burden: We believe the requirement for a grievance process will impose an estimated burden of 2 hours per hospital for a total of 500 annual burden hours.

2. § 482.25—Condition of Participation: Quality Assessment and Performance Improvement

a. Requirement: This section requires a hospital to have a quality assessment and performance improvement program that reflects the complexity of the hospital's organization and services (including those services provided under contract or arrangements) and implements actions that result in improvements across the full range of the hospital's services to patients.

b. Burden: We believe this requirement would impose an estimated burden of 3 hours per hospital for a total of 750 annual burden hours.

3. § 482.125(b)—Standard: Staffing

a. Requirement: This section requires a hospital to have an explicit process to determine on an ongoing basis the needed level of nurse staffing needs. This methodology and evidence of its use in meeting the nurse staffing needs of the patient must be available for public inspection.

b. Burden: We believe this requirement would impose an estimated burden of 3 hours per hospital for a total of 750 annual burden hours.

The total annual burden hours for implementation of the new proposed information collection requirements for hospitals is estimated to be 2,000 hours.

The paperwork burden for the proposed new information collection requirements would not be effective until it has been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained. Organizations and individuals desiring to submit comments on this paperwork burden should direct them to the Office of Management and Budget, Human Resources and Housing Branch, Room 10235, New Executive Office Building, Washington, D.C., 20503; Attention: Allison Herron Eydt, HCFA Desk Officer.

V. Responses 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.

List of Subjects

42 CFR Part 416

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV would be amended as set forth below:

A. Part 416 is amended as follows:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for part 416 continues to read as follows:

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

Subpart C—Specific Conditions for Coverage

2. Section 416.42(b) is revised to read as follows:

§ 416.42 Condition for coverage—Surgical services.

* * * * *

(b) *Standard: Administration of anesthesia.* Anesthesia is administered only by a licensed practitioner permitted by the State to administer anesthetics.

* * * * *

B. Part 482 is amended as follows:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 continues to read as follows:

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

Subpart A—General Provisions

§ 482.1 [Redesignated as § 482.5]

2. Section 482.1 is redesignated as § 482.5 in subpart A and is amended by adding a new paragraph (a)(6) to read as follows:

§ 482.5 Basis and scope.

(a) *Statutory Basis.*

* * * * *

(6) Section 1138 of the Act sets forth requirements for hospital protocols for organ procurement and standards for organ procurement agencies' agreements with hospitals for organ procurement.

§ 482.5 [Removed]

* * * * *

3. Section 482.2 is removed.

4. A new § 482.10 is added to subpart A to read as follows:

§ 482.10 Condition of participation: Patient rights.

A hospital must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* A hospital must inform each patient of his or her rights in advance of furnishing patient care. The hospital must have a grievance process and must indicate who the patient can contact to express a grievance.

(b) *Standard: Exercise of rights.*

(1) The patient has the right to be informed of his or her rights and to participate in the development and implementation of his or her plan of care.

(2) The patient has the right to make decisions regarding his or her care.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with those directives, in accordance with § 489.100, § 489.102, and § 489.104.

(c) *Standard: Privacy and safety.*

(1) The patient has the right to personal privacy and to receive care in a safe setting.

(2) The patient has the right to be free from verbal or physical abuse or harassment.

(d) *Standard: Confidentiality of patient records.*

(1) The patient has the right to confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable timeframe.

(e) *Standard: Seclusion and restraint.* The patient has the right to be free from the use of seclusion or restraint, of any form, as a means of coercion, convenience, or retaliation by staff. If seclusion or restraints are used (including psychopharmacological drugs used as restraints), they must be used in accordance with a patient's plan of care. Restraints or seclusion may be used only as a last resort and in the least restrictive manner possible, to protect the patient or others from harm, and must be removed or ended at the earliest possible time.

Subparts B and C [Removed]

5. Subparts B (§§ 482.11 and 482.12), C (§§ 482.21 through 482.43), and D (§§ 482.51 through 482.77) are removed.

6. New subparts B and C are added to read as follows:

Subpart B—Patient Care Activities

Sec.
482.15 Condition of participation: Patient admission, assessment, and plan of care.
482.20 Condition of participation: Patient care.
482.25 Condition of participation: Quality assessment and performance improvement.
482.30 Condition of participation: Diagnostic and therapeutic services or rehabilitative services.
482.35 Condition of participation: Pharmaceutical services.
482.40 Condition of participation: Nutritional services.
482.45 Condition of participation: Surgical and anesthesia services.
482.50 Condition of participation: Emergency services
482.55 Condition of participation: Discharge planning.

Subpart C—Organization Environment

482.110 Condition of participation: Administration of organizational environment.
482.115 Condition of participation: Infection control.
482.120 Condition of participation: Information management.
482.125 Condition of participation: Human resources.
482.130 Condition of participation: Physical environment.
482.135 Condition of participation: Life safety from fire.
482.140 Condition of participation: Blood and blood product transfusions.
482.145 Condition of participation: Potentially infectious blood and blood products.
482.150 Condition of participation: Utilization review.

§ 482.15 Condition of participation: Patient admission, assessment, and plan of care.

The hospital must conduct a comprehensive assessment of the care needs of each patient, including an initial assessment of posthospital needs, and must establish a coordinated plan for how all relevant hospital disciplines will meet those needs.

(a) *Standard: Admission and comprehensive assessment.*

(1) A patient is admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.

(2) The hospital must ensure that each patient receives a comprehensive assessment that identifies the patient's condition and care needs at the time of admission as well as an initial estimate of posthospital needs, if any. The assessment must be completed in a timely manner consistent with the patient's immediate needs and placed in the patient's medical record within 24 hours of admission. If an assessment is recorded before a scheduled admission, the hospital must document any changes in the patient's condition on admission and place the updated assessment in the medical record within 12 hours of admission. The comprehensive assessment must be updated when the patient's needs change.

(b) *Standard: Plan of care.*

(1) Each patient must have an initial written plan of care that meets the needs identified in the comprehensive assessment. The initial plan of care must be placed in the medical record within 24 hours of admission and must include, although not necessarily in one location in the medical record, care to be delivered by all relevant disciplines.

(2) The plan of care must be modified to meet any changes in the patient's condition that affect the patient's needs.

§ 482.20 Condition of participation: Patient care.

The hospital ensures that each Medicare patient is under the care of an appropriately qualified practitioner. The care provided to each patient is coordinated and based on the plan of care.

(a) *Standard: Assignment of responsible practitioner for Medicare patients.*

(1) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy who may delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism;

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry, but only with respect to functions which he or she is legally authorized by the State to perform;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; or

(vi) In the case of a patient receiving qualified psychologist services as defined in section 1861(ii) of the Act, a clinical psychologist, but only with respect to such qualified psychologist services and only to the extent permitted by State law.

(2) A doctor of medicine or osteopathy is on duty or on call at all times.

(3) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and is not specifically within the scope of practice of one of the other practitioners listed in paragraph (a)(1) of this section, as that scope is defined by the medical staff, authorized by State law, and limited, under paragraphs (a)(1)(v) and (a)(1)(vi) of this section, with respect to chiropractors and clinical psychologists, respectively.

(b) *Standard: Delivery of patient care.*

(1) For each patient, the hospital provides care and treatment interventions that are coordinated by all relevant disciplines and conform to the plan of care.

(2) The hospital evaluates the patient's progress as appropriate to the patient's condition and adjusts care, as necessary, when progress is not being achieved.

(3) Patient care services are provided in accordance with the order of practitioners who are qualified and have delineated clinical privileges as specified under § 482.125(a).

(4) If the hospital provides care to outpatients, that care meets the same requirements that apply to inpatient care. Inpatient care and outpatient care are coordinated to ensure continuity of care for patients who move between levels of care.

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

The hospital must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program. The program must reflect the complexity of the hospital's organization and services (including those services provided under contract or arrangement). The hospital must implement actions that result in improvements across the full range of the hospital's services to patients.

(a) *Standard: Program scope.*

(1) The hospital's quality assessment and performance improvement program must include, but not be limited to, the use of objective measures to evaluate—

(i) Access to care;

(ii) Patient satisfaction;

(iii) Staff, administrative and practitioner performance;

(iv) Complaints and grievances;

(v) Diagnostic and therapeutic services;

(vi) Medication error incidents, achievement of drug therapy goals and incidents of adverse drug effects;

(vii) Nutritional services, including patient's responses to therapeutic diets and parenteral nutrition, if used;

(viii) Surgery and anesthesia services;

(ix) Emergency services, if provided;

(x) Discharge planning activities;

(xi) Safety issues, including infection control and physical environment; and

(xii) Results of autopsies.

(2) In each of the areas listed in paragraph (a)(1) of this section, and any others the hospital includes, the hospital must measure, analyze, and track quality indicators or other aspects of performance that the hospital adopts or develops that reflect processes of care and hospital operations. These performance measures must be shown to be predictive of desired outcomes or be the outcomes themselves.

(3) The hospital must use hospital-specific data, as well as PRO data and any other available relevant data, as an integral part of its quality assessment and performance improvement strategy.

(4) Although a hospital is not required to participate in a PRO cooperative project, the hospital must be able to demonstrate a level of achievement through its own quality assessment and performance improvement strategy comparable to or better than that to be expected from such participation.

(5) The hospital must set priorities for performance improvement, considering prevalence and severity of identified problems, and giving priority to improvement activities that affect clinical outcomes.

(6) The hospital must take actions that result in performance improvements and must track performance to assure that improvements are sustained.

(b) *Standard: Program responsibilities.*

(1) The hospital governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff and administration officials are responsible for ensuring that the hospital-wide quality assessment and performance improvement efforts address identified priorities in the hospital and are responsible for the development, implementation, maintenance and evaluation of improvement actions.

(2) All hospital programs, departments and functions, including contracted services and services provided under arrangement, must be involved in developing, implementing, maintaining, and evaluating the hospital's program of quality assessment and performance improvement.

(c) *Standard: Autopsies.* The hospital must attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

§ 482.30 Condition of participation: Diagnostic and therapeutic services or rehabilitative services.

(a) The hospital is primarily engaged in providing, by or under the supervision of one of the practitioners described in § 410.20(b) of this chapter, either diagnostic and therapeutic services to inpatients, or rehabilitative services to inpatients.

(b) The hospital must provide diagnostic radiology services, including 24-hour emergency diagnostic radiology services, if the hospital provides full-time emergency services (see § 482.50(a)).

(c) The hospital must provide laboratory services, including 24-hour emergency laboratory services, to meet the needs of patients. The laboratory services must be furnished in accordance with part 493 of this chapter.

(d) If the hospital elects to offer other services in addition to the required services, they must be delivered in accordance with the requirements of this part.

§ 482.35 Condition of participation: Pharmaceutical services.

The hospital provides medication therapy, as needed, through a safe, accurate, effective system that minimizes adverse drug events and evaluates the patient's response to the medication therapy.

(a) *Standard: Adverse drug event monitoring.*

(1) The hospital develops and operates a system (manual or electronic) to search active clinical records for events that are likely to be associated with adverse drug events and refers these events to the hospital's quality assessment and performance program for action.

(2) The hospital must ensure that its overall medication error rate is no higher than 2.0 percent.

(3) The hospital must ensure that its patients experience no significant medication errors. For purposes of this section, medication errors are considered ''significant'' if they actually jeopardize or cause serious potential for jeopardizing the health and safety of the patient.

(b) *Standard: Drug management procedures.*

(1) All drugs and biologicals are stored in secure areas. In addition, all drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within secure storage areas. Only authorized personnel may have access to keys.

(2) The hospital keeps current and accurate records of receipt and disposition of all controlled drugs.

(3) Discrepancies in controlled drugs are reported to the individual responsible for pharmaceutical services and to the administrator of the hospital.

(4) A comprehensive drug information resource (computerized or hard copy) is available to professional staff for ordering, dispensing, and administering of medications. This information resource is readily available at common points of drug ordering, dispensing and administration in the facility, and is merged with, or located in close proximity to, individual patient information at those common points.

(5) Before medications are administered, a licensed nurse (that is, a registered nurse, licensed practical nurse, or licensed vocational nurse) or a doctor of medicine or osteopathy must review the individual patient's information, and the orders of the practitioner who prescribed the medication.

(6) Medications brought into the hospital by the patient are administered only after positive identification of the medications, and only on the order of the practitioner responsible for the care of the patient under § 482.15(a)(1), in accordance with hospital policy.

(7) The hospital has policies for discontinuing medications that are not specifically limited as to time and/or number of doses to be administered.

(c) *Standard: Discharge orders for psychopharmacological drugs.* Orders for psychopharmacological drugs are discontinued upon discharge of the patient, unless the patient has a psychiatric diagnosis listed in the Third or Fourth Edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM–III or DSM–IV), or in Chapter Five (Mental Disorders) of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) which is available through the Government Printing Office, Washington, DC, stock number 017–022–01392–4 (1977).

§ 482.40 Condition of participation: Nutritional services.

The hospital must provide each patient with adequate nutrition, including therapeutic diets or parenteral nutrition if needed.

(a) *Standard: Sanitary conditions.* The hospital must provide food to the patient that is obtained, stored, prepared, distributed and served under sanitary conditions.

(b) *Standard: Menus.* The hospital must prepare menus prepared in advance and meet the nutritional needs of the patients in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.

§ 482.45 Condition of participation: Surgical and anesthesia services.

If the hospital provides surgical or anesthesia services, they are provided through the use of qualified staff. The patient receives appropriate pre- and post-procedure evaluations, and all care is accurately documented.

(a) *Standard: Staffing.*

(1) Surgical procedures are performed only by practitioners with appropriate clinical privileges.

(2) Anesthesia is administered only by a licensed practitioner permitted by the State to administer anesthetics.

(b) *Standard: Evaluations.*

(1) A comprehensive assessment of the patient's condition is performed before surgery, except in emergency cases where a modified assessment is acceptable.

(2) A preanesthesia evaluation by an individual qualified to administer anesthesia is performed prior to the administration of anesthesia.

(3) A postanesthesia evaluation for proper anesthesia recovery is performed by an individual qualified to administer anesthesia.

(c) *Standard: Documentation of care.*

(1) The comprehensive or modified presurgical assessment described in paragraph (b)(1) of this section is entered in the patient record before surgery, except in emergency cases, where the assessment may be entered following surgery.

(2) A properly executed informed consent form for the operation is entered in the patient's record by the hospital before surgery, except in emergency cases where the delay needed to obtain consent would place the health or safety of the patient in serious jeopardy.

(3) The hospital maintains a complete, up-to-date operating room register.

(4) The hospital writes or dictates an operative report describing complications, reactions, length of time, techniques, findings, and tissues removed or altered immediately following surgery enters it in the patient's record promptly following surgery.

(5) The hospital maintains an intraoperative anesthesia record enters it in the patient's record promptly following surgery or any other procedures requiring anesthesia.

(6) The hospital writes a report of the results of the postanesthesia evaluation described in paragraph (b)(3) of this section and enters it in the patient's record promptly following completion of the procedure for which anesthesia was required.

§ 482.50 Condition of participation: Emergency services.

The hospital provides, within its capabilities and its stated mission, services appropriate to the needs of persons seeking emergency care. If the hospital provides emergency services on a full-time or part-time basis, it meets the applicable standard in paragraph (a) or paragraph (b) of this section, respectively; if the hospital does not provide any emergency services, it meets the standard in paragraph (c) of this section.

(a) *Standard: Hospitals providing full-time emergency services.* If the hospital provides emergency services on a 24-hour-per-day, 7-day per week basis, the hospital meets the following requirements at all times:

(1) The hospital has sufficient numbers of personnel, including doctors of medicine or osteopathy, other practitioners and registered nurses, to meet patient needs for emergency care.

(2) The services are appropriate to patient needs.

(3) The emergency services provided are integrated with other departments of the hospital.

(b) *Standard: Hospitals providing part-time emergency services.* If the hospital provides emergency services, but not on a 24-hour per day, 7-day per week basis, the hospital meets the following requirements:

(1) The hospital has fewer than 100 beds and is located in a rural area as defined in § 412.62(f)(1)(iii) of this chapter.

(2) The hospital establishes regular hours and days when the emergency services are available, and actually has services available at all of those times.

(3) The hospital notifies local emergency services personnel, law enforcement agencies, physician offices, and other health facilities of when it does and does not offer emergency services, and provides those it has notified with at least 5 calendar days' advance notice of any changes in its emergency services schedule.

(4) The hospital posts its days and hours of operation of emergency services in a conspicuous place where the public most commonly is informed of the hospital's location.

(5) The hospital complies with the requirements of paragraphs (a)(1) through (a)(3) of this section at all times when it does offer emergency services.

(6) The hospital complies with the requirements of paragraph (c) of this section at all times when it does not offer emergency services.

(c) *Standard: Hospitals not providing emergency services.* If the hospital does not provide emergency services, the hospital must provide for appraisal of emergencies, initial treatment, and referral when appropriate.

§ 482.55 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. This process assures that appropriate posthospital services are obtained for each patient, as necessary.

(a) *Standard: Identification of patients in need of discharge planning.* The hospital must identify, at an early stage of hospitalization, all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) *Standard: Discharge planning evaluation.*

(1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of the evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing posthospital services, including hospice services, and of the availability of those services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for posthospital care are made before discharge, and to avoid unnecessary delays in discharge.

(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(7) The evaluation must include a list of HHAs that are available to the patient, that participate in the Medicare program, the geographic area (as defined by the HHA) in which the patient resides, and that request to be listed by the hospital as available to provide home health services to patients the hospital discharges.

(c) *Standard: Discharge plan.* (1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(5) As needed, the patient and family members or interested persons must be counseled to prepare them for posthospital care.

(6) The discharge plan must inform the patient or patient's family as to their freedom to choose among participating Medicare providers of care when a variety of willing providers is available and must, when possible, respect patient and family preferences when they are expressed. However, the discharge plan must not specify or otherwise limit qualified providers that are available to the patient.

(7) The discharge plan must identify, in a form and manner specified by the Secretary, any home health agency to whom the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary consistent with section 1866(a)(1)(S) of the Act, or those entities that have a financial interest in the hospital.

(d) *Standard: Transfer or referral.* The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(e) *Standard: Reassessment.* (1) The hospital must reassess its discharge planning process on an ongoing basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

(2) The hospital's discharge planning process must be an integral part of the hospital's quality assessment and performance improvement program.

Subpart C—Organizational Environment

§ 482.110 Condition of participation: Administration of organizational environment.

A governing body, other organized group, or an individual has full legal authority and responsibility for the management and provision of all hospital services, and develops and implements policies and procedures necessary for the effective administration of the hospital. This includes care furnished under contracts or arrangements, fiscal operations, continuous quality assessment and performance improvement, and appointing a qualified administrator who is responsible for the day-to-day operations of the program.

(a) *Standard: Federal, State and local laws.* The hospital is in compliance with applicable Federal, State and local laws related to the health and safety of patients and licensure of hospitals.

(b) *Standard: Administrative responsibilities.* (1) The governing body, other organized group, or responsible individual is responsible for all services furnished to the hospital's patients, including outpatient services and those provided under contract or arrangements (including those for shared services and joint ventures), and ensures that the hospital is in compliance with all applicable conditions of participation and standards.

(2) The governing body, other organized group, or responsible individual must notify HCFA or the State survey agency when the hospital—

(i) Adds a new service category to the list of services it offers; or

(ii) Adds a new service site.

(3) The governing body, other organized group, or individual that assumes full legal authority and responsibility for the operation of the hospital is responsible for development, implementation, and administration of the institutional plan and budget. The institutional plan and budget must include, but are not limited to:

(i) An annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. (This paragraph does not require the preparation, in connection with any budget, of an item-by-item identification of the components of each type of anticipated expenditure or income.)

(ii) A capital expenditures plan for at least a 3-year period (including the year to which the operating budget described is applicable) that includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure in excess of $600,000 (or such lesser amount as may be established by the State in which the hospital is located, in accordance with section 1122(g)(1) of the Act) related to the acquisition of land, the improvement of land, buildings, and equipment, and the replacement, modernization, and expansion of the buildings and equipment that would, under generally accepted accounting principles, be considered capital items.

(iii) A plan submitted to the agency designated under section 1122(b) of the Act, or if no such agency is designated, to the appropriate health planning agency in the State (but this shall not apply in the case of a facility exempt from review under section 1122 by reason of section 1122(j)).

(iv) Review and updating at least annually.

(v) Preparation, under the direction of the governing body, other organized group, or responsible individual, by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution or agency.

(4) The governing body, other organized group, or individual that assumes full legal authority and responsibility for the operation of the hospital appoints the medical staff's members and approves its bylaws.

(c) *Standard: Organ procurement responsibilities.* (1) The governing body, other organized group, or responsible individual must ensure that the hospital has written protocols that—

(i) Identify potential organ donors as defined by the OPO with which the hospital has an agreement;

(ii) Assure, in collaboration with the OPO with which the hospital has an agreement, that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to donate;

(iii) Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors; and

(iv) Ensure that the hospital works cooperatively with the OPO with which the hospital has an agreement, in

educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs take place;

(2) The hospital must notify the OPO designated by the Secretary under § 486.316(c) of this chapter of all potential organ donors using protocols defined by the OPO.

(3) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term ''rules of the OPTN'' means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(4) For purposes of this standard, the term ''organ'' means a human kidney, liver, heart, lung, or pancreas.

§ 482.115 Condition of participation: Infection control.

The hospital maintains an effective infection control program that protects patients and hospital staff by preventing and controlling infections and communicable disease.

(a) *Standard: Sanitary environment.* The hospital must provide a sanitary environment by following acceptable standards of practice to avoid sources and transmission of infections and communicable diseases.

(b) *Standard: Infection control program.* The hospital must maintain an active program for the prevention, control, and investigation of infections and communicable diseases that—

(1) Is under the direction of a designated infection control officer;

(2) Is an integral part of the hospital's quality assessment and performance improvement program; and

(3) Includes a method of identifying problems and taking appropriate actions that result in improvement.

§ 482.120 Condition of participation: Information management.

The hospital maintains information systems to record, communicate, and measure hospital performance. The information systems may include manual systems, automated systems, or both, depending on the complexity of the hospital, to record and maintain the clinical and operations data necessary for patient care.

(a) *Standard: Health information system.* (1) The hospital maintains clinical records on all patients.

(2) The patient record must document the patient stay (whether inpatient or outpatient). This includes recording, to the extent they are performed or used, the diagnosis, comprehensive assessment and plan of care, evaluations, consent forms, notes on treatments, nursing, medications, reactions, a summary report with provisions for followup care, and any other relevant reports.

(3) The interdisciplinary plan of care is a part of the patient record, and any revisions to the plan of care are accurately documented by the hospital.

(4) The patient record must note, within 30 days of discharge, the final diagnosis and clinical outcomes of the patient stay.

(5) All patient record entries, including those made as a result of verbal orders, must be legible, dated, and authenticated in written or electronic form by whomever is responsible for ordering or providing the service.

(6) Patient records must be retained in a reproducible format for at least 5 years.

(7) The hospital must retain original films, scans, and other image records (or copies), as appropriate, for at least 5 years.

(8) If a hospital performs any type of transplants, it must provide requested transplant-related data to the Organ Procurement and Transplantation Network, the Scientific Registry, the organ procurement organizations, and the Department of Health and Human Services as requested by the Secretary.

(b) *Standard: Management of the information systems.*

(1) The information systems must be maintained to provide for the timely recording, integration, and retrieval of data as well as the transmission of data to authorized parties.

(2) The information systems must contain system standards and procedures to ensure the integrity, efficiency, confidentiality, and security of data.

(3) Medical information about the patient (inpatient or outpatient) must be available to all authorized professional personnel providing medical care to the patient.

§ 482.125 Condition of participation: Human resources.

All hospital areas are staffed with qualified personnel, who are present in sufficient numbers to meet the needs of the hospital's patients.

(a) *Standard: Credentials/qualifications.* (1) The hospital ensures that individuals who supervise and/or furnish services to hospital patients, including services furnished under contracts or arrangements, are qualified to provide or supervise the services, and that types of practitioners allowed to practice without direct supervision have delineated clinical privileges for these services.

(2) The hospital grants clinical privileges, and periodically reappraises and renews (or denies renewal of) those privileges. If State law requires that an employee, contractor, or a practitioner with practice privileges be licensed, the hospital verifies (and periodically reverifies) compliance with applicable licensure requirements, and documents that verification.

(3) The medical staff operates under bylaws that are approved by the governing body, establishes the criteria for selection of its members, examines the credentials of candidates and recommends eligible candidates to the governing body.

(b) *Standard: Staffing.* (1) Staffing for all services provided by the hospital reflects the volume of patients, patient acuity, and the level of intensity of the services provided to ensure that desired outcomes of care are achieved and negative outcomes are avoided.

(2) In implementing the requirements of paragraph (b) (1) of this section, the hospital must develop and use consistently an explicit process to determine on an ongoing basis the needed level of nursing staff (including registered nurses, licensed practical nurses, and nursing assistants). This methodology and evidence of its use in meeting the nursing staffing needs of the patients must be available for public inspection.

(3) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a waiver of the 24-hour nursing service requirement granted under § 488.54(c) of this chapter.

(4) A registered nurse must be immediately available for bedside care of any patient, when needed.

(5) A registered nurse must be responsible for the provision and evaluation of nursing care for each patient and must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized

qualifications and competence of the nursing staff available.

(6) The hospital must ensure that all licensed nurses working in the hospital adhere to the policies and procedures of the hospital. The hospital must provide for the adequate supervision and evaluation of the clinical activities of nonemployee nursing personnel.

(c) *Standard: Education, training, and performance evaluation.* (1) The hospital must ensure that all personnel furnishing health care services in the hospital are provided with the necessary education and training on the nature of their duties so that they can furnish services effectively, efficiently, and competently. This education and training includes, but is not limited to, the individual job description, performance expectations, applicable organizational policies and procedures, safety responsibilities, infection control program, and quality assessment and performance improvement activities within the hospital.

(2) All personnel furnishing health care services in the hospital must demonstrate in practice the skills and techniques necessary to perform their duties and responsibilities.

§ 482.130 Condition of participation: Physical environment.

The hospital must maintain a safe physical environment free of hazards for patients.

(a) *Standard: Safety management.* (1) The hospital must prevent situations that pose a threat to health or property whenever possible; when they do occur, the hospital must report and correct them promptly.

(2) The hospital must prevent equipment failures whenever possible; when they do occur, the hospital must report and correct them promptly.

(3) The hospital must promptly report and investigate all incidents that involve injury to patients or that involve damage to property.

(4) The hospital must have an emergency preparedness system for managing the consequences of power failures, natural disasters or other emergencies that disrupt the hospital's ability to provide care.

(b) *Standard: Physical plant and equipment.* (1) There must be procedures for the proper routine storage and prompt disposal of trash and medical waste.

(2) There must be proper light, temperature, and ventilation controls throughout the hospital including appropriate air exchanges for patient care.

(3) There must be emergency power and lighting for life-support equipment, regardless of location, and for emergency exit areas and stairwells. The hospital must make available in all other areas not served by the emergency supply source, battery lamps and flashlights. The hospital must make available facilities for emergency gas and water supply.

(4) All equipment used to furnish patient care services must be properly maintained.

§ 482.135 Condition of participation: Life safety from fire.

Except as provided in paragraphs (a) and (b) of this section, the hospital must meet the applicable provisions of the 1994 edition of the Life Safety Code of the National Fire Protection Association (LSC), which is incorporated by reference. Incorporation by reference of the LSC, 1994 edition, was approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1]

(a) *Waivers.* After consideration of State survey agency findings, HCFA may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of patients.

(b) *Exception.* The provisions of the Life Safety Code do not apply in a State where HCFA finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

§ 482.140 Condition of participation: Blood and blood product transfusions.

The hospital must administer blood and blood product transfusions according to approved medical staff and nursing policies and procedures, and ensure the safety of individuals being transfused within the facility.

(a) *Standard: Transfusion reactions.* The hospital must have procedures for identifying, averting, responding promptly to, investigating, tracking, and reporting blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

(b) *Standard: Safety and accessibility.* The hospital must take appropriate measures to ensure the positive identification of the blood or blood product and the recipient. Blood and blood product must be stored at the appropriate conditions, including temperature, to prevent deterioration. Blood and blood products must be readily accessible to the appropriate medical and nursing staff.

§ 482.145 Condition of participation: Potentially infectious blood and blood products.

(a) *Potentially HIV infectious blood and blood products.* Potentially HIV infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other follow-up testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(b) *Services furnished by an outside blood bank.* If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(1) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation.

(2) The results of the FDA-licensed, more specific test or other follow-up testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and lookback procedures are set forth at 21 CFR 610.45—et seq.)

(c) *Quarantine of blood and blood products pending completion of testing.* If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (b)(1) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(1) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(2) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive, the hospital

[1] When this proposed rule is adopted, the 1994 edition of the Life Safety Code will be available for inspection at the HCFA Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD, and at the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC. Copies of this publication may be purchased from the National Fire Protection Association, Battermarch Park, Quincy, MA 02269.

must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify patients in accordance with paragraph (d) of this section.

(d) *Patient notification.* If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (b) of this section) or released such blood or blood products to another entity or appropriate individual, the hospital must take the following actions:

(1) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(2) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (h) of this section, of the need for HIV testing and counseling.

(3) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (h) of this section, of the need for HIV testing and counseling.

(4) Document in the patient's medical record the notification or attempts to give the required notification.

(e) *Timeframe for notification.* The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless—

(1) The patient is located and notified; or

(2) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification time frame to exceed 8 weeks.

(f) *Content of notification.* The notification given under paragraphs (d) of this section must include the following information:

(1) A basic explanation of the need for HIV testing and counseling.

(2) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(3) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restrictions the program may impose.

(g) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(h) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

§ 482.150 Condition of participation: Utilization review.

The hospital must have a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) *Standard: Applicability.* The provisions of this section apply except in either of the following circumstances—

(1) A Utilization and Quality Control Peer Review Organization (PRO) has assumed binding review for the hospitals.

(2) HCFA has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.

(b) *Standard: Composition of utilization review committee.* A UR committee consisting of two or more practitioners must carry out the UR function. At least two members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.20(a).

(1) Except as specified in paragraphs (b)(2) and (3) of this section, the UR committee must be one of the following—

(i) A staff committee of the institution.

(ii) A group outside the institution that is established—

(A) By the local medical society and some or all of the hospitals in the locality; or

(B) In a manner approved by HCFA.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who—

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Has been professionally involved in the care of the patient whose case is being reviewed.

(c) *Standard: Scope and frequency of review.*

(1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of each of the following—

(i) Admissions to the institution.

(ii) The duration of stays.

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter.

(d) *Standard: Determination regarding admissions or continued stays.*

(1) The determination that an admission or continued stay is not medically necessary—

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified in § 482.20(a), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in § 482.20(a), and afford the practitioner

or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, not later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in § 482.20(a).

(e) *Standard: Extended stay review.* (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in § 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) *Standard: Review of professional services.* The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

Subpart E—[Redesignated as Subpart D]

Subpart E—Requirements for Specialty Hospitals is redesignated as Subpart D. Sections 482.60, 482.61, 482.62,and 482.66 are redesignated as §§ 482.155, 482.160, 482.165, and 482.170, respectively.

C. Part 485 is amended as follows:

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

1. The authority citation for part 485 continues to read as follows:

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

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

2. Section 485.639(c) is revised to read as follows:

§ 485.639 Condition of participation: Surgical services.

* * * * *

(c) *Administration of Anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws. Anesthesia is administered only by a licensed practitioner permitted by the State to administer anesthetics.

* * * * *

D. Part 489 is amended as follows:

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

1. The authority citation for part 489 continues to read as follows:

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

2. Section 489.53 is amended by republishing paragraph (a) introductory text, redesignating paragraphs (a)(6) through (a)(14) as paragraphs (a)(7) through (a)(15), respectively, and adding a new paragraph (a)(6), to read as follows:

§ 489.53 Termination by HCFA.

(a) *Basis for termination of agreement with any provider.* HCFA may terminate the agreement with any provider if HCFA finds that any of the following failings is attributable to that provider:

* * * * *

(6) It refuses to allow access to its facilities, or examination of its operations or records, by or on behalf of HCFA, as necessary to verify that it is complying with the provisions of title XVIII and the applicable regulations of this chapter, or with the provisions of this agreement. (However, this paragraph is not to be construed to require the disclosure of the records of a skilled nursing facility quality assessment and assurance committee, if such disclosure would be inconsistent with § 483.75(o) of this chapter.)

* * * * *

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

Dated: November 26, 1997.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: December 10, 1997.

Donna E. Shalala,

Secretary.

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