a. What is the increased cost of demarking to the government, to the importer, to the distributor, to the manufacturer, to the consumer?

b. What would be the volume of goods affected?

c. What would be the effect of the demarking requirement on the ability of firms to purchase trademarked goods abroad, import them into the U.S. and sell them at a cost lower than that of the authorized distributor? Would it vary among different goods? Are there cases where the effect would be to halt or significantly impair parallel imports?

d. Would a demarking requirement affect the manner or extent to which owners apply trademarks to goods? Would it affect the design of products?

e. Are there any other costs associated with mandatory demarking?

7. What are the benefits of mandatory demarking?

a. Describe the evidence demonstrating the existence and significance of any consumer information problems that may result from the gray market. To what extent would mandatory demarking address the free rider or consumer confusion or deception problems resulting from parallel imports? What relevant information could retailers tell consumers (in advertisements or face-to-face) concerning a parallel import? Could the product be advertised as identical to the trademarked product? How would the ability to provide this information affect any potential benefits of demarking?

b. How easy would it be to circumvent this requirement?

c. Are there any other benefits that should be considered?

8. Are there any other factors that are relevant to or affect parallel imports that have not been cited herein but that should be taken into account when formulating a policy on demarking of such goods?

Comparison of Labeling and Demarking

9. Compare the costs, and benefits of mandatory labeling and mandatory demarking. Which of these approaches would be better?

Comments

Comments and/or data submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), section 1.4, Treasury Department Regulations (31 CFR 1.4), and section 103.11(b), Customs Regulations (19 CFR 103.11(b)), between 9:00 a.m. and 4:30 p.m. on normal business days, at the Regulations Control Branch, Room 2426, U.S. Customs Service Headquarters, 1301 Constitution Avenue, NW., Washington, D.C. 20229

Drafting Information

The background explanation and questions contained in this document were prepared by the President's Economic Policy Council. However, personnel from the Customs Service and Treasury Department participated in its development.

William von Raab,

Commissioner of Customs.

Approved: June 13, 1986.

Francis A. Keating, II,

Assistant Secretary of the Treasury.

[FR Doc. 86-13760 Filed 6-16-86; 8:45 am]

BILLING CODE 4820-02-M

Sunshine Act Meetings

Federal Register
Vol. 51, No. 116
Tuesday, June 17, 1986

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Monday June 23, 1986.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposals regarding the Federal Reserve System's Employee Benefits Advisory Board.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: June 13, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-13774 Filed 6-13-86; 3:52 pm]

BILLING CODE 6210-01-M

3

SECURITIES AND EXCHANGE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: (51 FR 20920 June 9, 1986).

STATUS: Closed meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE PREVIOUSLY ANNOUNCED: Tuesday, June 3, 1986.

CHANGE IN THE MEETING: Additional meeting.

The following items will be considered at a closed meeting scheduled for Friday, June 13, 1986, at 10:00 a.m.

Institution of injunctive actions.

Institution of administrative proceeding of an enforcement nature.

Litigation matter.

Settlement of administrative proceeding of an enforcement nature.

Commissioner Grundfest, as duty officer, determined that Commission business required the above changes and that no earlier notice thereof was possible.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Jacqueline Higgs at (202) 272-2149.

June 11, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-13668 Filed 6-12-86; 4:06 pm]

BILLING CODE 8010-01-M

federal register

Tuesday
June 17, 1986

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 405, 412, 416, 417, 440, 441, 456, 482, and 489

Medicare and Medicaid Programs; Conditions of Participation for Hospitals; Final Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 412, 416, 417, 440, 441, 456, 482, and 489

[BERC-519-F]

Medicare and Medicaid Programs; Conditions of Participation for Hospitals

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

ACTION: Final regulations.

SUMMARY: These regulations revise the requirements that hospitals must meet in order to participate in the Medicare and Medicaid programs (Titles XVIII and XIX of the Social Security Act).

These revisions are intended to simplify and clarify Federal requirements, to provide maximum flexibility in hospital administration while strengthening patient health and safety, to emphasize outcomes rather than processes, to promote cost effectiveness while maintaining quality care, and to achieve more effective compliance with Federal requirements.

These regulations also incorporate conforming changes relating to certification of psychiatric hospitals and participation of tuberculosis hospitals made by the Deficit Reduction Act of 1984 (Pub. L. 98-369).

EFFECTIVE DATE: These regulations are effective on September 15, 1986.

FOR FURTHER INFORMATION CONTACT: Stanley Rosenfeld, (301) 594-5675.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

Conditions of participation (conditions) is the term used for the requirements that hospitals must meet in order to participate in the Medicare program. The current regulations containing the Medicare conditions are located in the Code of Federal Regulations at 42 CFR Part 405, Subpart J. Under the regulations at 42 CFR 440.10(a)(3) and 440.20(a)(3), hospitals are also required to meet the Medicare conditions of participation (except in the case of medical supervision of nurse-midwife services) in order to participate in the Medicaid program. These conditions implement sections 1814(a)(7), 1861 (e), (f), (g), (k), and (z), and 1903(g) of the Social Security Act (the Act) and are intended to protect patient health and safety and assure the quality of care provided to Medicare and Medicaid beneficiaries.

The conditions and accompanying standards specified in the regulations are used by our surveyors as a basis for determining (1) whether a hospital qualifies for a provider agreement under Medicare and Medicaid; and (2) whether a hospital that does not qualify or choose to participate in the Medicare program may, nevertheless, be paid for emergency services furnished to Medicare beneficiaries. In determining whether a hospital is in compliance with the conditions, HCFA must, in accordance with section 1865 of the Act, deem a hospital to meet certain conditions by virtue of its accreditation by the Joint Commission on Accreditation of Hospitals (JCAH) or the American Osteopathic Association (AOA).

There has been no substantial revision of the conditions since they were first published in 1966, despite changes in the state of the art. There have been significant changes in the organizational structure of hospitals and dramatic technological advancements since 1966. In addition, there is a need to provide for sufficient flexibility in the requirements to allow their application to both the smallest rural facility and to the most complex urban hospital centers.

II. Notices of Proposed Rulemaking (NPRMs)

A. General

On June 20, 1980, the Department published in the **Federal Register** a notice of proposed rulemaking (NPRM) to revise the hospital conditions (45 FR 41794). After that publication, HCFA initiated a process of review as part of the Secretary's efforts to reduce the burden of Federal regulations. Therefore, HCFA did not prepare a final rule for the June 20, 1980 NPRM, but rather established criteria to review the existinq conditions to determine—

1. What requirements are necessary to protect the health and safety of patients.

2. Whether the conditions contain only those requirements that are authorized by the statute.

3. What requirements unnecessarily overlap with similar requirements enforced by other Federal, State, or local government programs.

4. What requirements are consistent with our objective of permitting maximum flexibility in facility administration.

As a result of this review and our consideration of public comments on the June 20, 1980 NPRM, we published a second NPRM in the **Federal Register** on January 4, 1983 (48 FR 299). The amendments to the conditions proposed in the second NPRM took into consideration the fact that, in addition to Federal regulations, hospitals are subject to substantial State inspection through licensure programs and that there are nationally recognized standards of practice that are well

accepted and adhered to generally through a voluntary accreditation process. We maintained in the NPRM the basic function of the conditions of protecting patient health and safety. In addition, we focused on: (1) Eliminating unnecessary regulations and providing hospitals with greater flexibility; (2) replacing prescriptive administrative requirements with language that is stated in terms of expected outcome; (3) in most cases, giving responsibility to the hospital for choosing its own staff and delineating staff responsibilities rather than specifying Federal requirements for credentials and qualifications; (4) replacing specific details on maintaining adequate and safe facilities with general comprehensive statements; and (5) clarifying the regulations to avoid any implied suggestion that hospitals should organize their services into formal departments.

B. Overview of Comments

Over 36,300 public comments were received on the January 4, 1983 NPRM. Eighty-five comments were from professional medical and health care associations and groups representing institutions, practitioners, and health care personnel. The remaining comments were from State agencies, individual practitioners, social workers, medical librarians, respiratory therapy personnel, nurses, other health care personnel, and private individuals. The volume of the comments precludes detailed discussion, but we have incorporated many of the comments. Several provisions of the proposed rules, which simply restated the existing requirements, were opposed mainly because of their obsolescence. In these cases, we have revised the conditions to reflect current accepted practice. We received numerous specific comments that were intended to improve the clarity and consistency of the regulations. We have made changes to accommodate most of these comments. We also received a significant number of specific comments which we rejected because they would have hampered our general goal of providing hospitals maximum flexibility in administration while protecting patient health and safety, or because their general intent was already covered in the conditions.

III. Provisions of Final Regulations and Discussion of and Responses to Public Comments

A. Overview

These final regulations follow the basic approach of the January 1983 NPRM. This approach is designed to eliminate unnecessary provisions, delete overly prescriptive requirements, and revise requirements to reflect changes in the state of the art. We believe the revised, outcome-oriented conditions provide better guarantees of quality health care services for Medicare and Medicaid beneficiaries than the prescriptive rules that they replace. The revised regulations require hospitals to clearly demonstrate that they provide for the medical and medically-related needs of Medicare and Medicaid beneficiaries, while giving hospitals greater flexibility to achieve these goals. The new rules focus the attention of hospitals and government surveyors on the comprehensive needs of the patients, rather than outmoded and costly procedural requirements.

Because of the varied subject-matter and the number and complexity of public comments received, we will present the policy provisions of the final regulations and address public comments in the order of presentation of the conditions in the proposed regulations. Because the issue of the deletion of personnel credentials for hospital staff other than doctors of medicine or osteopathy relates to many different conditions, we will discuss it separately. The remaining provisions will be presented as follows:

For each condition, we will first summarize the existing provisions and the amendments proposed in the January 1983 NPRM. Second, we will summarize the public comments as they relate to that condition. Third, we will respond to the public comments and discuss the provisions of the final regulations, with an explanation of changes made in response to public comments or the rationale for not making further changes.

The final regulations are codified under a new Part 482 in the Code of Federal Regulations under Title 42, Chapter IV, Subchapter E (a redesignation from 42 CFR Part 405, Subpart J)

B. Personnel Credentials

• *Existing provisions.* Current regulations contain specific qualifications for hospital staff (social workers, nurses, medical records personnel, respiratory therapists and technicians, surgical technologists, radiology technicians, and medical librarians) and for directors of hospital units, departments, and services. These qualifications are heavily dependent on credentials awarded by private accreditation groups.

• *NPRM provisions.* In the January NPRM, we proposed to eliminate many of the current credential requirements. We made the proposal because those requirements (1) inappropriately restrict hospitals from selecting staff; (2) may superimpose the requirements of private groups over State laws; and (3) do not necessarily ensure the provision of quality care.

• *Public comments.* Many commenters objected to the deletion or omission of the credential requirements They argued that quality of care will deteriorate because they believe noncredentialed staff are not qualified to provide quality care. Others recommended more stringent qualifications than those under the current requirements (for example, that all social workers have master's degrees in social work and that social work assistants have bachelor's degrees).

Other commenters agreed with the deletion of the credential requirements for hospital staff other than doctors of medicine or osteopathy. They stated that it is inappropriate for the Federal Government to impose restrictions which may conflict with State and local laws; and that, irrespective of conflict with State and local laws, it is inappropriate for the Federal Government to promote the monopoly they believe has been created by private credentialing organizations. They believed that hospitals will not allow quality of care to deteriorate as a result of these deletions; that hospitals are in the best position to determine personnel criteria for their employees; and that credentials do not guarantee quality care.

• *Responses and provisions of final regulations.* We continue to believe that, in general, Federal credential requirements for hospital staff other than doctors of medicine or osteopathy inappropriately restrict hospital selection of staff (in particular in small hospitals in rural areas). We believe that hospitals are most capable of determining when specific credentials are necessary. In addition, we believe that Federal regulations should not establish requirements that are more restrictive than those set by State legislatures, unless we are convinced that Federal requirements are essential to patient health and safety and the provision of quality care. In addition, we agree that incorporating the standards of private credentialing organizations into the Federal conditions of participation can have the effect of reinforcing a tendency toward monopolistic results that cannot be justified on the grounds of protecting patient health and safety. Therefore, in the final regulations we have deleted the current credential requirements for most

hospital staff. The final regulations provide that these various types of hospital staff must have adequate education, experience, and training in accordance with acceptable standards of practice.

Although our general approach is to avoid the use of credential requirements, we have retained the credential requirements in certain highly specialized areas in which these qualifications are essential to patient health and safety and the provision of quality care. These include qualifications for directors of psychiatric services and psychiatric nursing services, and dermatologists who subspecialize in pathology and oral pathologists.

C. Provision of Emergency Services by Nonparticipating Hospitals (§ 482.2, previously § 405.1011).

• *Existing provisions.* Current regulations provide that a nonparticipating hospital that meets the requirements of section 1861(e) (1) through (5) and (e)(7) of the Act may be paid for emergency services furnished to Medicare beneficiaries.

• *NPRM provisions, public comments, and provisions of final regulations.* The NPRM made only clarifying editorial changes in this provision. We did not receive any specific public comments on the NPRM. We have adopted the NPRM provisions as final regulations.

D. Definition of Physician (§ 482.3)

• *Existing provisions.* The current regulations restate the requirement in section 1861(e)(4) of the Act that each patient be under the care of a physician, and also provide that specific services or functions must be performed by a physician. However the regulations do not contain an explicit definition of "physician." The omission of such a definition in the regulations has resulted in a common interpretation of "physician" to mean only a doctor of medicine or osteopathy. In addition, specific conditions imply that care may be provided only by doctors of medicine or osteopathy and do not recognize the present trend in hospitals of extending patient care responsibilities to other practitioners who are permitted to perform certain functions under State law.

• *NPRM provisions.* In the January 1983 NPRM, we proposed to alleviate this confusion by defining the term "physician." The proposed definition included all practitioners provided for under section 1861(r) of the Act. Section 1861(r) recognizes, for purposes of Medicare, the following practitioners who perform functions within the restrictions of State law and licenses:

(1) A doctor of medicine or osteopathy;

(2) A doctor of dental surgery or dental medicine;

(3) A doctor of podiatric medicine;

(4) A doctor of optometry, but only with respect to services related to the condition of aphakia; and

(5) 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.

We proposed this definition in order to make the use of the term "physician" in the revised regulations consistent with its use in the statute.

In the NPRM, we also proposed to use the term "medical staff" to replace "physician" in certain conditions relating to organization and operation of a hospital's professional medical staff. This would give maximum flexibility to a hospital in granting staff privileges and organizing its medical staff, and also reflects the present hospital trend of extending patient care responsibilities to various practitioners other than doctors of medicine or osteopathy. For example, a hospital could choose to grant staff privileges to nurse practitioners and nurse-midwives.

• *Public comments.* A number of commenters supported the proposal to include the categories of physicians recognized in the Social Security Act. Other commenters objected to the inclusion of podiatrists, chiropractors, and optometrists in the definition of physician. They believed that the inclusion of these practitioners would result in: (1) Deterioration of the quality of care (for example, they objected to the possibility that a chiropractor could fulfill the requirement that each patient be under the care of a physician); (2) the possibility of a participating hospital not having direction or involvement of doctors of medicine or osteopathy; and (3) a diminished role of doctors of medicine and osteopathy and a heightened role of other practitioners in hospital practices such as the granting of clinical privileges and recommendations for medical staff membership. In the opinion of these commenters, podiatrists, chiropractors, and optometrists were added to the statutory definition of physician only for coverage and reimbursement purposes. They recommended either deleting the definition or revising it to include only doctors of medicine or osteopathy, dentists, and oral surgeons.

Other commenters recommended a more inclusive definition than the one proposed—one that would prohibit discrimination against any class of practitioners. Some of the commenters recommended that the definition include psychologists, speech-language pathologists, and audiologists. They argued that these practitioners are well-trained professionals who should be granted the same status and rights as chiropractors, podiatrists, and optometrists. Others recommended including the limitations on performance of functions in accordance with State law and the restrictions on services specified in the Act.

• *Responses and provisions of final regulations.* We included a definition of the term "physician" in the proposed regulations because we wanted to eliminate the confusion that has resulted from the use of the term without a specific definition in current regulations. We selected the definition of "physician" in section 1861(r) of the Act because it is the only definition in the Medicare statute. However, it is apparent from the public comments received that adoption of the proposed definition in these final regulations could result in further confusion regarding which specific types of practitioners referred to in the section 1861(r) definition may perform certain functions and actions. Moreover, we recognize the concerns of those commenters who noted that the section 1861(r) definition was included in the statute primarily to describe the scope of services covered under Medicare, and argued that it should not be used to specify conditions of participation for hospitals.

To avoid further confusion regarding these issues, we have revised the final regulations to eliminate the definition and the use of the term "physician" and to state more specifically which categories of practitioners will be permitted to perform certain functions and actions. For example, we have specified that only a doctor of medicine or osteopathy or other licensed practitioner permitted under State law may admit patients (§ 482.12(c)). We have clarified certain provisions by specifying doctor of medicine or osteopathy where we are convinced, consistent with section 1861(e)(9) of the Act, that the requirement must be imposed to ensure patient health and safety—that is, the organization and conduct of medical staff (§ 482.22 (a) and (b)), composition of utilization review committee (§ 482.30(b)), radiologic services (§ 482.26(c)), pathology services (§ 482.27 (c) and (d)), supervision and direction of anesthesia services (§ 482.52), nuclear medicine services (§ 482.53), direction and

ordering of respiratory care services (§ 482.57), and provision of psychiatric services (§ 482.62 (b) and (c)).

The issue of recognizing doctors of medicine and osteopathy and other practitioners under applicable State law as part of the medical staff is discussed under sections III.F. and H. of this preamble.

E. Compliance With Federal, State, and Local Laws (§ 482.11, Previously § 405.1020)

• *Existing provisions.* Section 1861(e)(7) of the Act addresses State and local licensure requirements for hospitals participating in Medicare. If State or local laws provide for the licensing of hospitals, the Act requires the hospital to be licensed or to be approved by the appropriate State or local licensing authority as meeting the standards for licensure. Current regulations restate these statutory requirements and expand upon them by requiring compliance with all relevant laws (e.g., laws relating to staff licensure, fire and safety, postmortem examinations, and communicable diseases).

• *NPRM provisions.* The NPRM proposed to revise the regulations simply to restate the statutory requirements for meeting State and local licensure laws, and to require compliance with applicable Federal laws. We proposed to delete the reference to related laws.

• *Public comments.* Commenters objected to the requirement that hospitals must comply with other applicable Federal laws. They argued that this requirement exceeds the statutory authority of section 1861(e) and that it is inappropriate for HCFA to enforce Federal laws unrelated to the programs it administers. Several commenters recommended that we retain the requirement that the hospital assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

• *Responses and provisions of final regulations.* In the final regulations, we have adopted the NPRM language with several changes. We have revised the provision regarding compliance with Federal laws to specify that hospitals must comply with Federal laws *related to patient health and safety.* We made this change to clarify that, while hospitals are subject to Federal laws that govern matters such as minimum wages of employees, occupational safety and health, and civil rights, only factors related to patient health and safety are within the scope of this regulation and the legislative provision on which it is based. This change will allow a hospital to be found out of compliance based on a violation of Federal law only if the violation is one that could endanger patients' health and safety.

In addition, we have restored the requirement which ensures that hospital personnel are licensed or meet other applicable standards under State and local laws (§ 482.11(c)) as a health and safety factor. In view of our decision to delete specific personnel credential requirements wherever possible and to rely instead on State and local licensing laws as a means of ensuring that hospitals employ only qualified personnel, we believe it is essential to patient health and safety to impose this requirement.

F. Governing Body

1. Standard for Medical Staff (§ 482.12(a), previously § 405.1021(e))

• *Existing provisions.* Section 1861(e)(3) requires a hospital to have bylaws in effect for its staff of physicians. Current regulations specify detailed standards for appointment of members of the medical staff by the governing body of the hospital.

• *NPRM provisions.* We proposed to revise the regulations to indicate simply that the governing body must assure that medical staff is accountable to the governing body for the quality of patient care; organizes itself under bylaws as required by section 1861 (e)(3) of the Act; and provides that a physical examination be performed and a health history obtained no more than 7 days before or 60 hours after admission. (The 60-hour timeframe in the proposed rule was a change from the current timeframe of 48 hours.)

• *Public comments, responses, and provisions of final regulations.* The NPRM provisions have been revised in the final regulations to accommodate many of comments in this area.

One commenter recommended placing the medical staff standard in the medical staff condition because its content was more appropriate to that condition. Another commenter recommended that the regulations provide that a complete health history and comprehensive physical examination be required on each patient and that the examination be performed by or under the direct supervision of a privileged member of the medical staff who is qualified by education, training, and experience to perform it. Several commenters also stated that our proposal to extend the timeframe for completion of the physical examination and health history would reduce the timeliness, and therefore the usefulness, of the information.

We have accepted the commenters recommendations by moving the provisions on physical examination and health history and accountability in the governing body condition to the medical staff condition under § 482.22 (b) and (c)(5). To assure the health and safety of patients admitted for services in certified hospitals, we have also included language that specifies that the physical examination and health history must be performed by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law. We have also retained the 48-hour timeframe for completion of the physical examination and health history instead of the proposed 60 hours. This issue is discussed in detail under section III.J. of this preamble, which deals with comments on medical records. In addition, we have revised the governing body condition to specify and clarify the responsibilities of the governing body for the medical staff.

Several commenters recommended that the regulation require that the governing body provide a procedure for due process when an individual is denied either membership on the medical staff or clinical privileges. We have not accepted this recommendation because we believe that it is too prescriptive for Federal requirements and is unrelated to ensuring patient health and safety.

2. Standard for Chief Executive Officer (§ 482.12(b), previously § 405.1021 (f) and (g))

• *Existing provisions.* Current regulations specify that the governing body must appoint a hospital administrator, describe the qualifications for this position, and specify the details on how the administrator should perform his or her functions.

• *NPRM provisions.* In the NPRM, we proposed to revise the regulations by eliminating education and experience requirements applicable to an administrator. The proposed regulations would have retained the specific function by simply requiring the governing body to appoint a chief executive officer who would be responsible for managing the hospital. We proposed to delete the detailed provisions on how the administrator would carry out the responsibilities.

• *Public comments.* Commenters objected to the absence of qualification

requirements for the chief executive officer. They recommended that we provide either general or specific qualifications that must be met.

• *Response and provisions of final regulations.* The final regulations contain the language of the proposal. We have not made any changes because we believe that specifying qualifications for this staff member would reduce the governing body's flexibility in managing the facility. The governing body remains responsible for appointing the administrator. We believe the governing body's interest in assuring efficient administration of the hospital, consistent with its responsibility for the hospital's management, is a sufficient incentive for appointing qualified personnel. Furthermore, we believe that the absence of specific qualifications in the regulations will not adversely affect patient health and safety.

3. Standard for Care of Patients (§ 482.12(c), previously Physician Care, § 405.1021(h))

• *Existing provisions.* Section 1861(e)(4) of the Act requires that every patient be under the care of a physician. Current regulations require that a hospital have policies to assure that patients are under the care of a physician.

• *NPRM provisions.* We proposed to require that the governing body ensure the availability of physician care (in accordance with the proposed definition of physician specified under § 482.3), that patients actually be under a physician's care (not merely to require that the hospital have an established policy), that a physician admit all patients, and that a doctor of medicine or osteopathy be on duty or on call at all times.

• *Public comments, responses, and provisions of final regulations.* Several commenters indicated that the regulation, taken literally, would require each hospital to make available the services of all types of practitioners contained in the proposed definition of physician under § 482.3. They indicated that such a requirement would often contradict State law and would severely restrict the governing body's right to determine what categories of practitioners would be granted medical staff membership. Several commenters argued that it is contradictory to require that every patient be under the care of a physician and at the same time allow a hospital to open its medical staff to practitioners who do not meet the proposed definition of physician. Other commenters argued that, for health and safety reasons, each patient should be under the care of a doctor of medicine or osteopathy.

As discussed earlier, the public comments we received on the proposed definition of "physician" made it clear that the final regulations must specify in greater detail the functions and actions each type of practitioner is permitted to perform. We believe that this specificity is especially important in the standard on physician care implementing the statutory requirement that every patient be under the care of a physician. Therefore, we have revised the proposed standard on physician care to specify the types of practitioners included in the definition of "physician" in section 1861(r) of the Act, and to include the statutory restrictions on the practitioners' functions for which Medicare coverage is provided (e.g., for optometrists, services related to the condition of aphakia). However, our specificity in this standard on physician care is not intended to restrict the ability of doctors of medicine or osteopathy to delegate tasks to appropriate qualified health care personnel such as physician assistants, nurse practitioners, registered nurses, licensed practical nurses, etc., in accordance with State law. In addition, our use of the statutory restrictions in the context of a condition of participation that applies to all patients in a hospital does not mean that Medicare will cover or pay for hospital stays in which the patient is hospitalized solely for the purpose of receiving a type of service (e.g., the prescription of eyeglasses or contact lenses) that does not require inpatient hospitalization.

We have specified also that a doctor of medicine or osteopathy must be responsible for the care of each patient who has a medical or psychiatric problem requiring care or treatment that is not specifically within the scope of practice of other practitioners identified under section 1861(r) of the Act. We believe this approach will permit hospitals to adopt policies on medical staff membership and privileges that recognize the legitimate role of practitioners other than doctors of medicine or osteopathy in caring for patients. While still ensuring patient safety by requiring doctors of medicine or osteopathy to assume responsibility for care of patients with medical problems outside the scope of practice of other practitioners. As explained earlier, we have also deleted the proposed definition of "physician" in § 482.3.

4. Standard for Institutional Plan and Budget (§ 482.12(d), previously, Institutional Plan, § 405.1021(j))

• *Existing provisions.* Sections 1861(e)(8) and (z) of the Act require a hospital to have an annual operating budget and capital expenditure plan. Current regulations expand upon the statutory requirement by specifying detailed standards for. preparation and content of the plan and budget.

• *NPRM provisions.* We proposed to modify the regulations by simply incorporating the basic provisions contained in the Act.

• *Public comments.* Commenters recommended that we clarify the regulation to indicate that only the budget and financial documents must be prepared in accordance with generally accepted accounting principles since the principles apply only to these documents.

• *Response and provisions of final regulations.* We have adopted the proposed regulations as final with a clarifying change to indicate the application of accounting principles to the budget. We have also made a conforming amendment to this standard to reflect changes made by section 607 of the Social Security Amendments of 1983 (Pub. L. 98–21). Section 607 revised sections 1122(g) and 1861(z)(2) and added a new section 1122(j) to the Act to—

• Change the dollar unit in the definition of "capital expenditure" from $100,000 to $600,000 (or a lesser amount that may be established by the State in which the hospital is located in accordance with section 1122(g)(1) of the Act);

• Require that the plan must be submitted for review to a planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State; and

• Exempt capital expenditures from section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are federally qualified health maintenance organization (HMO) or competitive medical plan (CMP) enrollees and if the Department determines that the capital expenditure is for services and facilities that are needed for the HMO or CMP to operate efficiently and economically and if the services and facilities are not otherwise readily accessible to the HMO or CMP due to certain specified circumstances.

5. Standard for Contracted Services (§ 482.12(e))

• *Existing provisions.* The use of contracted services in hospitals has increased dramatically since 1965. Today, services frequently provided through contractual arrangements include nursing, pharmacy, emergency, dietary, laboratory, and radiology. Many of the conditions in the current regulations permit the use of contracted services. Although the services might be subject to survey under other conditions, such as nursing and pharmacy, it is difficult to survey for all aspects of these services when they are not provided on the hospital premises. For example, food for the hospital may be prepared elsewhere, and certain ancillary services may be provided off site. In addition, comments received on the 1980 NPRM highlighted the fact that there does not appear to be a clear understanding, or acceptance, of the hospital's responsibility for services provided under contract.

• *NPRM provisions.* The 1983 NPRM was intended to clarify that the hospital has ultimate responsibility for services, whether they are provided directly, such as by its own employees, by leasing, or through arrangement, such as formal contracts, joint ventures, informal agreements, or shared services. Because many contracted services are integral to direct patient care and are important aspects of health and safety, a hospital cannot abdicate its responsibility simply by providing that service through a contract with an outside resource. For purposes of assuring adequate care, the nature of the arrangement between the hospital and the "contractor" is irrevelant. The NPRM, therefore, proposed to specify that the governing body must be responsible for these services and that the services must be provided in a safe and effective manner.

As a result of the increased reliance on contracting for temporary nursing personnel by hospitals, the NPRM also included specific requirements to ensure that hospitals provide adequate supervision and evaluation of the clinical activities of nonemployee licensed nursing personnel (§ 482.23(b)(6)). This would ensure that contracted nursing employees are required to perform at the same level of competence as nurses employed directly by the hospital.

• *Public comments.* Commenters objected to the requirement that hospitals be responsible for services furnished in the hospital under contracts. They argued that the hospital should be responsible only for assuring that the contractor meets necessary standards and can provide reputable services.

• *Response and provisions of final regulations.* We have retained the standard for services provided under contract in the final regulations, but have revised it to indicate that the governing body is responsible for assuring that the contractor furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services. We have also revised the quality assurance condition (§ 482.21) to assure that services provided under contract that relate to patient health and safety are included for evaluation in the quality assurance plan.

6. Standard for Discharge Planning (proposed § 482.12(f), now § 482.21(b), previously § 405.1034(a)(4))

• *Existing provisions.* Under current regulations, planning for patient care after discharge is provided for under the standards for organization, direction, and personnel of the social work departments under the optional social services condition (The current regulations do not specifically refer to the term "discharge planning.")

• *NPRM provisions.* Because of the optional nature of social services in the current regulations and our belief that the organization of social work departments does not require Federal regulations, we proposed to delete this condition in our January 1983 NPRM However, we believe discharge planning is essential to total patient health and that this is a function that a hospital should provide. In addition, discharge planning has been linked to decreased rates of hospital readmissions. Therefore, in the NPRM, we proposed to add a new standard under the governing body condition that requires discharge planning. The governing body would have been responsible for assuring an ongoing effective program that provides for followup care for patients.

• *Public comments.* Most commenters favored including discharge planning requirements in the regulations. Some commenters suggested that we revise our proposed standard to require coordinated efforts of the hospital's services in planning for patient care after discharge. Other commenters suggested that we require specific types of personnel (for example, nursing or social services personnel) to be responsible for discharge planning. A commenter recommended that we consolidate numerous requirements related to patient care included in the governing body standards (e.g., physician care, discharge planning, social services) in a new patient care delivery condition because these requirements all pertain directly to patient care rather than to administration.

• *Responses and provisions of final regulations.* We agree that appropriate coordination of discharge planning among hospital services is essential and have revised the standard accordingly. However, we have not specified which hospital personnel must carry out this activity, since such specificity could unduly restrict a hospital's flexibility in meeting the discharge planning needs of its patients. We have transferred the discharge planning standard from the condition on governing body to the condition on quality assurance because we believe a hospital can achieve better compliance with the standard as a part of an effective quality of care assurance program. We have not developed a separate, comprehensive patient care delivery condition of the type recommended by one commenter. We believe that all conditions pertain to patient care delivery, and that to establish a particular condition in this manner could suggest, inappropriately, that any requirements not included in the condition are unrelated to patient care. We have, however, developed a standard that relates to the commenter's proposed patient care delivery condition under the condition relating to assuring quality of hospital care (§ 482.21). This standard deals with discharge planning (transferred from the governing body condition) and with social services. (Section III. CC. of this preamble contains a further discussion of the social services provisions.)

7. Deletion of Standards for Bylaws, Meetings, Committees, and Liaison (previously § 405.1021 (a), (b), (c) and (d))

The current regulations contain detailed standards regarding adopting bylaws, conducting meetings, appointing committees, and establishing liaison by the hospital's governing body. In the NPRM, we proposed to delete these provisions regarding bylaws, meetings, committees, and liaison because we considered them unnecessarily prescriptive. We believe that it is not necessary for Federal regulations to address these specific administrative issues. Rather, these provisions should fall under the discretion of individual facility management. No public comments were received in this specific area and the standards are deleted in the final regulations.

8. Deletion of Standard for Physical Plant (§ 405.1021(i))

The current regulations also contain under the governing body condition a requirement that the governing body be actively involved in maintaining the physical plant. In the NPRM, we proposed to delete this requirement as duplicative of the intent of the condition on physical environment. No specific comments were received on the deletion and this requirement is also deleted in the final regulation.

G. Quality Assurance (§ 482.21)

• *Existing provisions.* A number of the current regulations contain provisions that specify procedural requirements that hospitals must follow to assure quality care (fcr example, under the conditions and standards for organizational characteristics, committee functions, and personnel). We believe that a focused requirement would better address quality of care.

• *NPRM provisions.* We proposed to include a new condition of participation that would require the hospital to establish a hospital-wide quality assurance program aimed at identifying and correcting patient care problems. Specifically, we proposed to require that the hospital—

• Have a written quality assurance plan;

• Evaluate all organized services, nosocomial infections (that is, infections originating within a hospital), and medication therapy;

• Evaluate all surgery; and

• Document deficiencies and take appropriate remedial action.

• *Public comments.* One commenter recommended that we clarify what we meant by a quality assurance program "encompassing all practicing hospital staff." Similarly, other commenters indicated that it would be inappropriate for all organized services to be evaluated under a quality assurance program (for example, accounting, printing, etc.) and recommended that the program only relate to health and safety requirements.

• *Responses and provisions of final regulations.* Our intent was to establish a condition adequate to evaluate all patient care services in the hospital. Therefore, we have clarified the scope of the condition by indicating that the quality assurance program must evaluate the provision of patient care services and that the plan must apply to all organized services related specifically to patient care, including services provided under contract. We believe these changes will make it clearer that, while all patient care services furnished in the hospital (including services of doctors of medicine and osteopathy and other practitioners not employed by the hospital) must be evaluated, evaluation is not required for hospital support services, such as accounting, that do not affect patient care. We have made two other changes in the regulations to indicate that the quality assurance program must evaluate all medical and surgical services (not just surgical services) and that the hospital must not only document the appropriate remedial action but also the outcome of that action (§ 482.21 (a)(3) and (c)). As discussed under the governing body standard for discharge planning (section III.F. of this preamble) and under social services (section III. CC.), we have included a standard that provides for social work services and discharge planning as part of the quality assurance condition. The standard focuses on medically-related patient care services. It requires the hospital to have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services related to the medically related needs of patients. It also requires the hospital to have an effective, ongoing discharge planning program that facilitates the provision of followup care.

H. Medical Staff (§ 482.22, previously § 405.1023)

• *Existing provisions.* Current regulations provide specific requirements and detailed standards for bylaws, committees, meetings, and qualifications of medical staffs of hospitals.

• *NPRM provisions.* In the NPRM we proposed to delete thcse provisions that we believed were overly prescriptive or unnecessary and to modify others as follows:

1. To use the term "medical staff," not "physicians," to allow maximum flexibility to the hospital in granting privileges and organizing its professional staff. This reflects the present hospital trend of extending patient care responsibilities to practitioners other than doctors of medicine or osteopathy. (See discussion under Section III.D., Definition of Physician.)

2. To delete the standard regarding staff responsibilities to support hospital policies since this detail is not necessary for Federal regulations. However, the requirement that bylaws be enforced would have been retained.

3. To delete the standard on securing autopsies since autopsies depend on the consent of next-of-kin, except when legally mandated.

4. To delete requirements regarding consultations There is no indication that consultations, which are the direct responsibility of the attending physician, are being improperly conducted.

5. To combine and simplify requirements regarding staff appointments, staff qualifications, and staff officers (§ 405.1023 (d), (e), and (h)). The revision under the proposed regulations would have required: (a) a well-organized medical staff accountable to the governing body for the quality of medical care given to patients; (b) periodic appraisals of members of the staff; (c) the granting of clinical privileges only to those legally, professionally, and ethically qualified; and (d) an individual physician who is responsible for the organization and conduct of the medical staff. We proposed to maintain these requirements since there is evidence that a strong and responsible medical staff organization is related positively to the provision of quality care.

6. To delete the requirements regarding "other staff" (§ 405.1023(g)) since they are prescriptive without an apparent relationship to patient health and safety.

7. To simplify the requirement on bylaws. The revision under the proposed regulations would have required bylaws that enable the medical staff to carry out its responsibilities, and include a statement of qualifications for admittance to the staff and responsibilities of each category of medical staff.

8. To delete requirements on various specified committees (§ 405.1023(j)–(o)) as unnecessary and overly prescriptive. For example, the medical staff should have flexibility in determining whether a medical records committee is necessary. Also the issue of quality of care that formerly gave rise to the requirement for a tissue committee (§ 405.1023(o)) is now dealt with under another condition, quality assurance (§ 482.21).

9. To delete the requirement concerning meetings (§ 405.1023(p)). These meetings, such as those focusing on review of clinical work, were intended to assure quality of care. That intent would be provided for under the quality assurance condition.

10. To delete the requirements on organization, staffing, and responsibilities of medical staff departments and chiefs of services (§ 405.1023 (g) and (r)) as unnecessary and not affecting patient health and safety.

• *Public comments, responses, and provisions of final regulations.*

Comment: Some commenters recommended that the regulation be revised to prohibit the hospital or its medical staff from discriminating against any category of physician identified in the proposed § 482.3 by refusing to allow admittance to the staff or duties and privileges based on the category of a physician rather than individual capabilities.

Response: We have not accepted this recommendation because we wish to grant hospitals the flexibility to allow or to refuse to allow, practitioners other than doctors of medicine or osteopathy to join the medical staff and to obtain privileges if the hospital so chooses. To do otherwise could not give adequate deference to State laws that regulate hospitals or to changing practices in the delivery of medical care.

Comment: Commenters objected to the opening of the medical staff to practitioners other than doctors of medicine or osteopathy that they believed was implicit in the proposed rule's absence of a discussion of the composition of the medical staff. They argued that the medical staff functions of setting policies and procedures governing the hospital's provision of care, and the review and granting of clinical privileges, demanded the skills and training possessed only by doctors of medicine or osteopathy. Consequently, they believed that creating the potential for membership by other individuals would also create the potential for doctors of medicine or osteopathy to have a diminished impact on medical staff functions, resulting in loss of quality of patient care.

Response: We have revised the condition addressing the governing body responsibility for the medical staff (§ 482.12(a)) and the condition on the medical staff (§ 482.22) to clarify the governing body's responsibility to determine the composition of the medical staff and to approve the medical staff bylaws. As discussed earlier under section III. D., we have also revised portions of other conditions to require that only a doctor of medicine or osteopathy be permitted to perform certain functions and services where we believe the functions or services of a doctor of medicine or osteopathy are essential to patient health and safety.

As previously noted in response to a comment, we wish to grant hospitals the flexibility to allow, or to refuse, to allow, practitioners other than doctors of medicine or osteopathy to join the medical staff and to obtain privileges if the hospital so chooses. To do otherwise would not give adequate deference to State laws that regulate hospitals or to changing practices in the delivery of medical care.

Comment: Commenters objected to the requirement that a "physician" (as defined in the regulations) be responsible for the organization and conduct of the medical staff. They recommended that we specify that direction be provided either by a doctor of medicine or osteopathy or by a committee of physicians as defined in the NPRM, a majority of which would be required to be doctors of medicine or osteopathy.

Response: We have revised the regulation to require that an individual doctor of medicine or osteopathy be responsible for the conduct and organization of the medical staff. We believe that this change assures a necessary level of skills and education for the direction of the medical staff. We have not adopted the suggestion that we permit this responsibility to be assigned to a committee. We are concerned that division of responsibility for maintenance of quality of care standards among members of a committee could lead to inconsistent application of those standards, and that these inconsistencies, which could jeopardize patient health and safety, would be difficult to detect and correct if accountability is dispersed among the members of a committee. To ensure proper accountability for medical staff conduct and organization, we believe a single individual must have this responsibility.

We have also revised the regulation to indicate that, if a hospital chooses to have a medical staff executive committee, a majority of the committee members must be doctors of medicine or osteopathy. If the chairperson is a doctor of medicine or osteopathy, he or she could be designated as the individual responsible for the conduct and organization of the medical staff. If a hospital chooses to have a medical staff executive committee that acts for the staff under the same circumstances, we believe that it is necessary to patient health and safety that a majority of its members be doctors of medicine or osteopathy. We also believe that even if a hospital has a medical staff executive committee, it is necessary that an individual doctor of medicine or osteopathy be designated as the director to assure consistent application of standards essential to quality of care.

Comment: Commenters recommended that we continue the requirement for a joint committee to formalize liaison between the medical staff and the hospital's administration. The commenters argued that this committee is necessary to coordinate activities related to patient care and that without such a requirement coordination would falter.

Response: We have not accepted this recommendation because we believe that the requirement that the medical staff be accountable to the governing body for the quality of care makes the governing body responsible for assuring coordination of patient care services. We believe that how best to organize liaison and coordination of activities with the medical staff should be the internal decision of the hospital's management.

Comment: Commenters recommended that the regulations be revised to require the medical staff bylaws to contain a description of the organization of the medical staff, a list of recognized categories of medical staff, and enough latitude for nonphysician practitioners to perform physical examinations and health histories, if this practice is consistent with State laws and the wishes of the medical staff.

Response: We have revised the regulations to incorporate the first two recommendations because we feel the details of the recommendations are necessary to ensure that the medical staff functions in a manner that promotes patient health and safety. We have not accepted the third recommendation, but have instead specified that the physical examination and medical history must be performed by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law. We believe this provision is necessary to ensure that patients receive appropriate treatment for medical or psychiatric problems that may be present on admission, or are likely to arise during hospitalization.

Comment: In commenting on the proposed condition on medical staff, commenters recommended that if the medical staff is opened to individuals other than doctors of medicine or osteopathy, we should call the staff the "professional staff" or "organized staff" rather than "medical staff." They believed that the term "medical staff" connotes a staff of doctors of medicine or osteopathy, and that opening these staffs to other practitioners demands a change in the name of the staff to reflect accurately its composition.

Response: We have not accepted this recommendation because the term "medical staff" connotes a set of functions and responsibilities which this

regulation is not intended to change. The term is appropriately used to refer to the staff responsible for the medical care of patients, irrespective of the composition of that staff specified by the governing body.

Comment: Commenters were against deleting the requirement on autopsies. They cited autopsies as a significant tool for advancing medical knowledge.

Response: We agree with the commenters' statement on the value of autopsies and are convinced that autopsies are an essential educational tool which contributes to the quality of care furnished by a hospital. Therefore, we have revised the regulations to require that the medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest.

I. Nursing Services (§ 482.23, previously § 405.1024)

• *Existing provisions.* Section 1861(e)(5) of the Social Security Act requires that a hospital provide 24-hour nursing services. We believe that several of the standards for the condition that implement this statutory requirement are overly prescriptive, inflexible, and, in some areas, overlapping.

• *NPRM provisions.* In the NPRM, we proposed to replace the condition statement with the statutory language that requires 24-hour nursing care be furnished or supervised by a registered nurse, except for rural hospitals of 50 or fewer beds. We proposed to retain requirements on organization, staffing, administration of drugs, and delivery of care and to delete the standards on working relationships and staff meetings because we believed these issues are best addressed by the individual hospitals.

• *Public comments, responses, and provisions of final regulations.*

Comment: Commenters objected to the limited list of individuals permitted to administer drugs. They specifically objected to the omission of doctors of medicine or osteopathy as well as respiratory care personnel and specialized technicians (for example, radiologic technicians, cardiac catheterization technicians, etc.), citing their specialized training and unique skills as necessary to assure quality care. Other commenters objected to the imposition of Federal regulations over State laws. Some commenters objected to registered nurses being assigned responsibility for supervision of the administration of drugs by the individuals listed in the NPRM. They noted that some of these individuals are not licensed by States (for example, student nurses, medication technicians, etc.) and that registered nurses should not be responsible for their actions. Many commenters recommended that we adopt language that would allow administration of drugs by staff who are permitted to do so by State law and the rules and regulations of the medical staff.

Response: We recognize that certain professionals that were not listed in the NPRM have a legitimate role in administering drugs and are permitted to do so by State law and medical staff rules and regulations. We have deleted the specific listing and added a provision that requires preparation and administration of drugs and biologicals in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care, and accepted standards of practice. We have also specified that all drugs and biologicals must be administered by, or under the supervision of, nursing or other personnel in accordance with Federal and State laws, including applicable licensing requirements, and approved medical staff policies and procedures.

Comment: Commenters objected to restricting the acceptance of oral orders to registered nurses and licensed practical nurses. They noted that this restriction had the potential for creating health and safety hazards. Commenters argued that in order to assure accurate treatment, orders for highly specialized drugs and services should be taken by the specialized staff who would carry out the orders. They further noted that this requirement could cause a significant waste of nursing time better spent on patient care.

Response: We agree with these comments and have revised the regulations (§ 482.23(c)(2)(i)) to allow acceptance of oral orders by staff designated by medical staff policies and procedures, consistent with State and Federal laws. We believe this revision will assure patient health and safety, will maximize hospital flexibility in use of staff, and will enhance efficiency.

Comment: Some commenters noted that the language of the regulations conflicts with the statutory requirement on whether both a registered nurse and a licensed practical nurse must be available at all times for nursing services. Another commenter recommended that the regulation specify a ratio of nurses to patients which must be met for compliance with the standard to assure adequate staffing.

Response: We have revised the regulation to include the specific statutory language related to availability of nursing services as the statement of the condition. We have not included a specific ratio of nurses to patients because the need for nursing care varies from hospital to hospital and depends on services required. Any ratio established would be inadequate in some settings and unnecessarily prescriptive in others.

Comment: Commenters requested that the requirement that a registered nurse assign care to other nursing personnel be revised to allow the registered nurse to provide care as well as to supervise patient care.

Response: We do not believe it is necessary to make the recommended change. The language of this standard does not preclude the registered nurse from both assigning nursing care and providing care directly.

Comment: Commenters wanted the regulations to be revised to require the director of nursing to provide continuing training and orientation for the staff and to specify that the director of nursing is not required to supervise nonemployee nurses who do not perform services within the scope of responsibility assigned to the nursing service (for example, certified registered nurse anesthetists, nurse midwives, etc.).

Response: We have not accepted the recommendation to require the director of nursing to provide training and orientation because we believe that the need for training activities will be fulfilled through the quality assurance program. If a hospital and the governing body wish to carry out these activities through the director of nursing or other nursing staff personnel, they are free to do so.

We have revised the regulations to clarify that the director of nursing is responsible for supervision of only those clinical activities of nonemployee nursing personnel that occur within the responsibility of the nursing services.

Comment: Commenters objected to limiting the provision of blood transfusions to registered nurses with special training. They noted that this provision would prohibit physicians from performing transfusions as well as negate the effect of State laws which determine who may administer a transfusion. Many commenters recommended that we retain the applicable language in the current regulation.

Response: We have accommodated this recommendation by requiring that blood transfusions and intravenous medications be administered in accordance with Federal and State laws and approved medical staff policies and procedures. If they are administered by personnel other than doctors of

medicine or osteopathy, the personnel must have special training for this duty.

J. Medical Record Services (§ 482.24, previously § 405.1026)

• *Existing provisions.* Section 1861(e)(2) of the Act requires that a hospital maintain clinical records on all patients. The current regulations implementing this requirement specify a condition consisting of 10 standards and 32 factors, many of which overlap are inflexible, and are overly prescriptive. In addition, parts of these regulations have been made obsolete by changes in technology.

• *NPRM provisions.* In the NPRM, we recommended the following changes, the majority of which are intended to focus on outcome-related requirements, rather than process-oriented requirements:

1. *Preservation.* We proposed to remove the reference to statute of limitations and require retention of medical records for 5 years. (The final regulations clarify this retention period by specifying that records be preserved for *at least* 5 years to allow hospitals to retain records for a longer period, if they choose.)

2. *Personnel.* We proposed to delete all specific credential requirements for medical records personnel. We noted in the preamble that we have seen no evidence that specific credential requirements are indispensable in assuring the quality of the medical records.

3. *System details.* We proposed to modify these requirements to retain the requirements that the hospital maintain a system ensuring prompt location of a patient record by diagnosis and procedure, that the contents of the medical record contain sufficient information, and that the appropriate person sign the medical record. Other details would have been deleted.

• *Public comments, responses, and provisions of final regulations.*

Comment: Commenters recommended that we require "timely" rather than "immediate" retrieval of records by diagnosis or procedure or both. They noted that only sophisticated computerized records systems would allow immediate retrieval.

Response: We have revised the regulations to incorporate this recommendation because we believe that timely retrieval of records will be sufficient for meeting quality assurance and utilization review program requirements that this provision was intended to support.

Comment: A commenter recommended that we require a plan of treatment for each hospital patient rather than requiring one only for patients in psychiatric hospitals.

Response: We have not accepted this recommendation because in many cases creation of such a plan for patients other than psychiatric patients would be impossible until well into the stay when a diagnosis is established.

Comment: Several commenters recommended that we require a statement of the "outcome of hospitalization" in the medical record in lieu of a prognosis. They noted that often a prognosis is not available at discharge because it may depend on further treatment, the patient may be referred to a tertiary care facility, the disease may not be predictable, or the physician may not want to disclose the prognosis to the patient.

Response: We believe this recommendation is valid and have incorporated it in the regulations. We believe that a statement of the outcome of hospitalization would be as useful as, or in some cases more useful than, a prognosis.

Comment: One commenter recommended that we delete requirements for medical record documentation of nosocomial infections and adverse drug and anesthesia reactions and add a more general requirement for documentation of complications that occur during hospitalization.

Response: We have not made this change because we believe records that document nosocomial infections and drug and anesthesia reactions are essential to quality assurance and infection control programs, and thus have a direct bearing on the health and safety of patients.

Comment: A commenter recommended that we require that the record contain properly executed consent forms for those procedures and treatments determined by the medical staff to require written patient consent.

Response: We accepted this recommendation because we believe that, in general, it is appropriate for the medical staff to determine when written consent is necessary and have revised the regulations accordingly. We have also revised the provision to take into account the possibility that some State laws may require written consent under certain circumstances or for certain procedures.

Comment: A commenter recommended that we require interpretations of X-rays to be inserted in the medical record.

Response: We believe that § 482.24(c)(2)(iii), which requires inclusion of "appropriate findings by clinical and other staff involved in the care of the patient," subsumes the requirement recommended by this commenter.

Comment: Several commenters recommended that the regulation be revised to clarify that information from the records, not the records themselves, would be released to authorized individuals. They noted that actual records are generally released only in accordance with court orders, a subpoena, or a statutory requirement.

Response: We have revised the regulation to clarify the requirement for the release of information from the record or a copy of the record and to include a provision that original records are to be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas. It is essential to patient health and safety that original records be maintained in the hospital to facilitate treatment if the patient is readmitted. Duplication of the record carries a risk of omission or inadvertent alteration of information which could result in improper treatment.

Comment: One commenter objected to the requirement that records be maintained in original or legally reproducible form if the record is a radiologic image. The commenter argued that such images should be kept in their original state.

Response: We believe that the provisions of § 482.26(d) governing radiological services, which require the maintenance of image records for at least 5 years, ameliorates this concern.

Comment: Many commenters objected to our proposal to extend the maximum timeframe within which the medical history and physical examination information must be completed and typed in the chart from 48 to 60 hours after admission. They argued that extension to 60 hours could add a potential health and safety risk if physicians are allowed to delay the history and physical beyond 48 hours postadmission.

Response: We accept the commenters arguments that the health and safety issue is whether the physical and history are completed in a timely fashion, not whether clerical functions are completed. We also agree that any extension of the timeframe could add an element of risk to patient health and safety. We have, therefore, retained the current maximum timeframe of 48 hours in the final regulations, rather than the proposed maximum timeframe of 60 hours.

Comment: Commenters objected to proposed extension of the timeframe for completion of the record from 15 days

post-discharge to 30 days post-discharge. They argued that timely completion of the discharge summary is essential to post-discharge care and to timely billing.

Response: We have retained the proposed 30-day requirement because none of the commenters provided compelling reasons for a shorter timeframe. We believe that post-discharge care usually begins before conclusion of the current 15-day timeframe. Moreover, providers of post-discharge care can acquire necessary information from practitioners or other sources, regardless of the timely completion of the record. Since it is in the hospital's interest to bill promptly, we do not believe use of a longer timeframe will necessarily result in widespread delays in completing discharge summaries.

Other comments: Many commenters objected to the deletion of the requirement for credentialed medical records personnel. This is an issue that has been addressed as it relates to credentials of all hospital personnel other than physicians as defined in the NPRM. That discussion appears earlier under Section III.B. Personnel Credentials.

K. Pharmaceutical Services (§ 482.25, previously § 405.1027)

• *Existing provisions.* Current regulations mandate that pharmaceutical services be administered in accordance with accepted professional principles and recognized standards of practice to assure safe, accurate pharmaceutical regimes for patients. As currently written, this condition limits the hospital's ability to establish its own system for the control and administration of drugs.

• *NPRM provisions.* In the NPRM, we proposed to eliminate many of the specific and prescriptive details. We also proposed to modify the personnel standard to specify that if the hospital does not have a staff pharmacist, a designated individual must have responsibility for the day to-day operations of the pharmacy services. In addition, we proposed to specify that, when a pharmacist is not available, drugs may be removed only by personnel designated by the medical staff or pharmacy.

• *Public comments, responses, and provisions of final regulations.*

Comment: Commenters suggested that we clarify lines of responsibility for policies regarding removal of drugs from the storage area or pharmacy by specific adherence to policies of *both* the medical staff and the pharmacist. Other commenters recommended that, in specifying what personnel may remove drugs from the pharmacy or drug storage area in the absence of the pharmacist, four changes should be made: that we clarify that the requirement applies *at any time* the pharmacist is not available; that we delete "drug storage area" or not require that the drug storage area be locked; that we specify that the designated personnel must be licensed; and that we require that policies for removing drugs be approved by the pharmacy *and* the medical staff.

Response: We believe most of these suggestions would clarify the intent of the provision and the lines of authority for these services within the institution. We have made all changes except the following: We have not deleted "drug storage area" since we believe this should remain an option for smaller hospitals. In addition, we believe the control of substances requires a locked area, particularly where there is no pharmacist on duty full time. In lieu of requiring that personnel designated to remove drugs and biologicals be "licensed", we have required that they be designated in the policies of the medical staff and pharmaceutical service in accordance with Federal and State law.

Comment: Commenters suggested that we substitute the term "pharmaceutical service" for "pharmacist" to emphasize that the services performed are an integral part of the organized delivery of health care. Other commenters suggested changing the statement of the condition to clarify that the pharmaceutical service is responsible for quality, effective drug therapy.

Response: We have incorporated the first change where possible. We have not made the change if doing so would blur the lines of responsibility for functions that can only be performed by the pharmacist. We believe that the determination of the quality of drug therapy is very subjective.

Comment: Commenters requested that we modify the statement of the standard on delivery of services (§ 482.25(b)) to indicate that "applicable" standards of practice which are consistent with State law will be applied in distributing and administering drugs.

Response: We have accepted the comment as our intent is to require standards that are consistent with State and Federal laws.

Comment: Commenters suggested that the standards be further revised to reflect changes in pharmaceutical services over the past decade. They stated that "administration" of drugs is generally recognized as a nursing service and suggested that we use the concept of "control of drugs" as a function of the pharmaceutical service. Some commenters recommended that we specify permitted use of a unit dose system. Other commenters stated that we should include "biologicals" along with "drugs" in any provisions relating to pharmaceutical services since the term clarifies the substances to which the requirements apply.

Response: We have accepted these suggestions since they are reasonable, accurate reflections of present practice. However, we have not referred specifically to a unit dose system because we believe that the current language of the regulations does not preclude use of such a system.

Comment: Some commenters believed the requirements for protecting patients from toxic or dangerous medications to be contrary to our stated goal of stressing outcome rather than process. Other commenters want the prescribing practitioner, rather than the medical staff, to approve the automatic stoppage of dosages of dangerous drugs.

Response: The final regulations require a procedure for stopping open-ended drug orders, subject to approval by the medical staff. We have not restricted this requirement to toxic or dangerous drugs, since extended use of any drug product carries with it a potential risk to patient safety. We also do not believe these procedures should be left to the prescribing practitioner. We believe that consistent practices are necessary within the hospital, and such consistency would not be possible if individual practitioners were making ad hoc decisions.

Comment: Commenters suggested that the requirements regarding dispensing of drugs (§ 482.25(b)(1)) as well as the reporting of abuses or losses of controlled substances (§ 482.25(b)(7)) be amended to show that they are done in accordance with State and Federal laws.

Response: We have incorporated the suggested language, although a facility is required to meet all applicable State and Federal laws by virtue of other provisions. However, we believe repeating the requirement here would be useful.

Comment: Commenters suggested that we expand the list of information in § 482.25(b)(8) that must be made available for use by the professional staff to include information on drug therapy, potential side effects, toxicology, and other drug information and to define the professional staff to whom a formulary and information regarding drug interactions must be made available. Commenters also suggested that we replace the

requirement for a formulary with a requirement for a formulary system.

Response: We have accepted the suggestions for expanded professional information because we believe they provide the potential for improving the outcome of pharmaceutical services. We have also accepted the suggestion for a formulary system because we believe this is an effective way to assure quality pharmaceuticals at reasonable costs. We have not specified the professional staff to whom the information must be available because we believe the hospital would want to identify those individuals on the basis of the organization of the provision of these services.

Comment: Commenters stated that we have emphasized drug storage area and suggested that we delete the concept and stress that there must be an organized pharmaceutical service under the direction of a qualified registered pharmacist. Other commenters recommended that we define what constitutes a pharmacist's supervision if the hospital's pharmaceutical services consist of a drug storage area. Some commenters suggested that the regulations require that a pharmacist be on call or that a consultant pharmacist be available during times when the pharmacist is not there.

Response: We have made changes to stress the need for pharmaceutical services. The regulations already specifically require that a registered pharmacist direct the services and be responsible for developing, supervising, and coordinating all activities in pharmacy services. Our intent is that the pharmaceutical services meet the needs of patients, including the need for emergency services at times when the pharmacist is not there. We do not believe that prescriptive Federal regulations should be imposed on hospitals that could meet this requirement in other ways, consistent with Federal and State laws and the needs of patients. We have not deleted the language relating to drug storage areas because there are small institutions where this is the only way in which these services can be furnished. By stressing the soundness of policies and procedures in effect in the absence of the pharmacist responsible for the service, we believe we have adequately responded to the concerns of these commenters.

L. Radiologic Services (§ 482.26, Previously § 405.1029)

• *Existing provisions.* Current regulations provide that basic radiologic services must be available to patients and that these services must be provided in accordance with professionally approved standards for safety and personnel qualifications.

• *NPRM provisions.* We proposed to revise the condition statement to define more specifically what constitutes radiological services. We proposed to retain the basic factors relating to safety hazards and to revise the personnel standard to require that only a qualified radiologist, either full or part time, supervise the services and interpret films that require specialized knowledge. The current language in the regulations had been interpreted by some to mean that a radiologist must interpret or reinterpret every film. The proposed language would also make it clear that the radiologist needs to sign reports only of his or her interpretations.

We proposed to allow the medical staff and the individual responsible for radiological services to designate who is qualified to use radiological apparatus. We also proposed to modify the standard on signed reports to require that records of departmental activities be maintained and that radiological reports and films be preserved for 5 years. (As explained earlier, the final regulations require that records be preserved for at least 5 years.) Specific references to fluoroscopy and radium were to be deleted since the term radiology includes these items.

• *Public comments, responses, and provisions of final regulations.*

Comment: A number of commenters believed that the restriction of radiologic services to orders by practitioners with clinical privileges would prohibit a hospital from providing a community-wide service. They suggested that we allow fuller use of the service. Similarly, commenters believed the medical staff should be free to designate, by resolution, the acceptance of referrals of patients of practitioners not on the medical staff for diagnostic procedures.

Some commenters stated that the provision of radiologic services should be on the order of a doctor of medicine or osteopathy or other practitioner authorized under State law. Others believed the ordering practitioners should be identified as "fully licensed physicians or limited licensed practitioners" as stipulated in the determination of privileges under medical staff bylaws. Other commenters suggested that, if the ordering of radiologic services is granted to individuals outside the institution's medical staff or to practitioners with limited licenses, language be added to assure that the hospital is free to maintain standards of responsibility.

Response: We have revised the regulations to permit the medical staff and governing body to extend the use of the services, consistent with State law, to others outside the hospital. This will permit maximum flexibility of the hospital in responding to the needs of its service area. Nothing in the condition precludes the hospital from establishing standards of responsibility for the referring practitioners.

We believe the provision of the condition is sufficiently broad to encompass all potential disciplines that may be permitted to order radiologic services. We specify in the regulations that the services must be authorized only by practitioners with clinical privileges or, consistent with State law, by other practitioners authorized by the medical staff and the governing body to order the services. In many areas of the country, doctors of medicine or osteopathy other than radiologists may be interpreting certain categories of imaging procedures. It is not the intent of these regulations to change or dictate medical practices; instead, we want to structure our rules in a way that permits individual medical staffs to structure their procedures to address patient needs and local medical patterns of practice.

Comment: Commenters stated that the restriction of the application of the condition to ionizing radiology procedures is not appropriate since ultrasound procedures are also mentioned. They suggested that the appropriate location of the reference to these ionizing procedures is in the standard relating to safety for patients and personnel, and that the application of the entire condition be limited instead to diagnostic radiology procedures.

Response: We agree that the statement limiting application of the condition to ionizing procedures is not appropriate since new techniques are available for imaging. We have moved the statement to the standard relating to patient and personnel safety as suggested. We have not limited the application of the regulations to diagnostic radiation services because the regulations apply also to any therapeutic radiation services that are furnished.

Comment: Commenters questioned the NPRM specification of the individual who may designate which personnel may use radiologic equipment and administer procedures. They suggested that we not limit use to personnel designated as qualified by the individual responsible for the service or by the medical staff but extend use to personnel designated as qualified by the radiologist responsible for the service and fully licensed doctors of medicine or

osteopathy or limited licensed practitioners under privileges granted by the medical staff with the concurrence of the radiologist. Other commenters suggested that the attending practitioner rather than the medical staff should designate personnel.

Response: We have modified the language of this provision to clarify that the medical staff is the entity to designate who may use radiologic equipment and administer procedures. We believe that the medical staff's responsibility for the quality of patient care requires that the medical staff determine who may use radiologic equipment and administer procedures because of the risks to patient health and safety inherent in these services.

We do not believe that we can assume that the practitioner responsible for the patient's care would be familiar enough with equipment and procedures to designate who may use radiologic equipment and administer procedures.

Comment: Some commenters recommended that the regulations be modified to require that a radiologist must interpret all imaging procedures rather than only those procedures that require specialized knowledge. Other commenters suggested that we expand the requirement that a radiologist sign reports of interpretations to require other practitioners also to sign them. They argued that this expansion will afford protection to the patient and perhaps be a deterrent to clinicians to undertake imaging procedures.

Response: We believe requiring the radiologist to interpret all imaging procedures would create hardships for many hospitals that must rely on part-time or consultant radiologists. We also believe that the determination of those procedures that must be interpreted by a radiologist should be stipulated by the medical staff of individual hospitals. If a hospital wishes to have every procedure interpreted by a radiologist, there is no preclusion to that approach. Since the regulations are intended to permit hospitals to exercise flexibility in who may interpret radiologic services, we have made the recommended change that individuals designated by the medical staff must sign their own reports as well as that the radiologist is responsible for signing only his or her own reports. We believe the recommended approach is equitable and legally supportable.

Comment: Commenters believed we have created confusion by referencing a radiologist supervising the service in some places and an individual responsible for the service in others. They further commented that radiologists should be defined by credentials and that consistent and accurate terminology should be applied to doctors of medicine or osteopathy other than radiologists who may be permitted by the medical staff to perform and interpret some radiologic procedures. Some commenters suggested that we recognize that some hospitals use consulting radiologists in lieu of full-time or part-time radiologists.

Response: We have revised the regulations to clarify terminology relating to individuals responsible for various functions within the radiologic service to eliminate misunderstanding and to recognize use of consulting radiologists in some hospitals. We have not accepted the suggestion that radiologists be defined by specific credentials because we do not believe that the absence of credentials will imperil patient health or safety. However, we have provided that, for purposes of the regulations, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology. We believe this is sufficient specificity to protect patient health and safety.

Comment: One commenter recommended that the professionally approved standards for safety and personnel qualifications required in the statement of the condition be identified as those reported by the National Council for Radiation Protection and Measurements.

Response: We do not believe this level of detail is appropriate for Federal regulations. Therefore, we have not revised the proposed language.

Comment: Commenters suggested that the description of records to be retained be expanded to include films, scans, and other images. Other commenters suggested that the requirements for maintenance of radiologic records be cross-referenced to the requirements for medical records. They suggested deleting the details of the types of records to be maintained.

Response: We have expanded the description of the radiologic records to be retained as suggested to reflect a more complete listing. We have maintained the record retention requirement in the condition even though it is similar to the requirement on medical records. Since different employees manage the storage of radiologic records, and because, in some cases, different surveyors may evaluate compliance of the radiologic service as opposed to medical records, we believe it would be helpful to have the records retention rules stipulated in each respective area.

M. Laboratory Services (§ 482.27, previously § 405.1028)

• *Existing provisions.* Current regulations specify requirements to ensure the health and safety of patients who are furnished laboratory services in hospitals. Under current rules, if a hospital has a contractual agreement with an outside laboratory for laboratory services, the outside laboratory must be a Medicare-approved hospital or independent laboratory.

• *NPRM provisions.* The main thrust of the proposed revisions to this condition was to consolidate similar factors, clarify the intent, and establish uniformity in clinical laboratory requirements. The standards affected by the consolidation are: adequacy of laboratory services, clinical laboratory examinations, availability of facilities and services, laboratory report, tissue examination, and reports of tissue examinations. The revision also proposed to consolidate all personnel requirements in a single standard in order to eliminate the ambiguity in qualifications and clarify the responsibilities of the laboratory director. Of particular note is the distinction between those laboratory services that can be directed by a laboratory specialist qualified by a doctoral degree and those laboratory services that, by their nature, must be under the direction of an individual doctor of medicine or osteopathy.

Additionally, we proposed to eliminate the preference for the American Society of Clinical Pathologists registry in order to permit fair competition for technologist positions by otherwise qualified nonregistered professionals.

We proposed to delete the requirement for routine urinalysis and hemoglobin or hematocrit on admission of each patient. HCFA has reguested Medicare contractors to stop automatic payments for a variety of clinical tests which have sometimes been routinely performed on all Medicare admissions. This deletion would ensure that the regulations are consistent with this policy. The NPRM also proposed to delete the requirements on participation in staff, departmental, and clinicopathic conferences as unnecessarily prescriptive. We believe these conferences should be subject to administrative discretion based on the needs of the individual facility.

As noted in the proposal, HCFA is coordinating with FDA and the Center for Disease Control (CDC) of the Public Health Service future revisions of the

regulations concerning blood banking personnel, proficiency testing, and quality control.

• *Public comments, responses, and provisions of final regulations.*

Comment: A number of commenters suggested that a hospital's laboratory director be a doctor of medicine or osteopathy who is qualified by education and training, or a pathologist. They argued that the medical nature of the decisions made in laboratories requires participation of a practitioner with these credentials if the quality of services is to be assured. Others contended that removal of the requirement that a pathologist be available on a consultant basis would allow small, rural hospitals to dispense with a vital component of patient care—adequate laboratory services.

A number of other commenters favored laboratory direction by personnel with doctoral degrees in areas other than the physical, chemical, and biological sciences as well as other scientists or practitioners (other than doctors of medicine or osteopathy) with clinical training and experience. One commenter suggested that technical supervision and the ability to interpret tests requiring specialized knowledge, rather than specific credentials, be requirements for the laboratory director. Another suggested removal of the requirement for training and experience in the areas of services offered because it would place limitations on hospitals inadvertently.

Response: In the proposed rule, we made a distinction between certain laboratory services that, by their nature, must be under the supervision of a doctor of medicine or osteopathy and those that could be directed by a laboratory specialist with a doctoral degree. For example, anatomical pathology services must be supervised by a pathologist and transfusion services must be performed under the supervision of a pathologist or other doctor of medicine or osteopathy with training and experience in transfusion therapy (proposed § 482.27(c)(1) (ii) and (iii)). We have revised the requirements for training and experience to be consistent with existing widespread practice as well as our independent laboratory requirements, including those for technical supervision of transfusion services. We have not adopted the comment suggesting that we include a general provision that would allow nondoctoral scientists to serve as directors at this time. However, the Department has currently underway a thorough review of all clinical laboratory regulations. During the next year, the Department will be proposing regulatory and other reforms intended to reduce regulatory burden, remove inconsistencies and eliminate unnecessary credentialling requirements while continuing to ensure patient health and safety.

Comment: One commenter noted that the proposed wording of the provision that a board-certified oral pathologist *must* sign oral pathology tissue examination reports prevents pathologists who are not board-certified from signing the reports. Another organization requested inclusion of its name among the boards recognized for certification of dermatology and oral pathology. Another stated that private certification should not be the basis for qualifying signatures on tissue reports.

Response: The use of *must* in the provision on oral pathology tissue reports was a typographical error. We have corrected it by substituting "may." Although our general goal is to remove credential requirements for categories of hospital personnel in order to provide hospitals maximum flexibility, we have not removed credentials for pathologists of dermatology or oral pathology who may sign tissue examination reports. We have retained the requirements for board certification in these two limited areas that were published in the NPRM and have added other boards in an effort to assure that, if the reports of tests relating to skin and oral pathology are reviewed and signed by individuals other than the hospital's pathologist, the persons signing have adequate qualifications for this task. We believe the naming of specific board certifications in these cases is essential to patient health and safety. This approach is also consistent with the requirements placed on independent clinical laboratories and laboratories licensed to engage in interstate commerce under the Clinical Laboratories Improvement Act.

We have also corrected an inadvertent error in § 482.27(c)(1)(ii) that would have required tissue examination under the technical supervision of a pathologist or other individual who is certified in *both* skin and oral pathology, in cases where the laboratory performs anatomic pathologic services.

Comment: Several commenters recommended that tissue examinations and blood banking and transfusion services be performed or directed by a doctor of medicine or osteopathy rather than under the technical supervision of a doctor of medicine or osteopathy. Another suggested changing the qualification of the nonpathologist physician performing blood banking and transfusion services from "with at least 2 years of experience in immunohematology subsequent to graduation" to "qualified by appropriate training or experience in transfusion therapy."

Response: We have not changed the NPRM language in these final regulations in response to the first recommendation because we believe a hospital should have maximum flexibility to use personnel in the most effective manner and that technical supervision is more appropriate than direction for purposes of managing a subset of the total laboratory's services. A hospital is free to establish more stringent standards if it desires. We agree that the suggested language governing the experience of a doctor of medicine or osteopathy who is not a pathologist is less prescriptive and more appropriate to the types of services involved. However, we believe both training and experience are needed and have made this change in the final regulations.

Comment: Some commenters disagreed with the NPRM requirement that the medical staff and a pathologist determine which tissue specimens require a macroscopic (gross) examination or microscopic examination, or both, and pointed out that all tissue should receive a macroscopic examination.

Response: We have not accepted this comment because we believe that there are cases in which the medical staff may determine that macroscopic examination of tissues would not be productive. Therefore, we have permitted the medical staff to determine when tissues require only a macroscopic examination or both a macroscopic and a microscopic examination.

Comment: Commenters suggested that we move the provisions for the availability of blood and donors for emergency situations from the standard on the adequacy of laboratory services to the standard on blood and blood products.

Response: We have not accepted this suggestion because we believe the necessity and importance of providing blood in emergencies are highlighted in the standard for the adequacy of laboratory services. We believe the impact of this requirement would be lessened by placement in another standard.

Comment: Commenters recommended that we retain the requirement for the performance of routine urinalysis and hemoglobin or hematocrit tests for surgical patients or that the hospital be required to establish rules on when these tests must be performed routinely.

Response: We have not accepted this recommendation because we continue to believe the imposition of prescriptive requirements is inappropriate. We believe that it would be inappropriate for the Federal Government to require hospitals to provide specific services to patients. The ordering of specific services or routine tests should be the responsibility of the practitioner responsible for the patient's care. Moreover, retaining this requirement would be inconsistent with the policy discussed earlier under which Medicare contractors no longer make automatic payments for certain tests.

Comment: Commenters stated that the requirement for prompt antibody identification, while ideal, is not realistic for small hospitals and is unnecessary for successful transfusion therapy.

Response: We believe prompt antibody detection is necessary, particularly in cases of transfusion reaction, but we agree that identification of antibodies may occur later. We have revised the regulation to reflect this change.

Comment: Commenters recommended that the regulations make clear that transfusion services (and accompanying laboratory procedures) are sometimes contracted out and, in these cases, the contractor should retain samples of blood units rather than the hospitals.

Response: We believe that the procedures for retaining samples of blood units used by contractors of transfusion services vary widely. Therefore, we have revised the regulations on the basis of this comment to require retention of samples according to procedures established by the hospital. Thus, the hospital will be allowed maximum flexibility in arranging for this requirement to be met, but will still be responsible for assuring that samples are available.

Comment: Commenters argued that the FDA requirements for blood and blood products are sufficient for patient health and safety.

Response: This issue will be included among the issues to be addressed separately with FDA and CDC. Until these discussions take place, no change will be made. If a further change is needed, we will publish it in a future **Federal Register** document.

Comment: Some commenters believed that our failure to discuss the application of the condition to specialized laboratories leads to confusion. Others suggested that special purpose laboratories be exempt from the condition. Still others believed all laboratories should meet at least portions of the conditions.

Response: We have not made any changes on the basis of these comments due to the lack of an acceptable definition that distinguishes a "special purpose" laboratory from a "general" laboratory. We will include this issue, among others, for discussion with FDA and CDC.

Comment: Some commenters requested us to restore the statement: "The laboratory does not perform procedures and tests which are outside the scope and training of the laboratory personnel."

Response: We concur with the intent of this comment but believe it is adequately addressed in § 482.27(c) (3) and (4) that requires the laboratory director to assure that no procedures are performed outside the scope of the personnel's qualifications.

N. Food and Dietetic Services (§ 482.28, previously § 405.1025)

• *Existing provisions.* Current regulations provide for the existence of a professionally staffed dietary department integrated into the hospital. Detailed standards are included on organization, facilities, diets, and conferences.

• *NPRM provisions.* We proposed to retain the condition on food and dietetic services, but to delete requirements that are overly prescriptive and details that are no longer necessary. We proposed to delete—

• References to requirements for policies and procedures and the supervision of the staff;

• The specific details on the organization of the department;

• The detailed requirements for the facilities of the dietary department. We proposed to provide for a general statement under the condition on physical environment (§ 482.41(c)(4)) that the kitchen and dietetic services areas must be well-ventilated and properly equipped and maintained;

• The specific details relating to therapeutic diets;

• The requirement that the director of dietetics participate in meetings with other department heads.

We proposed this revision because we believed that it would be less prescriptive, but would not lower the quality of the dietetic services. The proposed § 482.28(a) provided for a full-time employee to serve as director of the food services and a qualified dietitian on a full-time, part-time, or consultant basis.

• *Public comments.* Commenters recommended that the regulations be revised to—

• Specify certain responsibilities and functions to be assigned to the dietitian. They considered that patient nutrition would suffer without this professional involvement.

• Specify that the director of the food service must be qualified by experience, education, and training.

• Specify that the organization of the dietetic services must be appropriate to the scope of the services offered.

• *Responses and provisions of final regulations.* We concur with the recommendation that the regulations specify general qualifications of the director of food service and have revised the regulations to specify that the director must be qualified by experience or training. We have not included the recommended specific responsibilities and functions of the dietitian because we believe to do so would be inconsistent with our stated objective of removing unnecessarily prescriptive requirements from Federal regulations. Hospitals wishing this level of participation by the dietitian would not be precluded from doing so if they desire.

We agree that the organization of the dietetic service should be appropriate to the scope of the services offered but believe that the regulations as proposed and as adopted as final accomplish this basic intent.

We have made an additional deletion in this condition of the credentials requirements. This is consistent with our basic approach to the issue of credentialing discussed earlier. We also have added a provision to the nutrition standard to specify that the nutritional needs of patients must be met in accordance with recognized dietary practices (for example, the dietary principles that are outlined in the publication, *Nutrition and Your Health: Dietary Guidelines for Americans*, published jointly by HHS and the U.S. Department of Agriculture).

The remainder of the proposed regulations are adopted unchanged as final.

O. Utilization Review (§ 482.30, previously § 405.1035)

• *Existing provisions.* Sections 1861 (e)(6) and (k) and 1902(a)(30) of the Act provide for utilization review (UR) of services furnished by institutions to individuals entitled to benefits under the Medicare and Medicaid programs. The current regulations at § 405.1035 that implement these sections contain detailed standards on approval and operation of the UR plan, written description of the plan, performance of review functions, admission review, extended stay review, records, administrative staff responsibilities,

medical care evaluation studies, and applicability to or coordination with other utilization review activities.

• *NPRM provisions.* In the January 1983 NPRM, we proposed to eliminate the overly prescriptive and detailed specifics of § 405.1035 by replacing the current regulations with language from the statute. The revised rule proposed to require the review of admissions, durations of stay, and professional services, with respect to medical necessity and for the purpose of promoting the most efficient use of facilities and services. Reviews would be conducted by a hospital committee or outside group and written notification of findings made to the patient, the physician, and the institution. The proposal also specified who can make determinations and the timeframe for notification of these determinations. Finally, the NPRM proposed to retain a provision found in current regulations that prohibits the committee's review from being conducted by a physician who was professionally involved in the case being reviewed or who is financially interested in the hospital.

• *Legislative and regulatory changes affecting hospital reimbursement and utilization review.* The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97–248) amended Part B of Title XI of the Social Security Act by establishing the Utilization and Quality Control Peer Review Organization (PRO) program. This program replaces the Professional Standards Review Organization (PSRO) program. The responsibilities that PROs are assuming are similar to those previously exercised by PSROs. PROs review health care services funded under Medicare to determine whether those services are reasonable, medically necessary, furnished in the appropriate setting, and are of a quality that meets professionally recognized standards. Congress created the PRO program in order to redirect, simplify, and enhance the cost-effectiveness and efficiency of the peer review of services reimbursed by Medicare.

Section 1902(d) of the Act was also amended by the Peer Review Improvement Act of 1982. If a State contracts with a PRO which has a Medicare contract to perform medical or utilization review functions under Medicaid, the utilization review requirements (including utilization review plans) can be deemed met under certain circumstances.

The Social Security Amendments of 1983 (Pub. L. 98–21) established a prospective payment system for Medicare and amended section 1866(a)(1)(F) of the Act to specify that hospitals seeking reimbursement under the prospective payment system must enter into agreements with PROs by specified dates to review the following:

• The validity of diagnostic and procedural information supplied by the provider.

• The completeness, adequacy, and quality of care provided.

• The appropriateness of admissions and discharges.

• The appropriateness of care provided or proposed to be provided for which payment is sought under an "outlier" basis under the prospective payment system.

On September 1, 1983, we published interim final regulations to implement a prospective payment system (PPS) for most Medicare inpatient hospital services, as required by the Social Security Amendments of 1983. (Those regulations were published in the **Federal Register** at 48 FR 39752.) To contribute to the implementation of the new legislation affecting Medicare payment, we established a new § 405.1042 in the September 1 document. That new section contains a special condition of participation setting forth revised utilization review requirements for hospitals paid under the prospective payment system. The intent of this special condition is to ensure that hospitals paid under prospective payment are not unnecessarily required to meet utilization review requirements designed to address the utilization problems of reasonable cost reimbursement. On January 3, 1984, we published a final version of the interim final regulations to implement the prospective payment system (49 FR 234). In that document, we revised the title and paragraph (c) of § 405.1042 for clarity, but did not make any other changes in that section.

The Deficit Reduction Act of 1984 (DRA) revised the provisions of the Social Security Amendments to require that all hospitals, not just those receiving payment under the prospective payment system, must maintain an agreement with a PRO. Effective November 15, 1984, all hospitals must have an agreement with a PRO as a condition of payment under Medicare.

In June 1984, HCFA began awarding contracts to PROs. On April 17, 1985, we published final regulations governing implementation of the PRO legislation (50 FR 15312). Those regulations specifically state that PRO review activities to determine whether inpatient hospital services are reasonable and medically necessary and are furnished at the appropriate level of care fulfill the utilization review requirements set forth in 42 CFR 405.1035 and 405.1042 (42 CFR 466.86(b)). The regulations also allow for Medicaid State plan requirements for utilization review (including utilization review plans) to be deemed met if the State agency contracts with a PRO performing Medicare review (42 CFR 456.2).

• *Public comments, responses, and provisions of final regulations.*

The new § 405.1042 did not replace the preexisting regulations under § 405.1035 for non-PPS hospitals, but adopted the January 1983 proposed provisions on utilization review as a condition of participation applicable to hospitals under the prospective payment system. Some of the public comments received on the January 1983 proposed regulations, as the comments related to prospective payment, were responded to in the preamble to the September 1983 document. Those comments and responses are equally applicable to the provisions for the hospitals that are not under the prospective payment system. Those comments and responses are cross-referenced here instead of being reprinted (see 48 FR 39790–39792). We also have not reprinted the public comments and responses on § 405.1042 that were published in the preamble to the January 3, 1984, final regulations. (We have redesignated § 405.1042 in these final regulations under the revised § 482.30, with some technical changes because the requirements for both PPS and non-PPS hospitals are contained in one section under the new Part 482, as explained below.)

Since all hospitals must now have an agreement with a PRO as a condition of payment under Medicare and the regulations under section 466.86(b) specify that PRO review activities fulfill the utilization review requirements for hospitals, we considered merely deleting current §§ 405.1035 and 405.1042, and not specifying any utilization review requirements in these regulations. However, this approach would not have provided any basis in our regulations for applying the provisions of sections 1861(e)(6) and (k) in those unusual cases in which a PRO does not in fact perform the review provided for in its contract with HCFA. To provide for such contingencies, we are issuing the utilization review requirements set forth in § 482.30 of these final regulations. These requirements, as well as the public comments on our proposals, should be viewed in the light of their extremely limited scope of applicability.

Three public comments relating to utilization review requirements in psychiatric hospitals were not

addressed in the September 1983 regulations. These are as follows:

Comment: One commenter noted that the UR requirements apply in psychiatric as well as general hospitals, and suggested that, because of this applicability, review should not be required merely for extended stays, but should be required on a specified basis that is appropriate to each patient's needs and treatment plan.

Another commenter objected to our proposal to delete a number of specific requirements related to psychiatric care from the current regulation (for example, the requirements for medical care evaluation studies). The commenter believed that these provisions provide important protections for psychiatric patients. One commenter suggested that the term "medical necessity" be changed to "psychiatric or medical necessity" to recognize that UR requirements will apply in psychiatric as well as general hospitals.

Response: We believe the statute and regulations already require the type of review of psychiatric care suggested by the commenter. Section 482.30(c) makes it clear that the UR committee's considerations cover not only the necessity for admissions and lengths of stay but also the provision of professional services. Because reviews may be conducted on a sample basis, hospitals are now free to select specific criteria involving patient treatment plans for scrutiny by the UR committee.

The revision of the previous utilization review condition was undertaken to remove the burdens of overly prescriptive requirements. This effort was not meant to substitute for professional judgments or to remove protections for classes of patients. The streamlining of review efforts should free hospitals from unnecessary burdens so they can give attention to the specific and specialized needs of their patient population. The responsibility for assuring that necessary reviews take place that are tailored to an institution's specific needs lies with the hospital's medical staff rather than the Federal Government. We have, therefore, retained the approach taken in the NPRM in the final regulations. As noted above, section 1861(k) and both the current and these final regulations require review of services furnished by hospitals, including psychiatric hospitals. We believe use of the new term suggested is not needed to clarify this, and could lead to confusion.

These final regulations contain, under one section (§ 482.30), the conditions relating to utilization review for both hospitals under the prospective payment system and hospitals under the cost reimbursement system. We have made several other clarifying changes. We have revised the regulation to specify that the utilization review condition is satisfied by PRO review activities to determine whether inpatient hospital services are reasonable and medically necessary and are furnished at the appropriate level of care and that the condition, unlike other conditions, applies only to Medicare and Medicaid patients. We have made a technical change by deleting the provision (at proposed § 482.30(d)(3)(iii)) that requires notice of the UR committee's determination regarding admission or continued stay no later than 2 days after the end of the certified period. A time limit is already specified in § 482.30(d)(3)(ii). In addition, we have eliminated the use of the term "final determination" throughout the condition to make it clear that a UR committee's determination regarding the need for a continued stay is not a "final determination" of the Secretary as that term is used in other parts of the Medicare regulations. We have also made changes in the regulations to eliminate potentially confusing use of the term "physician." For example, we have used the term "practitioner responsible for the patient's care" instead of "attending physician." These changes are needed for consistency with our approach to the definition of physician issues discussed elsewhere in this preamble. Other minor editorial changes have been made for clarity.

P. Physical Environment (§ 482.41, Previously § 405.1022)

• *Existing provisions.* Section 1861(e)(9) of the Act permits the Secretary to mandate requirements for hospitals relating to the health and safety of patients. One of these requirements addresses the physical environment of the hospital. Current regulations at § 405.1022 specify detailed standards for buildings, life safety from fire, sanitary environment, and diagnostic and therapeutic facilities.

• *NPRM provisions.* The NPRM proposed to make the following revisions:

1. Current § 405.1022(a) contains many details regarding the functional features of the physical plant. We proposed to revise the requirements to state that the condition of the physical plant and overall hospital environment must be developed and maintained so that the safety and well-being of all patients are maintained. We proposed to delete specific reference to isolated power since requirements pertaining to isolated power are contained in the Life Safety Code. We proposed to retain the elements addressing emergency power, gas, water, lighting, and obstacle-free corridors. All other elements and details would be deleted as redundant.

2. Current § 405.1022(b) mandates that hospitals comply with the 1981 edition of the Life Safety Code of the National Fire Protection Association and contains a "grandfather clause" to provide for facilities meeting the 1967 edition of the Code as of November 26, 1982. The regulations also require a hospital to maintain written evidence of regular inspection and approval by State or local fire control agencies. In the preamble to the 1983 NPRM, we erroneously cited the adoption of the 1981 edition as a proposed change to the regulations. The 1981 edition had already been incorporated in final regulations published on October 26, 1982 (47 FR 47388). We have retained the October 1982 final regulation changes in these regulations.

The National Fire Protection Association again has revised the provisions of the Life Safety Code in a 1985 edition. HCFA is developing a notice of proposed rulemaking as a separate document to address the application of the 1985 edition to hospitals and other Medicare and Medicaid providers and to solicit public comments. The provisions of this NPRM, when issued as final, will be incorporated in § 482.41 of these regulations.

3. In the NPRM, we noted that current § 405.1022(d) requires the hospital to provide adequate facilities for diagnostic and therapeutic services. We proposed to modify this provision by specifically requiring hospitals to provide adequate facilities for all services, not just diagnostic and therapeutic services.

• *Public comments.* A number of commenters expressed concerns relating to various technical aspects of the condition on physical environment. For example, they recommended that we include radiology in the list of areas that require emergency power and lighting.

• *Response and provisions of final regulations.* We believe the suggestions made by the commenters are too detailed for inclusion in Federal regulations. Therefore, we did not adopt these comments.

Q. Infection Control (§ 482.42, Previously § 405.1022(c))

• *Existing provisions.* Current regulations under the condition on physical environment discuss the sanitary environment of the hospital. In the United States, nosocomial infections occur in approximately 5 percent of the

patients admitted to acute-care hospitals. These infections subject patients to significant additional pain and risk, prolong a hospital stay by several days on the average, and lead to more than an extra billion dollars a year in direct hospital charges.

• *NPRM provisions.* Because of the enormity of the problem, we proposed to elevate infection control provisions to the level of a separate condition of participation. The proposal placed more accountability on hospitals to prevent, control, and report hospital infections and communicable diseases, and less emphasis on the number of persons necessary to accomplish the task. We proposed to delete the current requirement for an infection control committee and instead require designation of an infection control officer or officers. This flexibility would give hospitals the option of retaining existing committees, but hospitals with limited staff could comply by the designation of one person. We also proposed to require that the hospital keep a log to identify problems and that improvement be made when problems are identified.

• *Public comments.* One commenter recommended that we revise the requirement for an infection and communicable disease incident log to allow the hospital to determine what types of incidents would be documented in the log.

• *Response and provision of final regulations.* We are issuing this condition in the final rule as proposed, with some minor editorial changes and a clarifying change to indicate that the log must cover incidents of communicable diseases. We do not believe further changes are necessary. We believe that it is essential to compile and maintain all infection and communicable disease incident reports in a single source so that patterns of infection and communicable disease problems in the hospital as a whole can be identified and corrective action can be taken.

R. Surgical Services (§ 482.51, previously § 405.1031(a))

• *Existing provisions.* Current regulations outline detailed standards for policies and procedures for surgical privileges, maintenance of the operating rooms, and evaluation of the surgical patient.

• *NPRM provisions.* In the NPRM we proposed to convert these standards into a condition. We proposed to retain most of the current language on surgical services, but delete the overly prescriptive details about the operation of the service, such as the location of the operating room and the posting of operating room rules.

We also proposed to include under this condition the provisions that are currently under the nursing department located at § 405.1024(d) that specify supervision of operating rooms by a registered nurse and that permit surgical technologists and licensed practical nurses to serve as "scrub nurses" under the direct supervision of a registered nurse. Scrub nurses are those who scrub, dress in sterile garb, and manage the instruments at the operating practitioner' s direction.

The NPRM specified that only registered nurses may perform circulating duties in the operating room, except that licensed practical nurses and surgical technologists may assist in circulating duties under the direct supervision of a qualified registered nurse. Circulating duties include acquiring emergency equipment or staff and furnishing patient care services that require independent judgment and expertise. We noted that this proposal was different from that proposed in the 1980 NPRM that would have permitted licensed practical nurses and surgical technologists to perform circulating duties in the operating room.

• *Public comments, responses, and provisions of final regulations.*

Comment: Many commenters, mostly surgical technologists, objected to the continuance of the requirement that a registered nurse serve as the circulating nurse in the operating room, and that a surgical technologist or licensed practical nurse scrub under the supervision of a registered nurse. They stated that surgical technologists and licensed practical nurses are qualified through education and experience to perform these functions without supervision of a registered nurse. Commenters added that this requirement would contribute to higher hospital costs as registered nurses have higher salaries than licensed practical nurses or technologists. These individuals also stated that surgical technologists are better prepared for these responsibilities. Finally, many argued that regulation of these functions is an inappropriate Federal activity and that only State law and hospital rules and regulations should govern staffing of these functions.

Response: In response to these comments, we have revised these regulations to state that qualified registered nurses may perform circulating duties in the operating room, and that licensed practical nurses and surgical technologists may, in accordance with applicable State laws and approved medical staff policies and procedures, assist in circulatory duties under the supervision of a qualified registered nurse. For purposes of the regulations, we have broadened the supervision requirement and will consider it to be met if the qualified registered nurse is immediately available to respond to emergencies. In the NPRM we had proposed that the registered nurse supervision be direct, i.e., over the shoulder. We have modified our approach because we believe it will give hospitals maximum flexibility to manage their internal procedures, according to their medical staff policies, subject to applicable State law, and will recognize appropriately the special qualifications of surgical technologists. At the same time, however, the approach will help protect patient health and safety by ensuring the ready availability of a registered nurse who has training and experience in all aspects of comprehensive skilled patient care.

Comment: Some commenters objected to the requirement that a registered nurse supervise the operating room as it appears to preclude a hospital from having a doctor of medicine or osteopathy perform this function. Other commenters recommended that the regulation require that only a doctor of medicine or osteopathy supervise the operating room because only such an individual has training to assure quality care.

Response: We have revised the regulation to indicate that either a doctor of medicine or osteopathy or an experienced registered nurse may perform this function. We do not believe that it is essential in all circumstances that a doctor of medicine or osteopathy supervise the operating room. However, the revised language of the regulation will allow such supervision where the hospital chooses to do so.

Comment: One commenter recommended that we revise the regulation to specify that surgical privileges must be delineated for all physicians "*licensed to perform* surgery in accordance with the competencies of each physician *and supervised by a doctor of medicine or doctor of osteopathy.*" The commenter believed that, to assure quality of care, it is essential that the patient be under the overall supervision of a fully licensed doctor of medicine or osteopathy.

Response: We have not accepted this recommendation because we believe that compliance with the quality assurance condition will assure the quality of care.

Comment: One commenter recommended that we require the

hospital to have a committee of surgeons, anesthesiologists, and operating room nurses to develop operating room rules and procedures in order to assure the input of doctors of medicine or osteopathy in all major decisions regarding the operating room.

Response: We have not accepted this recommendation because we do not consider that it is necessary to patient health and safety for us to require this type of committee. We are confident that governing bodies and medical staffs of hospitals will assure the involvement of appropriate individuals where major decisions about the operating room are to be made.

7. Anesthesia Services (§ 482.52, previously § 405.1031(b))

• *Existing provisions.* Current regulations contain standards for staff privileges, administration of anesthetics, and the maintenance of strict safety controls.

• *NPRM provisions.* Because of certain risk factors associated with administration of anesthesia, we proposed to elevate the requirements for anesthesia services to the level of a condition. Many factors contribute to the risk associated with exposure to anesthesia. The anesthesia itself poses a threat, especially to the patient's respiratory and cardiovascular systems. Other factors identified by studies as affecting anesthesia outcome are the skills and knowledge of the anesthetist, familiarity with equipment, adequacy of the preanesthesia work-up, and the method and circumstances of anesthesia administration. Therefore, anesthesia services are considered a "high-risk" area. We proposed to retain the concept of the preanesthetic examination but require that the examination be done no longer than 48 hours before surgery by an anesthesiologist or person administering the anesthesia. We proposed to permit an anesthesia assistant (physician's assistant with specialized training in anesthesia) to administer anesthesia under the supervision of a physician. We also proposed to modify the condition to change the term "registered nurse anesthetist" to "certified registered nurse anesthetist (CRNA)."

• *Public comments, responses, and provisions of regulations.*

Comment: Three commenters requested that the requirement that CRNAs administering anesthesia be under the supervision of the operating physician be expanded to also permit supervision by anesthesiologists. They argued that this is consistent with current medical practice and beneficial to patient health and safety.

Response: We concur and have revised the regulation to reflect the recommendation.

Comment: One commenter recommended that the requirement for direction of the anesthesia services by a qualified physician be revised to require the director to be a doctor of medicine or osteopathy who is board certified in surgery and has at least 3 years of clinical training, 2 of which are in clinical anesthesiology.

Response: We agree with the recommendation that the director of the service be a doctor of medicine or osteopathy and have made the appropriate change. We have not accepted the additional certification and clinical training requirements because we believe that they may create a significant hardship in smaller and rural hospitals in trying to obtain individuals with these qualifications.

Comment: Several commenters requested that we delete the reference to administration of anesthetics by anesthesia assistants. They contend that anesthesia assistants are not trained in general patient care, which they stated is a critical requisite for individuals involved in the administration of anesthesia. Other commenters noted that these individuals are permitted to administer anesthesia under the supervision of the operating physician in freestanding ambulatory surgical centers (ASCs) and ambulatory surgery units of hospitals. Some commenters noted that the correct reference to this allied health profession is "anesthesiology assistants," whom they contend are trained only to perform duties under the direct supervision of an anesthesiologist.

Response: We have retained anesthesia assistants (properly called anesthesiology assistants) in the list of those who may administer anesthesia in hospitals. These individuals are permitted to perform these functions under some State laws and there is currently at least one university program in operation to train individuals for this allied health profession. However, since there is no nationally recognized accreditation and testing program for anesthesiology assistants, we have modified the qualification criteria in the regulations to specify that anesthesiology assistants must be permitted by State law to administer anesthesia, must have successfully completed a 6-year program for anesthesiology assistants, 2 years of which consist of specialized academic and clinical training in anesthesia, and must be under the direct supervision of an anesthesiologist who is physically present. The revised qualification criteria are consistent with the requirements for completion of the university program currently in operation and will ensure sound academic and clinical background in the administration of anesthesia.

Anesthesiology assistants are not educated and experienced in comprehensive patient care as are CRNAs. They are, instead, educated in performing specific skilled tasks related to the administration of anesthesia. While the general education of CRNAs in patient care enables them to function with a physician available in close proximity to assist in emergencies, the absence of specialized education in comprehensive patient care for anesthesiology assistants requires that a physician with specialized experience in anesthesia be physically present in the operating room to monitor the patient's condition. We have required that, unlike CRNAs, it is necessary for an anesthesiology assistant to have supervision by an anesthesiologist rather than the operating physician and also that the anesthesiologist must be physically present in the operating room.

Comment: One commenter stated that it would be impractical to require, in the case of outpatient surgical patients who are ordinarily discharged shortly after surgery, that a post-anesthesia follow-up report be completed within 48 hours of each operation. The commenter recommended that we permit an exception to the 48-hour rule for outpatients.

Response: We agree that the 48-hour report requirement is impractical for outpatient surgical procedures. However, we do not believe it would be consistent with patient health and safety simply to provide an exception to the 48-hour rule for outpatient surgical procedures. Therefore, we have modified the regulations to specify that, in the case of outpatient surgical procedures, the patient must be evaluated for proper anesthesia recovery in accordance with policies and procedures approved by the medical staff.

T. Nuclear Medicine Services (§ 482.53)

• *Existing provisions.* There is no existing condition of participation for hospitals that relates to nuclear medicine.

• *NPRM provisions.* In the NPRM, we proposed to add a new condition on nuclear medicine. The requirements of this condition would apply only to those hospitals that choose to provide nuclear medicine services. These requirements are necessary because of the inherent

risks of procedures that expose patients to non-contained (uncovered) radiation and the increase in the number of hospitals offering these services. Specifically, we proposed regulations to require that the director of the services be a physician qualified in nuclear medicine. Recognizing that there are a number of ways for a physician to become qualified in nuclear medicine, we did not define "qualified." The NPRM also proposed to require that radioactive materials be handled in accordance with acceptable standards of practice, that the facilities be maintained for safe and efficient performance, and that signed and dated reports be maintained. If the hospital does not have organized nuclear medicine services, radiopharmaceuticals would be evaluated under the laboratory, radiology, or pharmacy services, as appropriate.

• *Public comments, responses, and provisions of final regulations.*

Comment: A commenter suggested that we incorporate by reference the qualifications for the director of nuclear medicine services contained in the Nuclear Regulatory Commission's updated requirements for its licensure of physicians to use byproduct materials on humans (**Federal Register**, December 2, 1982, 47 FR 54376). The comnenter also noted that the National Council on Radiation Protection and Measurements provides recognized quidance on the safe handling of nuclear material, and suggested that we revise the regulations to require compliance with the Council s Report 70. Another commenter suggested that we require the director of the nuclear medicine service to be a fully licensed doctor of medicine or osteopathy.

Response: We agree with the suggestion that we require that the director of the nuclear medicine service be a doctor of medicine or osteopathy and have revised the regulations accordingly. However, we have not adopted the recommendation that we explicitly require compliance with the Nuclear Regulatory Commission's regulations or with Report 70 of the National Council on Radiation Protection and Measurements. We believe that adopting the former comment could cause an unnecessary duplication of other Federal requirements and that the latter recommendation is addressed by our general requirement that nuclear medicine services meet patient needs in accordance with accepted standards of practice.

Comment: A commenter suggested that we permit nuclear medicine services to be ordered only by a doctor of medicine or osteopathy because of the inherent hazards of this type of treatment. Another suggested that we revise the provision on who must order nuclear medicine services to change "a practitioner with clinical privileges" to "a physician whose scope of licensure and whose defined staff privileges allow such referrals."

Response: We have not adopted the former comment because we do not believe it is essential to patient health and safety to permit only doctors of medicine or osteopathy to order these services. However, we concur with the latter suggestion to the extent that we believe that specifying that nuclear medicine services are to be provided by a practitioner whose scope of licensure and whose defined staff privileges allow such referrals will provide adequate safeguards for patients and, at the same time, permit hospitals and their medical staffs to determine, within the restrictions imposed by Federal or State licensure laws, which practitioners will be permitted to order nuclear medicine services. Therefore, we have revised the regulations accordingly.

Comment: One commenter suggested that we require written policies and procedures for the delivery of nuclear medicine services to make it easier for State survey agencies to determine compliance with the condition.

Response: In view of the specificity of the requirements of the condition, we do not believe State surveyors will have difficulty in determining compliance. Moreover, requiring hospitals to have written policies and procedures would increase the paperwork burden for hospitals without necessarily enhancing the health and safety of hospital patients. Therefore, we did not adopt this suggestion.

Comment: One commenter suggested that we specify in the regulations that hospitals may furnish nuclear medicine services under an arrangement with another organization.

Response: The language of the new § 482 12(e), which sets forth a specific standard for contracted services, makes it clear that hospitals may furnish services under arrangements. Therefore, we do not believe it is necessary again to specify this in this section.

U. Outpatient Services (§ 482 54, Previously § 405 1032)

• *Existing provision.* Current regulations require that organized outpatient departments of hospitals have effective policies and procedures, be appropriately staffed, maintain medical records, and have suitable facilities. Detailed standards are provided in each area.

• *NPRM provisions.* We proposed to modify this condition to retain only two of the standards, organization and personnel, and delete the others as being overly prescriptive and duplicative of requirements found in other conditions.

• *Public comments.* Commenters recommended that we specify in the condition the qualifications of the individual who will direct outpatient services.

• *Response and provision of final regulation.* We have adopted the condition in the final rule as it was proposed. We have not specified qualification requirements for the director of services because we believe that it is essential that individual hospitals have the flexibility to determine the qualifications of professionals who direct most of the organized services in the institution, a point we have discussed earlier under personnel credentialing. The scarcity in some health care disciplines of personnel with credentials from private professional groups in some rural and inner urban areas necessitates alternatives to the use of credentialed personnel.

V. Emergency Services (§ 482.55, Previously § 405.1033)

• *Existing provisions.* Current regulations specify requirements for hospitals that choose to provide emergency services. This condition includes requirements for the organization and direction of the service, standards for emergency facilities, and medical and nursing personnel, and requirements for emergency room records.

• *NPRM provisions.* We proposed to remove those standards that were overly prescriptive and overlap with requirements of other conditions. In the NPRM, we proposed to modify the condition statement to assure that the hospital meets the emergency needs of patients in accordance with acceptable standards of practice. In addition, we proposed to add a new standard to specify that if the hospital does not have an emergency department, it must have written referral procedures or be part of a community-wide emergency services program.

• *Public comments.* Many commenters recommended that emergency services be supervised by a doctor of medicine or osteopathy. Commenters also recommended that the requirements relating to a hospital that does not have an organized emergency service be moved to the governing body condition to emphasize the mandatory

rather than optional nature of this requirement. One commenter requested that we retain the requirement that a physician see every patient who arrives at the hospital for emergency treatment.

• *Responses and provisions of final regulations.* We believe that the NPRM language relating to the supervision of the emergency services allows hospitals maximum flexibility in their organization and staffing of the service and that Federal requirements for education or experience of supervisors would be counter-productive. We believe that the medical staff's overall responsibility for quality of care will ensure that the emergency services are appropriately supervised by a member of that staff. In addition, we believe that many emergency room visits are for non-urgent problems that could be screened out or managed by someone with lesser skill and education than a doctor of medicine or osteopathy.

We concur with the commenters that the development and implementation of specific policies and procedures relating to the handling of emergencies in the absence of an organized service should be a mandatory rather than an optional requirement. We have, therefore, revised the governing body condition to add a requirement (§ 482.24(f)) that if the hospital does not have an organized emergency department or service, the governing body must assure that the medical staff has written policies and procedures for appraisal and initial treatment of emergencies, and referral when appropriate.

We do not agree that it is necessary for every patient who arrives at a hospital for treatment to be seen by a doctor of medicine or osteopathy. We believe that development of emergency service procedures by the medical staff will assure that care is provided by a doctor of medicine or osteopathy when it is necessary. We have, however, revised the regulations to indicate that emergency service personnel must be qualified in emergency care. We have made this change to ensure that personnel are qualified to determine when care by a doctor or medicine or osteopathy is needed.

The remainder of the proposal is being adopted as final without further change.

W. Rehabilitation Services (§ 482.56, previously § 405.1031(d))

• *Existing provisions.* Current regulations contain standards for organization of and procedures for providing rehabilitation services such as physical, occupational, and speech therapy, and detailed credentials for staff.

• *NPRM provisions.* We proposed to simplify these provisions by stating that if the hospital provides for physical or occupational therapy (whether or not the services are provided by a distinct department), those services would have to be furnished under the supervision of a qualified therapist. We included a cross-reference to § 405.1702(j) which specifies qualification requirements for speech pathologists.

• *Public comments.* Commenters made the following recommendations:

—That we require a physician (i.e., a doctor of medicine or osteopathy) to direct the services because of the skills and knowledge of this type of individual. They believed that this requirement would assure the quality of patient care. Some commenters stated that the absence of physician direction of the services was inconsistent with our requirement for physician direction in comprehensive outpatient rehabilitation facilities (CORF).

—That physical therapists be allowed to prepare the plan for therapy. They stated that this approach represents current practice.

—That, if audiology services are offered, we require that they be furnished by or under the supervision of a qualified audiologist.

• *Responses and provisions of final regulations.* We have adopted this condition in the final regulations as it was proposed, with one exception. We have deleted the qualification requirements for therapists and specified responsibility of medical staff for determining requirements to reflect our basic approach of removing credential requirements. We have not required a doctor of medicine or osteopathy to direct the services because we believe that such a requirement is overly prescriptive and may have the unintended affect of discouraging necessary, but limited, rehabilitation services in smaller hospitals. In an acute care setting, doctors of medicine or osteopathy are readily available and involved in planning patient care services. In an outpatient setting, such as in a CORF, however, the type of services given involves many health care professionals and the coordinative role by a doctor of medicine or osteopathy assures the continuity of care without duplication or overlap. As a result of enactment of section 2342 of the Deficit Reduction Act of 1984, Pub. L. 98–369, physical therapists are authorized under law to prepare therapy plans. These regulations, as drafted, do not need to be modified. A change is planned to conform 42 CFR 405.1635(d) to the statute. We did not accept the recommendation that audiology services be furnished by or under the supervision of a qualified audiologist because it is inconsistent with our stated objectives of removing unnecessarily prescriptive requirements from Federal regulations. We believe the qualifications of personnel should be at the discretion of the medical staffs of individual hospitals.

X. Respiratory Care Services (§ 482.57)

• *Existing provisions.* Current regulations do not contain specific standards on respiratory care services.

• *NPRM provisions.* We proposed to add a new condition that would apply only if the hospital has organized respiratory care services. The proposed regulations described staffing requirements.

• *Public comments, responses, and provisions of final regulations.*

• *Comment:* Commenters recommended that we require that respiratory care services be provided only on the orders of a doctor of medicine or osteopathy. They noted that the multiple uses of these services require medical evaluation and recommendation of their use. Other commenters argued that we should require direction of respiratory care services by a doctor of medicine or doctor of osteopathy. They noted that, since this is a high-risk service with the potential for overutilization, such direction is the only effective means of evaluating the quality and appropriateness of service provided.

Response: We have revised the regulations to specify that these services be provided only on orders of a doctor of medicine or osteopathy because we are convinced that the requirement is necessary to patient health and safety. We created this condition because we recognized the risks in these services and we believe that this change is appropriate. For similar reasons, we have required that there be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly. The director of respiratory care may serve on either a full-time or part-time basis. These requirements are consistent with the JCAH requirements for medical direction of respiratory care services, except that we have explicitly allowed the director to serve on a part-time basis. We adopted a provision for part-time service in order to avoid imposing undue hardship on smaller hospitals while still assuring the health and safety of patients requiring these services.

Comment: One commenter urged that we require the director of a respiratory care laboratory to be a pulmonologist or other doctor of medicine or osteopathy who is well-trained in pulmonary physiology.

Response: We have not accepted this recommendation because we are not convinced that there is a risk to patient health and safety if such a burdensome requirement is omitted.

In addition to these changes, we have revised the regulation to specify that it applies if the hospital provides any respiratory care services, without regard to how the services are organized.

Y. Specialty Hospitals—Special Rules for Psychiatric and Tuberculosis Hospitals

1. General Provision (§ 482.60, Previously § 405.1036)

• *Existing provisions.* Current regulations describe the special conditions that apply to psychiatric and tuberculosis hospitals, including special requirements and conditions for medical records and staffing.

• *NPRM provisions.* In the NPRM, we proposed to simplify the provisions for psychiatric and tuberculosis hospitals. The proposed condition would have required these facilities to be accredited by the Joint Commission on Accreditation of Hospitals or, if a distinct part of an institution, meet the requirements applicable to general acute care hospitals (§ 482.11 through § 482.57). In addition, we proposed to require that these hospitals keep sufficient clinical records and meet staffing requirements determined by HCFA to be necessary for carrying out an active treatment program. In addition, we invited comments on the feasibility of flexibly applying the medical records and staffing requirements for psychiatric hospitals to inpatient psychiatric units of general acute care hospitals, so that psychiatric patients are afforded equal protection regardless of the setting. When the general hospital conditions were originally developed, few acute care hospitals had psychiatric sections. Those that did generally had small units. Currently there are more than 1,300 psychiatric units in general hospitals, but there are no specialized standards applicable to those units.

• *Legislative changes.* The Deficit Reduction Act of 1984, Pub. L. 98–369, enacted July 18, 1984, deleted the requirement that psychiatric hospitals must be accredited by the JCAH (section 2340). In addition, section 2335 deleted specific references to tuberculosis hospitals and institutions and inpatient tuberculosis hospital services in titles XVIII and XIX of the Social Security Act in recognition of advances in treatment of tuberculosis. Patients with tuberculosis who require hospitalization now are cared for in facilities such as general hospitals that do not specialize exclusively in the treatment of this disease. The statutory provision does not change current policy on payment for hospital services to tuberculosis patients under Medicare and Medicaid. Any eligible individual with tuberculosis continues to be entitled to receive covered hospital services under these programs. We are revising proposed § 482.60 of the Medicare regulations and §§ 440.10, 440.40, 440.140, 440.150, 440.170, 440.250, 441.11, 441.13, and 456.51 of the existing Medicaid regulations to conform them to the statutory change.

• *Public comments, responses, and provisions of final regulations.*

Comment: Several commenters objected to the requirement that psychiatric hospitals be accredited by JCAH. They recommended that this accreditation be optional. One commenter objected to the continued omission of accreditation by the American Osteopathic Association (AOA) in lieu of JCAH accreditation or compliance with the general hospital conditions for distinct part psychiatric units. They recommended that we include language which would not preclude such deeming in the future.

Response: As stated earlier, section 2340 of Pub. L. 98–369 deleted the provision under the statutory definition of psychiatric hospitals under section 1861(f) of the Act that required JCAH accreditation. Thus, psychiatric hospitals (including a distinct part of institutions that are devoted to psychiatric care and services) can now meet all requirements for participation applicable to general acute care hospitals, except the utilization review requirements in sections 1861(e)(6) and (k) of the Act, either by JCAH accreditation or by meeting the hospital conditions of participation established in the Act. We have revised § 482.60 of these final regulations to reflect this change.

Comment: Commenters stated that the special conditions should not be applied to psychiatric units in general hospitals because these units typically serve a different type of patient than the psychiatric hospitals to which the special conditions are applicable. Some argued that the special conditions were clearly intended to ensure the existence of active treatment in freestanding psychiatric hospitals, and thus are not applicable to an acute care setting.

Conversely, some commenters argued that it is inappropriate to have two different sets of health and safety rules for patients in different hospital settings but with the same illnesses. They argued that either the special conditions should be applied to psychiatric units as well as psychiatric hospitals, or they should be eliminated for psychiatric hospitals. Commenters further argued that hospitals that meet the JCAH consolidated standards for psychiatric care should be deemed to meet the special conditions for psychiatric hospitals and, if the special conditions are applied to psychiatric units of acute hospitals, for those units. They believed that the JCAH requirements are sufficient to satisfy the statutory requirements in section 1861(f) for records and staffing in psychiatric hospitals, and that we are being unnecessarily inflexible in failing to deem accredited JCAH hospitals to be in compliance with the special conditions.

Other commenters argued that the special conditions should be revised to provide more flexibility so that they could be appropriately applied to psychiatric services in psychiatric units of acute care hospitals. They argued that the proposed special conditions are too specific, detailed, and prescriptive in all areas (including credentialing) for application in either setting.

Response: We have decided not to apply the special psychiatric conditions to psychiatric units of acute short-term hospitals. While there are some similarities between the conditions of patients in psychiatric units of short-term hospitals and the conditions of those treated in psychiatric hospitals, we are not convinced that these similarities are extensive enough to make it essential, for protection of patient health and safety, to apply the special conditions to psychiatric units. Moreover, some units provide services to patients who are significantly unlike patients in psychiatric hospitals. In these cases, it would clearly be inappropriate to impose the special conditions.

In separate regulations published on January 3, 1984 (49 FR 234), we have issued criteria that are to be used in identifying those distinct part psychiatric units that are similar enough to freestanding psychiatric hospitals (and different enough from short-term acute care hospitals) to warrant their exclusion from the prospective payment system for hospitals. In order to qualify for exclusion, these units must meet the special clinical records and staffing criteria at § 405.471(c)(4)(ii)(D) (recodified as § 412. 27 (c) and (d) on

March 29, 1985, 50 FR 12745). These criteria are similar to those contained in the special conditions of participation for psychiatric hospitals. Consequently, hospital units that are similar enough to psychiatric hospitals to warrant exclusion will be required to meet the same standards as psychiatric hospitals.

In addition, we have not specified that hospitals that meet JCAH consolidated standards for psychiatric care are deemed to meet the special conditions for psychiatric hospitals. The special conditions are governed by the statutory authority in sections 1861(f) (3) and (4) of the Act. We are currently considering whether it would be appropriate to deem the special conditions for section 1861(f) psychiatric hospitals as being met based on JCAH requirements.

We do not agree with the comments stating that the proposed special conditions are unnecessarily specific, detailed, and prescriptive. The conditions we proposed are significantly less prescriptive than the previous special conditions, and we do not believe further revision is needed.

2. Special Staff Requirements

• *Psychiatric Hospitals (§ 482.62, previously § 405.1038).* Current regulations specify detailed requirements for staff providing services in psychiatric hospitals. In the NPRM, we proposed:

—To simplify the current detailed specifications regarding staff in general to reflect instead the responsibilities and functions that are appropriate to a psychiatric hospital staff (§ 482.62(a)).

—To retain the requirement that the director of the inpatient psychiatric services meet the requirements for examination by the American Board of Psychiatry and Neurology (§ 482.62(b)). We believe that a director with these qualifications is necessary to monitor and assure the appropriateness of physician services. Similarly, the qualifications for the director of psychiatric nursing services would be retained to assure quality care.

—Under psychological services, to use the general language of the 1980 NPRM by stating that the director must be eligible to be considered a professional psychologist according to the American Psychological Association's standards for providers of psychological services (§ 482.62(e)). Current regulations (§ 405.1038(e)) discuss such details as whether or not the director has a doctoral degree.

—Under social services, to allow equivalent training and experience to substitute for the master's degree requirement for the director of social services (§ 482.62(f)).

• *Tuberculosis Hospitals (§ 405.1040, proposed § 482.64).* Current regulations specify details on the number and qualifications of staff to carry out an active program of treatment for patients. In the NPRM, we proposed to limit the requirements to the statutory language because of the small number of hospitals to which these requirements would apply.

As discussed earlier under section III.Y.1., section 2335 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) deleted the special staffing requirements for tuberculosis hospitals by removal of the references to tuberculosis hospitals. Therefore, we have made conforming changes in these final regulations by deleting the proposed § 482.64 that contained the special staffing requirements.

• *Public comments.*

No comments were received on the proposed changes to staff requirements of tuberculosis hospitals.

Comment: A commenter objected to the omission of the American Osteopathic Board of Neurology and Psychiatry from the specified credentials for the director of inpatient services in a psychiatric hospital. The commenter pointed out that this Board has requirements equivalent to those of the Board cited in the regulations.

Response: We agree and have revised the regulation to include the American Osteopathic Board of Neurology and Psychiatry.

Comment: Some commenters objected to the requirement that the director of clinical services in a psychiatric hospital meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology. They argued that psychologists and others may be fully capable of performing this function.

Response: We have not changed the regulation because we believe that the unique skills of a doctor of medicine or osteopathy with advanced training and experience in psychiatry or neurology are necessary to manage and evaluate the care being provided. Only such an individual can assure that the staff members, including doctors of medicine and osteopathy, are meeting the full range of patient needs, including medical needs.

Comment: One commenter indicated that it is inappropriate to require that the director of psychological services must be "eligible" to be considered a professional psychologist by the American Psychological Association's standards. The commenter argued that use of the term "eligible" implied that there was an examination to be taken or the granting of a credential made by the organization when this is not the case. The commenter pointed out that, rather, there is a set of standards the hospital or surveyor would use to assess the individual.

Response: We have revised the regulation to accept the comment.

Comment: One commenter requested that we reinstate the requirement that the director of psychiatric nursing be a professional registered nurse. This commenter pointed out that a nurse with this level of training is needed to perform the duties of a psychiatric nursing director.

Response: We agree and have made this change.

Comment: Commenters objected to the deletion of the specific requirements regarding what therapeutic activities must be provided and the credentials of staff providing them. They argued that this provision has greatly enhanced the rehabilitation of psychiatric patients and to delete these requirements would adversely affect patients recovery.

Response: We have not changed the regulations because we believe that the deleted requirements concerning therapeutic activities were overly and unnecessarily prescriptive. We believe that the hospital should have the flexibility to determine which activities are most appropriate to its patient population and to determine the criteria to be met by employees providing these services.

In addition, we have made one clarifying change in the regulations. In the NPRM (§ 482.62(c)), we proposed to require that if medical and surgical diagnostic and treatment services are not available within the institution, qualified consultants or attending physicians must be immediately available, or a transfer agreement with a Medicare certified general hospital must be established. In these final regulations, we have revised this provision to state that if medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to assure that they are immediately available or must have an agreement for transfer with a general hospital that participates in Medicare. We believe this change in wording will avoid any possible confusion regarding the meaning of "qualified consultants or attending physicians" and will make it clearer that it is the availability of services that is crucial to compliance with this requirement.

3. Special Medical Record Requirements (§ 482.61)

• *Existing provisions and NPRM provisions.—Psychiatric Hospitals (§ 405.1037, now § 482.61).* Current regulations specify special medical record requirements for psychiatric hospitals. In the NPRM, we proposed to retain the condition and elevate the requirements on the psychiatric evaluation, the treatment plan, progress notes, and the discharge summary to standards. These standards form the most critical elements of the psychiatric record. Adequate documentation provides the means for measuring the degree and intensity of active treatment mechanisms used, and active treatment is the principal concern of the special statutory provisions dealing with psychiatric hospitals. Specifically, the psychiatric evaluation, which contains a mental status examination, forms the foundation of the diagnostic decisionmaking process. The psychiatric evaluation, completed within 60 hours of admission, provides a critical data base upon which decisions regarding specific methods of treatment are based.

The individualized treatment plan is critical because it (1) forces the focus of attention on each patient as a unique individual; (2) provides a systematic approach to care of patients and the documentation of what happens to them; (3) assists staff in their understanding of the patient and his or her needs; and (4) conforms with legislative and judicial concerns that treatment be appropriate and that reimbursement be for active psychiatric treatment rather than custodial care.

Documentation of progress is necessary to determine patients response to treatment planning, treatment, and discharge planning. It serves to apprise all staff about patients progress and any new problems or regression.

Discharge planning and follow-up services are part of the continuum of total care and treatment planning. Appropriate discharge planning assists in reducing unnecessary readmissions.

—Tuberculosis Hospitals (§ 405 1039, proposed § 482.63). Current regulations specify detailed requirements for maintenance of medical records in the tuberculosis hospital. We proposed in the NPRM to limit these requirements to the statutory language. Again, because of the statutory removal of the special provisions on medical records for tuberculosis hospitals, we have deleted all the requirements from these final regulations.

• *Public comments.* No comments were received on the proposed changes to maintenance of medical records by tuberculosis hospitals.

Comment: Commenters objected to the treatment plan requirements for psychiatric hospitals, arguing that they are too detailed and prescriptive. They argued that this approach may be inappropriate to the needs of some patients, and that in some States with cost containment mechanisms, the hospitals will not be allowed to recoup the costs of developing, revising, and reviewing treatment plans. They recommended that the requirement be revised to provide more flexibility, as provided for by JCAH.

Response: We have not made any changes in the regulations because we believe that the plan of treatment requirement is as flexible as it can be and still assure the maintenance of quality care.

Comment: One commenter recommended that we revise the psychiatric provisions of the regulation to require that the attending psychiatrist perform the psychiatric evaluation, provide the admitting diagnosis, sign the discharge summary, and supervise the other staff involved in the patient's care, including any psychologist providing services to the patient.

Response: We have not accepted this recommendation because we do not believe that that level of specificity is necessary to assure health and safety.

We have adopted the proposed regulations without change as final regulations.

Z. Special Requirements for Hospital Providers of Long-Term Care Services (Swing-Beds)

In the 1983 NPRM, we inadvertently omitted provisions currently set forth in § 405.1041, which contains a condition and standards for hospitals that provide posthospital extended care services as swing bed hospitals, in our proposed redesignation of Subpart J of Part 405 to the new Part 482. We have established a new § 482.66 for these provisions. The substance of the condition and standards has not been revised. We have made minor editorial changes and a technical change in the redesignated § 482.66(a)(2) by substituting the term "urbanized" for "urban" to reflect current Census Bureau terminology.

AA. Dental Services (§ 482.12. previously § 405.1031(c))

• *Existing provisions.* Current regulations under § 405.1031(c) contain specific standards on the organization of dental services, staff qualifications and bylaws, and dental records.

• *NPRM provisions.* Doctors of dental surgery or dental medicine were included in the definition of "physician" that we proposed in the NPRM (§ 482.3), and the provisions of the proposed physician care standard (§ 482.12(c)) would have applied to these practitioners and their services. In addition, to the extent these practitioners are granted membership on hospital medical staffs, the proposed condition on medical staff (§ 482.22) would have applied to the practitioners and their services. In view of these requirements, we proposed to delete the separate standard on dental services.

• *Public comments and provisions of final regulations.* No specific comments were received on the deletion of this standard. Although we have taken a different approach to the issues raised by our proposal to define "physician," as explained earlier in this preamble, we wish to note that the governing body condition (specifically § 482.12(a)) requires that the medical staff be accountable to the governing body for the quality of care provided to patients. In addition, the provisions on quality assurance will apply to dental services as well as other patient care services. We believe these provisions will be adequate to ensure that dental services to hospital patients do not result in risk to their health and safety. Therefore, we have not included a separate standard for dental services in these final regulations.

BB. Medical Library (§ 405.1030)

• *Existing provision.* Current regulations require the hospital, as a condition of participation, to maintain a medical library in or adjacent to the facility. The library must contain modern textbooks, journals, and periodicals.

• *NPRM provision.* In the NPRM, we proposed to delete the requirement for a medical library. The proposal was based on our belief that this should not be a Federal requirement, but that each hospital should have the flexibility of deciding if it wants to have a medical library.

• *Public comments.* Many commenters objected to the deletion of the requirement that a hospital have a medical library. They perceived the maintenance of medical information as being crucial to the assurance of quality care. Commenters argued that small and rural hospitals, to which these conditions apply most directly, would be more affected by the deletion as they are more likely to lack professional continuing education programs.

• *Response and provisions of final regulations.* We have not accepted the commenters' recommendation to

maintain this condition. We continue to believe that this should not be a Federal requirement, but that each hospital should have the flexibility of deciding whether to maintain a medical library Medical information impacts on quality of care only if practitioners and staff use it. The mere existence of this information with no parallel requirement for staff to use it gives no assurance that quality of care is enhanced. If the medical staff believes it is essential to quality of care, the staff may pursue the issue with the governing body.

CC. Social Services (§ 405.1034, now § 482 21(b))

• *Existing provisions.* Current regulations specify the standards hospitals must meet if the hospital chooses to provide social work services through an organized distinct social work department. The regulations include details on organization of the social work department, the qualifications of the persons providing social work, and coordination with other departments. The Social Security Act does not require that hospitals provide social services to their patients; they may be provided as an optional service.

• *NPRM provisions.* The NPRM proposed to delete the requirements relating to the optional condition for provision of social services. However, it proposed to mandate under the governing body condition a specific discharge planning requirement, which was a more general requirement under the optional social services condition. We made this proposal because we believe social services is a service that does not require Federal regulation. While social services can be helpful as part of total patient care planning, there is no indication that direct risks to patient health or safety may result in the absence of Federal standards. In fact, we believe that, with the elimination of these prescriptive requirements, hospitals may feel freer to provide social services to their patients

Although there would no longer be a condition on social services under the NPRM, social services would continue to be a covered service under Medicare payment policies.

• *Public comments.* A large number of commenters objected to the deletion of the social service condition. They argued that social services are essential to patient health and safety because of the social worker's role in patient education, counseling, discharge planning, and maximizing the patient's adjustment to illness or disability. One commenter recommended inclusion of a general condition with no specific factors or standards. Many commenters favored including discharge planning requirements and suggested that we require "coordinated" planning. Others suggested that social services personnel be responsible for discharge planning.

• *Response and provisions of the final regulations.* We recognize that social services can make an important contribution to the health and safety of patients, and can enhance the quality of care furnished in an institution. Moreover, we are aware that, in many hospitals, social workers have primary responsibility for ensuring that patients receive appropriate care after they are discharged from the hospital. However, we are also aware that hospitals may choose to make social services available to their patients in different ways, depending on such factors as the patients' needs, the types of nursing and other staff involved in patient care, the hospital's arrangements with social workers in the community, and the availability of qualified social work personnel. We continue to believe that retaining the current prescriptive requirements for the provision of social services would restrict rather than increase hospitals' ability to provide social services to their patients. Therefore, we have not adopted the comments suggesting that we retain the current social services condition.

We have added a new standard to provide for social work services as part of the quality assurance condition (§ 482.21) because social services are so closely linked to the overall quality of care furnished in a hospital. The revised standard focuses on medically-related patient care services. It requires the hospital to have an effective, ongoing discharge planning program that facilitates the provision of followup care. It also requires the hospital to have an ongoing plan, consistent with available community and hospital resources, to provide or make available services related to the medically-related social work, psychological, and educational needs of patients. We have deleted the discharge planning standard proposed under the governing body condition (proposed § 482.12(f)).

IV. Waiver of Proposed Rulemaking to Incorporate Provisions of the Deficit Reduction Act of 1984

We publish rules without a notice of proposed rulemaking when we find that proposed rulemaking is impractical, unnecessary, or contrary to the public interest. Under section III.Y. of this preamble, we have already discussed the deletions we are making in these final Medicare regulations to conform the regulations to the statutory removal of the requirement that psychiatric hospitals must be certified by JCAH and the amendments we are making to the Medicare and Medicaid regulations to conform them to the statutory removal of all references to tuberculosis hospitals and institutions and the special requirements they had to meet. These requirements were removed by sections 2335 and 2340 of the Deficit Reduction Act of 1984 (Pub. L. 98–369, enacted on July 18, 1984).

These changes to our regulations merely conform them to provisions of the statute which are already in effect. The provisions of the law are so specific that they do not allow further interpretation. Delay to issue a proposed rule for these provisions would serve no practical purpose. Therefore, we find good cause for not issuing proposed rulemaking to incorporate the cited provisions of Pub. L. 98–369.

V. Impact Analyses

A. Executive Order 12291

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any regulations that are likely to have an annual effect on the economy of $100 million or more, cause a major increase in costs or prices, or meet other threshold criteria that are specified in that Order. (In addition, section 2 of the Order establishes a general requirement that, among alternative approaches to any given regulatory objective, an agency shall, to the extent permitted by law, choose the approach involving the least cost to society. We have abided by this principle in developing these regulations.)

Under existing regulations, approximately 5,200 of the 6,700 hospitals participating in Medicare and Medicaid are voluntarily accredited by the JCAH or the AOA, and are therefore deemed to meet most of the conditions of participation. Accredited hospitals are generally larger than nonaccredited hospitals. In fact, as of July 1, 1985, 1,082 of the 1,520 nonaccredited hospitals have fewer than 50 beds.

We expect these regulations to reduce costs incurred by nonaccredited hospitals in meeting the conditions of participation. We do not have sufficient information to estimate the amount of the reduction reliably. However, taking into account our experience with existing regulations, and the number and size of the hospitals affected, we believe that these reductions, while significant (see regulatory flexibility discussion below), will not reach $100 million.

We have determined that these final rules do not meet the criteria for a

"major rule" under Executive Order 12291. Therefore, a regulatory impact analysis is not required.

B. Regulatory Flexibility Act

1. *Overview.* In the preamble to the proposed regulations we published on January 4, 1983, we noted that those regulations would, if implemented, have a significant impact on a substantial number of small entities. Therefore, under 5 U.S.C. 603 (enacted by the Regulatory Flexibility Act, Pub. L. 96–354), we were required to prepare and make available for public comment an initial regulatory flexibility analysis. The preamble to the proposed regulations, which discussed in detail the projected impact those regulations would have on small entities, constituted the initial regulatory flexibility analysis. As required by 5 U.S.C. 604, we have now prepared a final regulatory flexibility analysis. This analysis, together with the other parts of this preamble, identifies those provisions of the final regulations that we expect will have the greatest impact on small entities, and discusses the impact we expect each provision to have.

For purposes of the Regulatory Flexibility Act, all hospitals participating in the Medicare program are considered small entities. As a result, this analysis does consider the impact on hospitals in general. However, we have given special attention to hospitals with fewer than 100 beds, since this is a generally accepted size standard in the hospital industry.

One major effect of these regulations will be to increase hospitals' flexibility to determine the most effective ways to comply with the revised conditions of participation. We expect hospitals to develop different approaches to compliance on the basis of the resources of the hospitals, differences among laws in various localities, and other factors. In addition, most of the hospitals subject to these conditions are paid under the prospective payment system for Medicare inpatient hospital services, which establishes incentives for hospitals to reconsider and improve their operations. Thus, while it is clear that the revised regulations will affect hospital costs, we are not able to estimate how each individual hospital will react to the increased flexibility provided by these regulations, or to determine in quantitative terms the effect of the hospitals' reactions. We have, therefore, prepared this analysis in qualitative rather than quantitative terms.

In the discussion below of particular provisions of these final rules, we have tried not to duplicate discussion and analysis from other parts of this preamble unnecessarily. Therefore, at the end of each numbered heading, we give a citation to the main preamble discussion of those provisions, which summarizes the provisions of existing rules and the NPRM proposals and justifies our final decision. The discussion below focuses primarily on comments explicitly related to the impact of the NPRM provisions, and our responses to those comments.

2. *Removal of Credential Requirements for Hospital Personnel (III.B.).* Many commenters opposed our proposal to delete the current credential requirements, and some commenters suggested that we impose even more specific and stringent requirements. In general, the commenters who favored imposition of credential requirements argued that elimination of the credential requirements would:

- Encourage hospitals to employ poorly qualified staff;
- Reduce the quality of patient care; and
- Increase hospital costs in the long run, since lower quality care will increase the length of patient stays.

Many other commenters, however, supported our proposals. In general, these commenters argued that elimination of federally mandated credential requirements would:

- Avoid potential conflict between Federal requirements and those imposed by State and local laws;
- Prevent private credentialing organizations from creating a monopoly with respect to the staffing of certain hospital positions; and
- Allow hospitals greater flexibility to determine personnel criteria.

Provisions of final regulations and projected impact on small entities. In the final regulations, we have:

- For hospital staff who are not doctors of medicine or osteopathy (with certain exceptions, such as staff performing scrub and circulating duties in operating rooms and administering anesthesia), generally avoided the use of personnel qualification requirements based on credentials issued by private professional groups; and
- For directors of hospital services, generally specified qualifications that are stated in terms of medical or osteopathic training and specialization rather than in terms of credentials issued by private professional groups.

See the earlier preamble discussion of the qualifications for directors of inpatient psychiatric services, laboratory services, and psychiatric nursing services for exceptions concerning direction of services. See earlier preamble discussions and sections 13 and 14 of this Impact Analysis for discussion of qualifications of staff performing scrub and circulating duties in operating rooms and administering anesthesia.

We believe the primary impact of these provisions will be to increase individual hospitals' flexibility to set personnel requirements that are appropriate to the needs of their patients, consistent with State and local laws and medical staff requirements, and cost-effective in terms of the types and qualifications of personnel available in each area. We believe this increased flexibility will be especially useful to small hospitals located in rural or other areas in which there may be a shortage of credentialed personnel, since it will permit them to adopt other standards (e.g., experience requirements) to assess the qualifications of employees. We also believe the final regulations will increase competition among potential employees by removing artificial barriers to employment in certain jobs. Thus, it is likely that the final regulations will enable small hospitals to reduce their costs by increasing the number of candidates for each hospital position.

We do not agree with those commenters who stated that removal of credential requirements will decrease the quality of hospital care and thus lead to long-term cost increases. State and local laws, medical staff requirements, and the potential for malpractice liability all provide hospitals with powerful incentives to avoid personnel decisions that reduce the quality of the patient care they provide.

3. *Definition of "Physician" (III.D.).* In the NPRM, we proposed to define "physician" as it is defined in section 1861(r) of the Social Security Act. As noted in our earlier discussion of this issue, this definition sets up the Medicare coverage rules for specified services of certain practitioners (e.g., chiropractors are defined as physicians only with respect to manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist). The definition is not stated in a context that indicates it is to be used to set hospital conditions for patient health and safety. Nevertheless, the term was used in the proposed requirements for the directors of numerous services, for the individual responsible for conduct and organization of the medical staff

with respect to patient admissions, performance of the patient history and physical, orders for services, and the general requirement that the patient be under the care of a physician, and elsewhere throughout the proposed regulations.

Commenters argued that use of the section 1861(r) definition (because it considers chiropractors and optometrists to be physicians within statutory restraints) would decrease overall quality of care and increase utilization of services. They alleged that the categories of practitioners, other than doctors of medicine or osteopathy, that are included in the section 1861(r) definition lack skills in general patient care. These commenters claimed that this would result in increased rates of complications, nosocomial infections, and communicable diseases.

These adverse consequences would result in higher hospital costs through increased lengths of stay, readmissions and higher use of necessary ancillary services and drugs.

They further argued that utilization of days of care and of ancillary services would increase because these other practitioners lack the judgment and skill needed to order services and to analyze test results properly.

Provisions of final regulations and projected impact on small entities. The final regulations delete the definition of the term "physician" and generally avoid use of the term. Instead, they identify the specific type of practitioner who may fulfill each function. Consequently, the practitioner identified for each function has been selected to represent the minimum level of training and skill which we believe is necessary to assure an acceptable level of patient care.

We believe that the selection of the appropriate minimal level of training and skill for each function will avoid confusion that might have occurred had we used the term "physician" as defined in section 1861(r) of the Act. At the same time, we have tried to give hospitals the flexibility they need by designating in each case the *minimum* qualifications appropriate to a function. Since, in the great majority of instances, current hospital and physician authority is already in conformance with these provisions, we do not expect a significant impact from these requirements.

4. *Application of Requirements to Types of Services Rather Than to Departments (II.B.3.).* In general, commenters did not express opposition to this proposal and did not state that the proposal would increase the cost or burden of compliance with the conditions. However, one commenter recommended that we require each type of service to be provided in accordance with written policies and procedures approved by the medical staff and governing body.

Provisions of final regulations and projected impact on small entities. In the final regulations, we have stated the conditions for hospital services in terms of whether services are provided rather than in terms of the way in which their provision is organized. We have taken this approach to ensure that patients receive uniform levels of protection from health and safety hazards, and to avoid any intrusive requirement on how hospitals organize the delivery of services.

We did not adopt the comment suggesting that services be provided only in accordance with written policies and procedures, since we believe that doing so would impose a burdensome paperwork requirement on hospitals without resulting in any corresponding benefit to patient health and safety.

We believe the impact of this feature of the final regulations will be to increase hospitals' flexibility to provide services in the way that is best adapted to their organizational structures, their patients' needs, and other factors that affect their operations. We expect this increased flexibility to result in reduced costs for hospitals, since each hospital will have greater freedom to provide services in the most cost-effective manner.

5. *Removal of Prescriptive Administrative Requirements (III.F. and H.).* The current regulations at § 405.1021 (governing body) and § 405.1023 (medical staff) contain certain prescriptive administrative requirements, such as those that deal with mandatory committees and committee meetings. In the NPRM, we proposed to remove most of these prescriptive administrative requirements, and to replace them with language stated in terms of expected outcomes. In general, commenters did not state that our proposals would have an adverse impact on hospitals or their patients. However, some commenters recommended that we continue to require a joint committee to allow more formal liaison between hospital medical staff and administrators. These commenters argued that formalized liaison is needed to ensure proper coordination of patient care activities.

Provisions of final regulations and projected impact on small entities. In the final regulations, we have continued to use language stated in terms of desired outcomes rather than prescriptive administrative requirements to help ensure proper administration. In particular, we have included a requirement that the medical staff be accountable to the governing body for the quality of patient care. We believe this requirement will be sufficient to ensure proper coordination of patient care services.

We believe the primary effect of these provisions of the revised regulations will be to permit hospitals and their medical staffs to develop the administrative mechanisms and procedures that are best suited to the size of each hospital, the composition of its medical staff, and the type of services its patients require. We expect the final provisions to reduce hospital administrative costs and permit administrators and medical staff members to operate more efficiently.

6. *Removal of Specific Requirements Relating to Physical Plant, Dental Services, Social Work Departments, and Medical Libraries (III.P, III.AA., III.BB., and III.CC.).* As explained above, in the NPRM we proposed to delete current regulations containing specific standards for physical plant and dental services (§§ 405.1021(i) and 405.1031(c)), and conditions for medical libraries and social work departments (§§ 405.1030 and 405.1034).

We did not receive any comments relating specifically to the potential impact of deleting the standards for physical plant and dental services. With respect to our proposals to delete the conditions on social work departments and medical libraries, we received a large number of comments. These comments are discussed in detail earlier in this preamble. With respect to the potential impact of our proposals, commenters raised the following issues.

- *Social work departments.* Many commenters state that the condition on social work departments should not be deleted because social services are essential to patient health and safety. These commenters stated that social workers play an important role in patient education, counseling, discharge planning, and maximizing patients adjustments to illness or disability. These commenters believe that deleting the condition will discourage hospitals from providing effective, professionally managed social services.
- *Medical library.* Many commenters stated that maintenance of medical information is crucial to the provision of quality care, and that deleting the medical library condition would discourage hospitals from maintaining this information. Some commenters stated that this effect would be most acute in small and rural hospitals, since those hospitals are most likely to lack

professional continuing education programs.

Provisions of final regulations and projected impact on small entities. In the final regulations, we have maintained the approach taken in the NPRM with regard to specific requirements on physical plant, dental services, and medical libraries. With regard to social services, we have not adopted the comments recommending that we retain the current social services requirements. However, we have added a provision under the new condition on quality assurance (§ 482.21) that will require hospitals to provide for social work services as part of their quality assurance efforts.

We expect that removal of the current conditions on medical libraries and social services will increase hospitals' flexibility to determine the most effective and efficient ways of making medical information available to their employees and their medical staff members, and making social services available to their patients. For example, some small hospitals may find it more cost effective to eliminate their medical library or to maintain collections of medical books, periodicals, and other information at various locations in the hospital, rather than to maintain a central medical library. Also, small hospitals may choose to make social services available to their patients in various ways, based on factors such as patients' needs, the types of nursing and other staff involved in patient care, the availability of social work personnel in their communities, and the availability of social services from agencies in those communities.

We do not expect the removal of the physical plant standard to have a significant impact on hospitals, since this amounts only to the elimination of a duplicative requirement already found in the condition on physical environment. In the case of dental services, we expect the primary impact of the final regulations to be an increase in hospitals' flexibility to set, in cooperation with their medical staffs, standards appropriate to their particular situations. This increased flexibility should produce corresponding cost savings.

7. *Elevation from Standards to Conditions of Requirements on Infection Control, Surgery, Anesthesia, and Rehabilitation (III.Q., III.R., III.S., and III.W.).* In the NPRM, we proposed to delete certain overly prescriptive requirements from these provisions, and to elevate each of them to the level of a condition. We did not receive any public comments that dealt specifically with the potential impact of the proposals on infection control, anesthesia, or rehabilitation. With respect to the proposed condition on surgery, the comments related to impact dealt almost exclusively with the provision that would require circulating duties in an operating room to be performed by a registered nurse, or by a surgical technologist or licensed practical nurse under the direct supervision of a registered nurse. Since these comments were not related to the elevation of the surgical standard to a condition, we have discussed them separately below.

Provisions of final regulations and projected impact on small entities. In these final regulations, we have retained separate conditions for infection control, surgery, anesthesia, and rehabilitation.

Under Medicare, a hospital's participation may not be terminated because of its failure to be in substantial compliance with a particular standard. However, termination may result if a hospital is not in substantial compliance with a condition. Our decision to elevate certain requirements to the level of conditions will, therefore, increase hospitals' accountability for compliance with these requirements and is likely to increase the compliance costs the hospitals incur. We expect that these increased compliance costs will be offset, at least to some extent, by the increased flexibility provided by our removal of overly prescriptive requirements from the regulations. (Under the condition on infection control, for example, individuals could perform functions for which the current regulations require committees.) Thus, while we expect that some small hospitals will incur increased compliance costs, we do not believe the extent of the impact on these hospitals will be significant.

8. *Addition of Conditions on Quality Assurance, Respiratory Care, and Nuclear Medicine (III.G., III.X., and III.T.).* We did not receive any comments that dealt specifically with the impact of the NPRM proposal to create new conditions for quality assurance and nuclear medicine. We did receive comments on the impact of the NPRM proposal to add the new condition on respiratory care. Some comments stated that respiratory care services create a risk for patients, and may be overutilized. Excessive utilization of these services would, of course, increase hospital costs. These commenters suggested that we permit the services to be ordered only by doctors of medicine or osteopathy, and that only these practitioners be permitted to direct respiratory care services.

Provisions of final regulations and projected impact on small entities.

• *Quality assurance.* In the final regulations we have made clarifying changes in the proposed condition and have expanded it to include general requirements relating to social services and discharge planning. Complying with the new quality assurance condition will impose additional costs on hospitals (e.g., costs of preparing a quality assurance plan). However, these additional costs may be largely offset by the removal of other, more prescriptive requirements that were intended to assure quality care. As a result, we do not expect the new condition to have a significant impact on hospitals.

• *Respiratory care.* We have adopted the recommendations of the commenters who believe that these services should be ordered and directed only by doctors of medicine or osteopathy. We are not requiring full-time physician direction, hence, we do not expect small hospitals to incur higher costs for respiratory care services because of this requirement. We believe that savings will result from avoiding excessive utilization of respiratory care services which might occur if doctors of medicine or osteopathy did not order the services.

• *Nuclear medicine.* We received comments suggesting that we incorporate by reference certain requirements and standards of the Nuclear Regulatory Commission and the National Council on Radiation Protection. We also received comments suggesting that we permit nuclear medicine services to be ordered only by a doctor of medicine or osteopathy. We have not adopted these specific recommendations in the final regulations. However, hospitals that use nuclear materials are already tightly regulated by the Nuclear Regulatory Commission and by State laws. Moreover, nuclear medicine programs typically are concentrated in large rather than small hospitals. Thus, we do not expect the final condition on nuclear medicine services to have a significant impact on small hospitals.

9. *Application of Special Conditions for Psychiatric Hospitals to Psychiatric Units of General Hospitals (III.Y.1.).* In the NPRM, we proposed to simplify the special conditions for psychiatric hospitals, and invited comment on whether those conditions should be applied to psychiatric units of general hospitals. Some commenters favored application of the special psychiatric conditions to psychiatric units of general hospitals, while others opposed this approach. Many of the commenters who opposed application of the special

conditions to general hospital psychiatric units stated that applying these conditions would impose an additional burden on the hospitals, and would not be necessary to protect patients health and safety.

Provisions of final regulations and projected impact on small entities. The final regulations do not require psychiatric units of general hospitals to meet the special psychiatric conditions. These special staffing and medical records requirements would have increased burden and costs for hospitals with psychiatric units. As explained earlier, hospital psychiatric units that meet certain requirements similar to these, included in 42 CFR 412.27, may qualify for exclusion from the prospective payment system. However, we do not believe these requirements are necessary for all hospital psychiatric units participating in the Medicare program. Therefore, we are leaving hospitals the flexibility to determine whether it would be advantageous for them to have their units excluded from prospective payment. If a hospital unit is sufficiently similar to psychiatric hospitals to be excluded, the requirements are appropriate. Conversely, if a psychiatric unit is not different enough from other hospital operations to justify exclusion, it would be inappropriate to impose the special conditions.

10. *Revisions to Utilization Review Requirements (III.O.).* In the NPRM, we proposed to eliminate the most prescriptive and detailed provisions of the regulations in effect when the NPRM was published, and to replace them with language from the statute. Commenters expressed differing opinions with respect to the procedure to be followed before the utilization review committee decides that a continued stay is not medically necessary. Some commenters stated that giving the attending physician the opportunity to present his or her opinion before making a determination would induce the physician to order more services to justify a continued stay. This would unnecessarily increase hospital costs. However, another commenter recommended that the patient as well as the attending physician be notified before a determination is made. This commenter reasoned that any additional cost associated with notification of the patient would be warranted, since it would help prevent premature discharges.

Some commenters recommended that we specify that decisions regarding admissions or continued stay be made only by a staff committee consisting of two or more doctors of medicine or osteopathy. This would increase hospital costs, because doctors of medicine or osteopathy generally receive higher levels of compensation than other practitioners. Other commenters, however, suggested that we enable hospitals to minimize the cost of compliance with the utilization review condition by permitting a subgroup of the utilization review committee, or an individual designee, to conduct admission or continued stay reviews.

Commenters also expressed different views regarding the general usefulness of the utilization review condition. Some commenters stated that removing all utilization review requirements from the regulations would be more cost-effective, since hospitals could then integrate their utilization review activities with their overall quality assurance efforts. Other commenters, however, stated that more prescriptive requirements would provide greater protection against excessive utilization than the requirements in the NPRM, and therefore concluded that use of more prescriptive requirements would result in a net reduction in hospital costs.

Provisions of final regulations and projected impact on small entities. The provisions of the final regulations are described earlier in this preamble. As we noted in that discussion, our primary objective in developing the final provisions has been to give hospitals as much flexibility as possible, subject to the limitations of section 1861(k), to conduct utilization review.

Since these final utilization review provisions are much less prescriptive than those previously under § 405.1035, it might appear that they would reduce hospital costs. However, we were enjoined from implementing many of the previous provisions, and those provisions therefore did not have any actual cost impact. Moreover, the utilization review requirements will not apply to any hospital for which a PRO is performing review activities to determine whether inpatient hospital services are reasonable and medically necessary and are furnished at the appropriate level of care. Since all hospitals are now required to have contracts with PROs for the performance of such reviews, it is likely that the new utilization review provisions will apply only in a very few cases. In these cases, we expect that the costs of compliance with utilization review procedures would be offset largely or entirely by the reduction or elimination of excessive utilization that we expect to result from those procedures. On balance, it is likely that efficiently conducted utilization review will reduce rather than increase hospital costs.

11. *Reduction of Medical Record Requirements (III.J.).* Comments on the impact of the proposed change to the staffing requirement are included under the discussion on credentials (IV.B.2).

The only other comments related to impact were on the expansion of the timeframes for completion of the physical examination and history. Commenters argued that allowing an extra 12 hours for the physical and history would slow treatment, cause increased costs, and result in a deterioration in the quality of care. Commenters also argued that expansion of the timeframe, for record completion, from 15 to 30 days post-discharge, would adversely impact post hospital care and slow cash flow, since record completion is necessary before billing.

Provisions of final regulations and projected impact on small entities. The final regulations delete the detail on indexing, filing, staffing, and centralization of records. This added flexibility should permit more efficient operation of the service.

The final regulations maintain the current timeframe, 48 hours, for the conduct of a history and physical. This should result in no impact.

The final regulations expand the timeframe for completion of the record from 15 to 30 days, as proposed. We believe that post discharge care should not suffer since such care is usually arranged before the 15 day limit anyway. Furthermore, any hospital which chooses is free to retain the 15 day requirement or impose a more stringent timeframe on its staff in order to facilitate its billing and cash flow.

12. *Revision of Provisions Regarding Administration of Drugs and Acceptance of Oral Orders (III.I.).* Many commenters, primarily respiratory therapists, objected to the proposed rule. Commenters indicated that individuals other than those on the lists have administered drugs and accepted oral orders for many years. They noted that JCAH has recognized this for some time as accepted practice and that if the NPRM were finalized without change numerous specialized therapists and technicians (e.g. respiratory therapists, cardiac catheterization technicians, radiology technicians, etc.) would be precluded from an appropriate function. They argued that these individuals' jobs would be jeopardized, that quality of care would deteriorate, and that the cost of care would rise.

Provisions of final regulations and projected impact on small entities. The final regulations leave the decision of who may administer drugs and accept oral orders to the medical staff rules and regulations, in accordance with State law. Consequently, there should be no impact on current practice created by release of the final regulations.

13. *Operating Room Scrub and Circulating Responsibilities (III.R.).* The 1983 NPRM provided that surgical technologists and licensed practical nurses (LPNs) could scrub under registered nurse supervision and could perform circulating duties under direct registered nurse supervision. Many commenters believe that this regulation will have a serious negative impact on the use of surgical technologists and will result in higher hospital costs as surgical technologists and LPNs are replaced by registered nurses. They stated that the release of a 1980 NPRM, which would not have required registered nurse supervision or presence in the operating room, prompted many hospitals to allow surgical technologists and LPNs to scrub and circulate without registered nurse oversight. Consequently, although the 1983 NPRM would have expanded the role of surgical technologists and LPNs permitted under regulations, by allowing them to perform circulating functions under the direct supervision of a registered nurse, commenters argued that it, in fact, would severely restrict their functions as compared with current practice.

Provisions of final regulations and projected impact on small entities. As discussed previously in this preamble, these regulations, in response to comments, will permit surgical technologists and LPNs to assist with circulating duties if certain conditions are met. This change further expands, rather than restricts, the role of surgical technologists and LPNs. The change is not expected to have a significant detrimental impact on surgical technologists and LPNs. Further, it will ensure the ready availability of a registered nurse to respond to emergencies. We do not believe this will result in any significant changes in current practice or in inappropriate restriction of functions.

14. *Administration of Anesthesia (III.S.).* The NPRM proposed to permit anesthesia assistants (properly called anesthesiology assistants) to administer anesthesia under the same conditions as CRNAs. Several commenters asserted that permitting these assistants to perform this function would have an adverse impact on patient care.

Provisions of final regulations and projected impact on small entities. As discussed earlier, we have retained anesthesiology assistants in the list of individuals who may administer anesthesia in hospitals. However, we have revised the qualifications criteria and required that anesthesiology assistants be under the direct supervision of an anesthesiologist who is physically present. There is currently at least one university that trains these personnel and the revised qualifications criteria are consistent with that university's program. Very few of the hospitals affected by these conditions would be burdened by these requirements, since there are relatively few active anesthesiology assistants, and the number of individuals in this health care training area has diminished. Consequently, although there will be some burden resulting from the credential and supervision requirements it will be confined to a few hospitals and localities, and will not be substantial.

15. *Specialty Hospitals (III.Y.).* As discussed above, we have amended the final requirements for specialty hospitals to conform to sections 2335 and 2340 of Pub. L. 98–369. The elimination of special requirements for tuberculosis hospitals will have no impact, since there are no longer any hospitals certified under those requirements. We expect that the deletion of the requirement that psychiatric hospitals be accredited by JCAH will also have a negligible impact. For the most part, psychiatric hospitals will choose to remain accredited. In any event, a hospital will have no additional burden imposed on it by this change.

C. Paperwork Reduction Act of 1980

Sections 482.12 (d), (e), and (f), 482.21, 482.22(c), 482.24 (b) and (c), 482.25(a)(3), 482.26(d), 482.27(a) (2), (3), and (4)(ii), 482.30 (c)(1) and (d)(3), 482.41(b)(3), 482.42(a)(2), 482.51 (a)(4) and (b) (1) and (6), 482.52(b), 482.53(d), 482.56(b), 482.57(b)(1), 482. 60(c), 482. 61. (a) , (b), (c), (d), and (e), and 482.62(a) of these regulations contain information collection requirements that are subject to review by the Executive Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. We are submitting these requirements to OMB for approval. We will publish a notice in the **Federal Register** when approval is obtained.

VI. REDESIGNATION TABLE

Old Part 405	New Part 482
405.1011	482.2
405.1020	482.11
405.1021(a)–(d)	482.12
405.1021(e)	482.12(a)
405.1021(f) & (g)	482.12(b)
405.1021(h)	482.12(c)
405.1021(i)	482.41
405.1021(j)	482.12(d)
405.1022	482.41 and 482.42
405.1023	482.22
405.1024 except (d)	482.23
405.1024(d)	482.51
405.1025	482.28
405.1026	482.24
405.1027	482.25
405.1028	482.27
405.1029	482.26
405.1030	Deleted
405.1031(a)	482.51
405.1031(b)	482.52
405.1031(c)	Deleted as duplicative of 482.22
405.1031(d)	482.56
405.1032	482.54
405.1033	482.12(f)
405.1034	Deleted. Provision included as part of 482.21(b)
405.1035	482.30
405.1036	482.60
405.1037	482.61
405.1038	482.62
405.1039	Deleted. Provisions removed by law.
405.1040	Deleted. Provisions removed by law.
405.1041	482.66
405.1042	482.30

VII. List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Health facilities, Medicare.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedures, Health maintenance organization (HMO), Medicare.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 441

Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Prescription drugs, Reporting and recordkeeping requirements.

42 CFR Part 456

Administrative practice and procedure, Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 482

Administrative practice and procedure, Certification of compliance, Contracts (Agreements), Health care, Health facilities, Health professions, Hospitals, Laboratories, Medicare, Onsite surveys, Outpatient providers, Reporting requirements, Rural areas, X-rays.

42 CFR Part 489

Clinics, Health care, Health facilities, Medicare, Provider agreements, Rural health clinics, Termination procedures.

Title 42—Public Health

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter IV is amended as follows:

A. The table of contents to Chapter IV is amended by adding a new Part 482 to Subchapter E to read as follows:

* * * * *

SUBCHAPTER E-STANDARDS AND CERTIFICATION

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

B. Part 405 is amended as follows:

1. The table of contents is amended by removing and reserving Subpart J to read as follows:

Subpart J—[Reserved].

* * * * *

2. The authority citation of Subpart A continues to read as follows:

Authority: Secs. 1102, 1814, 1815, 1861, 1866(d), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395g, 1395x, 1395cc(d), and 1395hh).

§ 405.162 [Amended]

3–6. In Subpart A, § 405.162, the reference in paragraph (a) to "§ 405.1035 and 405.1042" is changed to read "§ 482.30 of this chapter".

7. The authority citation of Subpart B continues to read as follows:

Authority: Secs. 1102, 1831–1833, 1835–1843, 1861, 1862, 1866, and 1871 of the Social Security Act, 42 U.S.C. 1302, 1395j–1395l, 1395m–1395v, 1395x, 1395y, 1395cc, and 1395hh, unless otherwise noted.

§ 405.231 [Amended]

8. In Subpart B, § 405.231, under paragraph (l)(1), the reference to "Subparts, J, K, and L of this part" is changed to "Subparts K and L of this part and Part 482 of this chapter"; under paragraph (l)(3), the reference to "Subparts J and K of this part" is changed to read "Subpart K of this part and Part 482 of this chapter"; under paragraph (m)(1), the reference to "Subparts J, K, and L of this part" is changed to read "Subparts K and L of this part and Part 482 of this chapter"; and under paragraph (m)(2), the reference to "Subparts J and K of this part" is changed to read "Subpart K of this part and Part 482 of this chapter".

§ 405.232 [Amended]

9. In Subpart B, § 405.232, under paragraph (f), the reference to "§ 405.1028 or § 405.1029" is changed to read "§ 482.26 or § 482.27".

10–12 The authority citation of Subpart D continues to read as follows:

Authority: Secs. 1102, 1814(b), 1815, 1833(a), 1861(v), 1871, 1881, 1886, and 1887 of the Social Security Act (42 U.S.C. 1302, 1395f(b), 1395g, 13951(l), 1395x(v), 1395hh, 1395rr, 1395ww, and 1395xx).

§ 405.434 [Amended]

13. In Subpart D, § 405.434, under paragraph (b), the reference to "§ 405.125" is changed to read "§ 409.20" and the reference to "§ 405.1041" is changed to read "§ 482.66 of this chapter".

14. In Subpart D, § 405.453, under paragraph (d)(5)(i)(A), the reference to "§ 405.1041" is changed to read "§ 482.66".

15. The authority citation of Subpart J is removed.

16. The content of Subpart J (§§ 405.1011 through 405.1042) is removed and reserved, to read as follows:

Subpart J [Reserved. See Part 482.]

17. The authority citation of Subpart K continues to read as follows:

Authority: Secs. 1102, 1814, 1832, 1833, 1861, 1863, 1865, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395k, 1395l, 1395x, 1395z, 1395bb, 1395cc, and 1395hh).

§ 405.110 [Amended]

18. In Subpart K, § 405.1101, paragraph (a)(3), the reference to "405.1021(f)" is changed to read "§ 482.12(b)".

§ 405.1128 [Amended]

19. In Subpart K, § 405.1128, the reference in paragraph (a) to "§§ 405.1028 and 405.1029" is changed to read "§§ 482.26 and 482.27 of this chapter", and the reference in paragraph (b) to "§ 405.1028(j)" is changed to read "482.27(d) of this chapter" and the reference to "§ 405.1028(j)(1), (3), (4), (6), and (9)" is changed to read "§ 482.27(d)(1), (2), (3), and (6) of this chapter".

20. The authority citation of Subpart O continues to read as follows:

Authority: Secs. 1102, 1866, 1869, 1871, 1872, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395cc, 1395ff, 1395hh, 1395ii, and 1395ww).

§§ 405.1501 and 405.1502 [Amended]

21. In Subpart O, §§ 405.1501(a)(1) and 405.1502(a), the reference to "Subparts J, K, L, or Q of this Part 405" and "Subparts J, K, L, or Q of this part" are changed to read "Subparts K, L, or Q of this part and Part 482 of this chapter". In § 405.1505(b), the reference to "Subparts J, K, or L of this part" is changed to read "Subpart K or L of this part and Part 482 of this chapter".

22. The authority citation of Subpart P continues to read as follows:

Authority: Secs. 1102, 1814, 1835, 1871, and 1883 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395n, 1395hh, and 1395tt), unless otherwise noted.

§ 405.1627 [Amended]

23. In Subpart P, § 405.1627, the section heading is amended by removing the phrase "or tuberculosis".

405.1629 [Amended]

24. In Subpart P, § 405.1629, the section heading is amended by removing the phrase "tuberculosis hospital services and inpatient"; the undesignated introductory paragraph is amended by removing "and tuberculosis" and "tuberculosis and" wherever they appear; and paragraphs (c) and (d) are removed and reserved.

§ 405.1630 [Amended]

25–26. In Subpart P, § 405.1630, paragraph (b)(1) is amended by removing the phrase "tuberculosis and".

27. The authority citation of Subpart S continues to read as follows:

Authority: Secs. 1102, 1814, 1861, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395x, 1395hh) unless otherwise noted.

§ 405.1901 [Amended]

28. In Subpart S, § 405.1901, the reference in paragraph (b)(2) to "Subparts J, K, L, M, N, Q, or U of this part, Subpart C of Part 418, or Subpart A of Part 491" is changed to read "Subparts K, L, M, N, Q, or U of this part, Subpart C of Part 418, Part 482, or Subpart A of Part 481 of this chapter". The reference in paragraph (d)(1) to "Subpart F of 42 CFR Part 482" is changed to read "§ 482.30 of this chapter". The text of paragraph (d)(2) is revised to read "(2) The additional special staffing and medical records

requirements that are considered necessary for the provision of active treatment in psychiatric hospitals (section 1861(f) of the Act) and implementing regulations; and".

§ 405.1910 [Amended]

29. In Subpart S, § 405.1910, the reference in paragraphs (a) and (d) to "Subpart J of this part" is changed to read "Part 482 of this chapter".

§ 405.1913 [Amended]

30. In Subpart S, § 405.1913, the reference in paragraph (b) to "§ 405.1035(f) and (g) and § 405.1137(a)" is changed to read "§ 405.1137(a) and § 482.30 of this chapter"; and the five references in paragraphs (b), (c), (d), and (g) to "§ 405.1035 or § 405.1137" are changed to read "§ 405.1137 or § 482.30 of this chapter".

PART 412—PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES

C. Part 412 is amended as follows:

1. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102, 1871, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395ww).

§ 412.23 [Amended]

2. In § 412.23, paragraph (a)(2), the cross-reference to "Subpart J of Part 405 of this chapter" is changed to read "Part 482 of this chapter".

PART 416—AMBULATORY SURGICAL SERVICES

D. Part 416 is amended as follows:

1. The authority citation of Part 416 continues to read as follows:

Authority: Secs. 1102, 1832(a)(2), 1833, 1863, and 1864 of the Social Security Act (42 U.S.C. 1302, 1395k(a)(2), 13951, 1395z, and 1395aa).

§ 416.41 [Amended]

2. In § 416.41, the reference to "§ 405.1011 of this chapter" is changed to read "§ 482.2 of this chapter".

PART 417—HEALTH MAINTENANCE ORGANIZATONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

E. Part 417 is amended as follows:

1. The authority citation of Part 417 continues to read as follows:

Authority: Secs. 1102, 1833(a)(1)(A), 1361(s)(2)(H), 1871, 1874, and 1876 of the Social Security Act as amended (42 U.S.C. 1302, 13951(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, and 1395mm); section 114(c) of Pub. L. 97-248 (42 U.S.C. 1395mm note); and section 1301 of the Public Health Service Act (42 U.S.C. 300e).)

§ 417.207 [Amended]

2. In Subpart B, § 417.207, the reference in paragraph (a) to "Subparts J, K, L, and Q, of this part" is changed to read "Subparts K, L, and Q of this part and Part 482 of this chapter".

PART 440—SERVICES: GENERAL PROVISIONS

F. Part 440 is amended as follows:

1. The authority statement for Part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 440.1 [Amended]

2. In § 440.1, the reference to "§§ 405.1041 and 447.280 of this chapter" is changed to "§§ 447.280 and 482.66 of this chapter".

§ 440.10 [Amended]

3. In § 440.10, the section heading is amended by removing the phrase "tuberculosis or"; and paragraph (a)(3) is amended by removing the phrase "tuberculosis or" and changing the reference "§ 405.1035" to "§ 482.30".

§ 440.40 [Amended]

4. In § 440.40, the section heading and paragraph (a) are amended by removing the phrase "tuberculosis or".

5. Section 440.140 is revised to read as follows:

§ 440.140 Inpatient hospital services, skilled nursing facility services, and intermediate care facility services for individuals age 65 or older in institutions for mental diseases.

(a) *Inpatient hospital services.* (1) "Inpatient hospital services for individuals age 65 or older in institutions for mental diseases" means services provided under the direction of a physician for the care and treatment of recipients in an institution for mental diseases that meets the requirements specified in § 482.60(b), (c), and (e) of this chapter and—

(i) Meets the requirements for utilization review in § 482.30(a), (b), (d), and (e) of this chapter; or

(ii) Has been granted a waiver of those utilization review requirements under section 1903(i)(4) and Subpart H of Part 456 of this subchapter.

(2) "Institution for mental diseases" means an institution that is primarily engaged in providing diagnosis, treatment, or care of individuals with mental diseases, including medical care, nursing care, and related services.

(b) *Skilled nursing facility services.* "Skilled nursing facility services for individuals age 65 or older in institutions for mental diseases" means skilled nursing facility services as defined in § 440.40 that are provided in institutions for mental diseases, as defined in paragraph (a) of this section.

(c) *Intermediate care facility services.* "Intermediate care facility services for individuals age 65 or older in institutions for mental diseases" means intermediate care facility services as defined in § 440.150 of this subpart, that are provided to recipients who are—

(1) Determined under §§ 456.360–456.372 of this subchapter to be in need of services; and

(2) In institutions for mental diseases, as defined in paragraph (a) of this section.

§ 440.150 [Amended]

6. In § 440.150, the section heading and paragraph (a) are amended by removing the phrase "tuberculosis or".

§ 440.250 [Amended]

7. In § 440.250, paragraph (d) is amended by removing the phrase "tuberculosis or".

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

G. Part 441 is amended as follows:

1. The authority citation of Part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

§ 441.11 [Amended]

2. In § 441.11, paragraph (b)(3) is revised to read "(3) For a facility or program providing inpatient psychiatric service for individuals under age 21, the termination by the agency of its provider agreement."; and in paragraphs (c)(2), (4), and (6), the phrase "tuberculosis or" is removed.

§ 441.13 [Amended]

3. In § 441.13, paragraph (a)(2) is amended by removing the phrase "tuberculosis or".

§ 441.40 [Amended]

4. In § 441.40, the reference to "§ 405.1011" is changed to read "§ 482.2".

PART 456—UTILIZATION CONTROL

H. Part 456 is amended as follows:

1. The authority citation of Part 456 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 456.51 [Amended]

2. In § 456.51, paragraph (a)(1) is amended by removing the phrase "tuberculosis or"; and paragraph (a)(2) is removed and reserved.

§ 456.501 [Amended]

3. In § 456.501, under paragraph (c), the reference to "§§ 405.1035, 405.1036, and 405.1137 of this chapter" is changed to read "§§ 405.1137, 482.30, and 482.60 of this chapter".

I. A new Part 482 is added to Subchapter E to read as follows:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

Subpart A—General Provisions

Sec.

Subpart B—Administration.

Subpart C—Basic Hospital Functions

Subpart D—Optional Hospital Services

Subpart E—Requirements for Specialty Hospitals.

Authority: Secs. 1102, 1814(a)(7), 1861 (e), (f), (k), (r), (v)(1)(G), and (z), 1864, 1871, 1883, 1886, and 1905(a) of the Social Security Act (42 U.S.C. 1302, 1395f(a)(7), 1395x (e), (f), (k), (r), (v)(1)(G), and (z), 1395aa, 1395hh, 1395tt, 1395ww, and 1396d(a)).

Subpart A—General Provisions

§ 482.1 Basis and scope.

(a) *Basis in legislation.* (1) Section 1861(e) of the Act provides that—

(i) Hospitals participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.

(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the distinct part meets the records and staffing requirements that the Secretary finds necessary.

(3) Section 1905(a) of the Act provides that "medical assistance" (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See §§440.10 and 440.165 of this chpater.).

(b) *Scope.* Except as provided in Subpart S of Part 405 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

§ 482.2 Provision of emergency services by nonparticipating hospitals.

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if—

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e) (1) through (5) and (7) of the Act. See 42 CFR 405.152, 405.157, and 405.158 for provisions regarding emergency services.

(b) Secton 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

Subpart B—Administration

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

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The hospital must be—

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

§ 482.12 Condition of participation: Governing body.

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. However, if a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this Part that pertain to the governing body.

(a) *Standard: Medical staff.* The governing body must:

(1) Determine, in accordance with State law, which categories of partitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Assure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

(7) Ensure that under no circumstances is the accordance of staff

membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.

(b) *Standard: Chief executive officer.* The governing body must appoint a chief executive officer who is responsible for managing the hospital.

(c) *Standard: Care of patients.* In accordance with hospital policy, the governing body must ensure that the following requirements are met:

(1) Every patient is under the care of:

(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to 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 who is legally authorized to practice optometry by the State, but only with respect to services related to the condition of aphakia; or

(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.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, the patient is under the care of a doctor of medicine or osteopathy.

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

(4) A doctor of medicine or osteopathy is responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and that is not specifically within the scope of practice, as defined by the medical staff and permitted by State law and as limited by paragraphs (c)(1) (iv) and (v) of this section, of any of the practitioners specified in paragraphs (c)(1) (ii) through (v) of this section.

(d) *Standard: Institutional plan and budget.* The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See Part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because—

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(6) The plan must be reviewed and updated annually.

(7) The plan must be prepared—

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(e) *Standard: Contracted services.* The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

(f) *Standard: Emergency services.* (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of § 482.55.

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

Subpart C—Basic Hospital Functions

§ 482.21 Condition of participation: Quality assurance.

The governing body must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care.

(a) *Standard: Clinical plan.* The organized, hospital-wide quality assurance program must be ongoing and have a written plan of implementation.

(1) All organized services related to patient care, including services furnished by a contractor, must be evaluated.

(2) Nosocomial infections and medication therapy must be evaluated.

(3) All medical and surgical services performed in the hospital must be evaluated as they relate to appropriateness of diagnosis and treatment.

(b) *Standard: Medically-related patient care services.* The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the

medically-related needs of its patients. The hospital also must have an effective, ongoing discharge planning program that facilitates the provision of followup care.

(1) Discharge planning must be initiated in a timely manner.

(2) Patients, along with necessary medical information, must be transferred or referred to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(c) *Standard: Implementation.* The hospital must take and document appropriate remedial action to address deficiencies found through the quality assurance program. The hospital must document the outcome of the remedial action.

§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a) *Standard: Composition of the medical staff.* The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(d) *Standard: Autopsies.* The medical staff should 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.

§ 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) *Standard: Organization.* The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) *Standard: Staffing and delivery of care.* The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) 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 24-hour nursing waiver granted under § 405.1910(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse 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) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) *Standard: Preparation and administration of drugs.* Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under § 482.12(c). When telephone or oral orders must be used, they must be—

(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

(iii) Used infrequently.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the

personnel must have special training for this duty.

(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§ 482.24 Condition of Participation Medical Record Services.

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

(a) *Standard: Organization and staffing.* The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) *Standard: Form and retention of record.* The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) *Standard: Content of record.* The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

(i) The author of each entry must be identifed and must authenticate his or her entry.

(ii) Authentication may include signatures, written initials or computer entry.

(2) All records must document the following, as appropriate:

(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

§ 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical services must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2) Drugs and biologicals must be kept in a locked storage area.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceutical at reasonable costs.

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) *Standard: Radiologic services.* The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precutions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal or radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

§ 482.27 Condition of participation: Laboratory services.

The hospital must maintain, or have available, adequate clinical laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a Medicare approved facility.

(a) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a Medicare approved hospital or independent laboratory, that meet the needs of the patients and the medical staff.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(i) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(ii) Except as specified in paragraphs (a)(3) (iii) and (iv) of this section, the tissue examination reports must be signed by a physician certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possessing qualifications that are equivalent to those required for certification (board eligible).

(iii) In the case of tests limited to skin pathology, the tissue examination reports may be signed by an individual—

(A) Certified in dermatopathology by the American Board of Dermatology or American Board of Pathology; or

(B) Possessing qualifications that are equivalent to those required for certification (board eligible).

(iv) In the case of tests limited to oral pathology, the tissue examination reports may be signed by an individual—

(A) Certified in oral pathology by the American Board of Oral Pathology; or

(B) Possessing qualifications that are equivalent to those required for certification (board eligible).

(4) For emergency situations, the hospital must—

(i) Directly provide a minimum blood supply;

(ii) Have a list of donors and equipment to obtain blood quickly; or

(iii) Contract with blood banks or other institutions to obtain blood quickly.

(b) *Standard: Laboratory management.* The clinical laboratory must meet the management requirements specified in § 405.1316 of this chapter.

(c) *Standard: Personnel.* The facility must provide personnel to direct and conduct the laboratory services.

(1) The laboratory director must be technically qualified to supervise the laboratory personnel and test performance.

(i) The director must be a pathologist or other doctor of medicine or osteopathy with training and experience in clinical laboratory services, or a laboratory specialist with a doctoral degree in physical, chemical or biological sciences, and training and experience in clinical laboratory services.

(ii) If the laboratory performs anatomic pathology services, the tissue examination must be performed under the technical supervision of a pathologist or other individual who meets the requirements of paragraphs (a)(3) (iii) or (iv) of this section.

(iii) If the laboratory performs blood banking and transfusion services they must be performed under the technical supervision of a pathologist or other doctor of medicine or osteopathy with training and experience in transfusion therapy.

(2) The laboratory director must—

(i) Provide technical supervision of the laboratory services; and

(ii) Assure that tests, examinations, and procedures are properly performed, recorded, and reported.

(3) The laboratory director must ensure that the staff—

(i) Has appropriate education, experience, and training to perform and report laboratory tests promptly and proficiently;

(ii) Is sufficient in number for the scope and complexity of the services provided; and

(iii) Receives in-service training appropriate to the type and complexity of the laboratory services offered.

(4) The laboratory technologists must be technically competent to perform test procedures and report test results promptly and proficiently.

(d) *Standard: Blood and blood products.* The hospital must ensure that there are facilities for procurement, safe keeping, and transfusion of blood; and that blood products are provided or readily available.

(1) The hospital must maintain, as a minimum, proper blood storage facilities under adequate control and supervision of the pathologist or other authorized doctor of medicine or osteopathy.

(2) In the case of services provided by an outside blood bank, the hospital must have an agreement governing the procurement, transfer, and availability of blood that is reviewed and approved by the medical staff and administration.

(3) There must be provision for prompt blood grouping, antibody detection, and compatibility testing; and for laboratory investigation of transfusion reactions, either through the hospital or by arrangements with others on a continuous basis, under the supervision of a doctor of medicine or osteopathy.

(4) Blood storage facilities in the hospital must have an adequate

temperature alarm system that is regularly inspected.

(5) According to the hospital's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions. The hospital must promptly dispose of blood not retained for further testing that has exceed its expiration date.

(6) The hospital, according to its established procedures, must promptly investigate all transfusion reactions occurring in its own facility and make recommendations to the medical staff regarding improvements in transfusion procedures.

(e) *Standard: Proficiency testing.* The laboratory must meet the proficiency testing provisions specified in §§ 405.1310(c) and 405.1314(a) of this chapter.

(f) *Standard: Quality Control.* The laboratory must meet the quality control requirements specified in § 405.1317 of this chapter.

§ 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) *Standard Organization.*

(1) The hospital must have a full-time employee who—

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

(b) *Standard: Diets.* Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect 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) *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 hospital.

(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 of the 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 § 482.12(c)(1).

(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—

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

(B) Established 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) Was 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—

(i) Admissions to the institution;

(ii) The duration of stays; and

(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 of § 482.12(c), 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 § 482.12(c), 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, no 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 § 482.12(c);

(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.

§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) *Standard: Life safety from fire.*

(1) The hospital must meet the applicable provisions of the 1981 edition of the *Life Safety Code* of the National Fire Protection Association that apply to hospitals. (Which is incorporated by reference [1]

[1] Incorporation of the 1981 edition of the Life Safety Code which is also referenced in other parts of Chapter IV, was approved by the Director of the **Federal Register** on September 28, 1981. The code is available for inspection at the Office of the **Federal Register** Information Center, Room 8301, 1110 L Street N.W., Washington, D.C. Copies may be obtained from—

National Fire Protection Association, Battery March Park, Quincy, Mass. 02269.

(i) Any facility that on November 26, 1982 complied, with or without waivers, with the requirements of the 1967 edition of the *Life Safety Code,* is considered to be in compliance with this standard so long as the facility continues to remain in compliance with that edition of the Code.

(ii) Afer consideration of State survey agency findings, HCFA may waive specific provisions of the *Life Safety Code* which, 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.

(iii) 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.

(2) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(3) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(4) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(c) *Standard: Facilities.* The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

§ 482.42 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) *Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services.* The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospitalwide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

If any changes in this Code are also to be incorporated by reference, a notice of that effect will be published in the **Federal Register.**

Subpart D—Optional Hospital Services

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub nurses" under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the surpervision of a qualified registered nurse who is immediately available to respond to emergencies.

(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(b) *Standard: Delivery of service.* Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

(4) There must be adequate provisions for immediate post-operative care.

(5) The operating room register must be complete and up-to-date.

(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) *Standard: Organization and Staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered by only—

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA) who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiology assistant who is permitted by State law to administer anesthesia, who has successfully completed a 6-year program for anesthesiology assistants, 2 years of which consist of specialized academic and clinical training in anesthesia, and who is under the direct supervision of an anesthesiologist who is physically present.

(b) *Standard: Delivery of services.* Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

(2) An intraoperative anesthesia record.

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.

(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

§ 482.53 Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(b) *Standard: Delivery of service.* Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(2) There is proper storage and disposal of radioactive material.

(3) If clinical laboratory tests are performed in the nuclear medicine service, the service must meet the requirement for clinical laboratories with respect to management, adequacy of facilities, proficiency testing and quality control (see § 482.27 (a), (b), (e), and (f)).

(c) *Standard: Facilities.* Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be—

(1) Maintained in safe operating condition; and

(2) Inspected, tested, and calibrated at least annually by qualified personnel.

(d) *Standard: Records.* The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

§ 482.54 Condition of participation: Outpatient services.

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization.* Outpatient services must be appropriately organized and integrated with inpatient services.

(b) *Standard: Personnel.* The hospital must—

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

§ 482.55 Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* If emergency services are provided at the hospital—

(1) The services must be organized under the direction of a qualified member of the medical staff;

(2) The services must be integrated with other departments of the hospital;

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

(b) *Standard: Personnel.* (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

§ 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

(a) *Standard: Organization and staffing.* The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of services.* Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

§ 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(a) *Standard: Organization and Staffing.* The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the requirements for clinical laboratories with respect to management adequacy of facilities, proficiency testing, and quality control. (See § 482.27(a), (b), (e) and (f) for requirements applicable to laboratories).

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

Subpart E—Requirements for Specialty Hospitals

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospitals must—

(a) Be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit HCFA to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and

(d) Meet the staffing requirements specified in § 482.62.

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contracts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) *Standard: Psychiatric evaluation.* Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) *Standard: Treatment plan.*

(1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's

progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) *Standard: Personnel.* The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

(1) Evaluate patients;

(2) Formulate written individualized, comprehensive treatment plans;

(3) Provide active treatment measures; and

(4) Engage in discharge planning.

(b) *Standard: Director of inpatient psychiatric services; medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical (physician) staff.

(c) *Standard: Availability of medical personnel.* Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) *Standard: Nursing services.* The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.* The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate, information with sources outside the hospital.

(g) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program.

(1) The program must be appropriate the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

§ 482.66 Conditions of participation—Special requirements for hospital providers of long-term care services ("swing-beds").

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from HCFA to provide post-hospital extended care services, as specified in § 405.120, and be reimbursed as a swing-bed hospital, as specified in § 405.434:

(a) *Standard: Eligibility.* A hospital must meet the following eligibility requirements: (1) The facility has fewer than 50 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 405.453(d)(5);

(2) The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census;

(3) When required by State in which it is located, the hospital has been granted a certificate of need for the provision of long-term care services from the State health planning and development agency (designated under section 1521 of the Public Health Service Act);

(4) The hospital does not have in effect a 24-hour nursing waiver granted under § 405.1910(c); and

(5) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(b) *Standard: Skilled nursing facility services.* The facility is substantially in compliance with the following skilled nursing facility requirements contained in Subpart K of Part 405 of this chapter.

(1) Patients' rights (§ 405.1121(k)(2), (3), (4), (7), (8), (10), (11), (13), and (14);

(2) Specialized rehabilitative services (§ 405.1126(a), (b), and (c));

(3) Dental services (§ 405.1129);

(4) Social services (§ 405.1130);

(5) Patient activities (§ 405.1131); and

(6) Discharge planning (§ 405.1137(h)).

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

The authority citation of Part 489 continues to read as follows:

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

§ 489.21 [Amended]

J. In Part 489, § 489.21, the reference in paragraph (b)(3) to "Subparts J and K of Part 405" is changed to read "Subpart K of Part 405 and Part 482 of this chapter."

(Catalog of Federal Domestic Assistance Program No. 13.714—Medical Assistance Program; Program No. 13.773—Medicare: Hospital Insurance; Program No. 13.744—Medicare: Supplementary Medical Insurance)

Dated: February 21, 1986.

Henry R. Desmarais,

Acting Administrator, Health Care Financing Administration.

Approved: April 26, 1986.

Otis R. Bowen,

Secretary.

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