DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 405, 481, and 482

Medicare and Medicaid Programs; Conditions of Participation: Hospitals

AGENCY: Health Care Financing Administration (HCFA) HHS.

ACTION: Proposed rule.

SUMMARY: The proposed amendments would simplify the regulatory requirements which hospitals must meet to be certified for participation in Medicare and Medicaid. Current regulations would be amended to take into consideration changes in the delivery of hospital services and in the training and roles of health personnel. The amendments would add greater requirements for accountability while allowing flexibility for hospitals in performing administrative and managerial functions.

The amendments are intended to hold down costs while maintaining an acceptable level of patient care. The amendments establish minimum requirements and are not intended to limit hospitals from establishing higher requirements.

DATE: Consideration will be given to written comments or suggestions received on or before August 19, 1980.

ADDRESS: Address comments to: Administrator, Health Care Financing Administration, Department of Health, Education, and Welfare, P.O. Box 17082, Baltimore, Maryland 21235.

In commenting, please refer to file HSQ–16–P. Comments will be available for public inspection Monday through Friday, from 8:30 a.m. to 5:00 p.m. beginning approximately 2 weeks after publication in Room 5220, Switzer Building, 330 C Street, SW., Washington, D.C. 20201 (202–245–0365).

FOR FURTHER INFORMATION CONTACT: Mrs. Janet Harryman, Director, Division of Hospital Services, Office of Standards and Certification, Health Standards and Quality Bureau, HCFA, 6401 Security Boulevard, Baltimore, Maryland 21235 (301–594–9712).

SUPPLEMENTARY INFORMATION:

Background

The present regulations which set forth the conditions of participation for hospitals have been in effect, with only minor modifications, since the beginning of the Medicare program on July 1, 1966. Changes in methods of health care delivery, the need to control the increasing cost of hospital care, and the Department's commitment to simplifying HEW regulations are the principal reasons for the proposed revisions. Experience has shown that the existing requirements are unnecessarily restrictive, especially for small rural hospitals, in terms of allocation of resources and performance of administrative and managerial functions. As an example, it is unnecessary to require a medical staff of three or four physicians to constitute itself formally as numerous committees, as required in the current regulations. At the same time, there is strong opposition to the creation of different classifications of hospitals, with differing requirements for each class.

On November 2, 1977, the Health Care Financing Administration (HCFA) published a general notice in the **Federal Register** (42 FR 57351) requesting participation from hospital accrediting bodies, State agencies, and hospital, health professional, and consumer organizations in the revision of the health and safety regulations for hospitals participating in the Medicare and Medicaid programs. HCFA drafted specifications for these regulations and distributed them, upon request, to more than 700 organizations, hospitals, and individuals. Written comments from over 160 sources were received, reviewed, and evaluated. In addition, HCFA staff met with 30 professional health organizations during November and December 1977 to hear their views on the proposed revisions. We considered more than 2,000 comments in drafting these proposed hospital regulations.

General Considerations

The proposed regulations present amendments which take into account technological advances and changes in patterns of delivery of health care. In addition, current regulations have been revised for clarity and readability.

1. *Recodification and reorganization*—These amendment would be codified in a different location in the Code of Federal Regulations and would be organized very differently from the current regulations. To make comparison easier, we have included redesignation and derivation tables. The derivation table lists all sections of the proposed amendments, the section numbers of related provisions of the current regulations, if applicable, and the nature of the change. The redesignation table lists all sections of the current regulations, the relevant section numbers of the proposed revision, if applicable, and the nature of the change.

2. *Clarity and applicability*—The regulations would be simplified and shortened and much of the technical language removed by these amendments. We anticipate that the revised requirements would be more comprehensible to hospitals and the public.

These requirements will be applied to all types of hospitals, small and large, rural and urban, recognizing variations in the services furnished and the staff available. The current regulations have been frequently criticized by small, rural hospitals as being inappropriate to their situation and resources. We had considered issuing different regulations for each class of hospital. After weighing the arguments against this which were raised by the hopsital industry, and evaluating a research project to develop model standards for small rural hospitals, we have concluded that the problems attendant to such an approach outweigh the expectable benefits. Accordingly, those amendments are general and flexible in nature, in order to permit application to differing institutional situations. This approach has the support of many small and rural hospitals, as they considered that separate standards would have potential inequities of classification and might bear some stigma in the view of the public.

We have been especially concerned to ensure that we do not inadvertently include requirements which would be disproportinately burdensome to small and rural hospitals, and our objectives in revision have been consistent with the President's Small Business Initiative. The proposal personnel qualifications would recognize experience and training as well as academic credientialing. The number and qualifications of staff members required would be related to the scope and complexity of services offered.

In order to retain flexibility and provide a mechanism to ensure uniform application of the requirements by surveyors, we will develop measurement criteria for assessment of compliance. These criteria would be applied on the basis of each hopsital's bed size, type, scope, and range of services offered, and would take into account organization and level of services, type and numbers of staff required, and administrative controls. When they are fully developed, the measurement criteria will be published in the **Federal Register.**

3. *Personnel utilization*—Changing patterns of education have resulted in changes in the delivery of health care. There are now many types of specially trained health personnel, the this has resulted in changing and differing staff roles in the performance of many duties.

In order to recognize these changes, and local differences in the availability and utilization of different classes of trained staff, we have framed the proposed revision to allow hospitals to use professional and clinical service staff more effectively and economically.

4. *Compatability of requirements with regulatory and accrediting bodies*—Hospitals are deemed to meet most of the requirements for participation by virtue of accreditation by either the Joint Commission on Accreditation of Hospitals (JCAH) or the American Osteopathic Association (AOA). Therefore, the amendments would incorporate definitions and requirements similar to those used by national accrediting and professional organizations and by other Federal regulatory agencies wherever possible. These changes have been proposed in order to achieve greater compatibility among standard setting organizations. For example, the new proposed conditions for respiratory care, nuclear medicine, and psychiatric services establish Federal requirements for services already covered by JCAH standards.

Hospitals also come under the jurisdiction of numerous other Federal, State, and local government agencies and private organizations. These groups have promulgated such a variety of requirements that it is probably impossible to completely avoid issuing a rule without some duplications or contradictions. However, we have avoided explicit inconsistencies with these other requirements when possible. Others will be identified through comment.

5. *Administrative and managerial requirements*—The current regulations require each participating hospital to have certain committees, and have many provisions on meetings of committees and departments and on minutes to be kept. These amendments would not require the formation or continuance of any particular committees. They would specify functions to be performed and, where appropriate, the parties that would be responsible for these functions. However, generally hospitals would be allowed administrative and managerial flexibility in the execution of these functions.

6. *Cost impact*—We do no expect that any of the proposed amendments will have an inflationary effect, as the cost impact on hospitals would not be greater than that of the current regulations. There will be implementation costs due to publication and distribution of revised requirements, and the training of surveyors to apply the requirements. There may be overall savings in hospitals able to allocate personnel and other resources more effectively. Some hospitals should also be able to reduce or simplify recordkeeping and reporting activities because of the elimination of committee requirements.

We have completed a threshold study on the cost impact of these revisions, pursuant to the Departmental guidelines published in the **Federal Register** on October 16, 1979 (44 FR 59662), and have concluded that a regulatory analysis is not necessary. Copies of this study are available to the public on request. However, due to difficulties of analysis, the findings of this study are tentative. We are having a more detailed cost analysis conducted, which will be completed before we issue a final rule, and which will also be made available.

In the course of development of the revision, we have identified the following provisions as potentially increasing or decreasing costs. Any specific comments on these or on other provisions would aid our analysis of the prospective cost and burden of these proposed amendments.

Potential Cost Increases

482.3 Personnel Qualifications:
- More accountability required for Directors of Surgical Service
- Qualifications for Director of Nuclear Medicine Service
- Qualifications for Director of Radiologic Service
- Qualifications for Psychiatric Nurse
- Specific qualifications for Radiographer, Radiotherapist, and Radiation Therapy Technologist
- Qualifications for Respiratory Therapist and Respiratory Therapy Technician

482.21(a) Revision ensures that all services are supervised
482.21(a) Requires facility access for the handicapped [1]
482.21(e) Establishment of Quality Assurance Program
482.21(h) Establishment of written policies governing Patient Rights
482.22(b) Limitations placed on patient care rendered by house staff
482.25(a) Requirements established for pharmacist supervision in compounding, packaging, and dispensing of drugs
482.25(b) Delivery of Service
- Establishment of a drug standard by each hospital
- Revision requires review of medication orders by pharmacist before drug is dispensed, and reporting of drug irregularities, abuses, and misuses by pharmacist
- Required information system on drug interactions, etc.

482.26(b) & (c) Establishment of specific requirements for radiologic equipment design and operation [2]
482.27(b) Establishment of special diet training after discharge
482.27(d) Revision requires menu planning, assurance of nutritional adequacy, and bedtime nourishment upon request
482.28(a) Adoption of 1973 edition of NFPA Std. 101, (Life Safety Code)
482.28(b) Adoption of 1973 edition of NFPA Std. 56A, (Inhalation Anesthetics), 1976 edition of Std. 56B (Respiratory Therapy) and 1977 edition of Std. 56F (Nonflammable Medical Gas Systems)
482.28(b) Adoption of 1977 edition of NFPA Std. 76A, (Essential Electrical Systems for Hospitals)
482.28(d) Revision requires single rooms with private toilet and handwashing facilities for isolation of patients
482.28(d) Revision requires a nurse call system for each patient room
482.41(b) & 482.42(a) Evaluation of privileges by surgical and anesthesia services
482.42(b) & 482.42(d) More restrictive requirements for delivery of anesthesia services
482.43 New requirements for nuclear medicine [2]
482.44(b) More restrictive requirements for outpatient surgery
482.45 More restricitve requirements for emergency services
482.46 New and more restrictive requirements for rehabilitation services
482.47 New and more specific requirements for respiratory care
482.49 New requirements for special care units
482.50 New requirements for psychiatric services in general hospitals

Potential Cost Savings

482.3 Personal Qualifications:
- Deletion of special training requirements in addition to licensure for pharmacists
- More flexible qualifications established for Non-dietitian Director of Dietetic Services and Dietitian
- Allowance for on-the-job training for Director of Medical Record Service
- Requirements for Director of Psychiatric Services reduced
- Establishment of alternative qualifications for Director of Rehabilitation Service
- Recognition of alternative staff resources (Physician Assistant, Nurse Practitioner, Nurse Midwife)
- Establishment of alternative qualifications for Occupational Therapist, Occupational Therapy Assistant, and Physical Therapy Assistant

482.21(a) Simplification of meeting and committee requirements of governing body
482.22 Deletion of committee and meeting requirements for medical staff

[1] This is already required under Section 504 of the Rehabilitation Act. Therefore, this provision of the conditions would not impose new costs, but is only a cross-reference.

[2] These provisions include references to regulations and recommendations of other agencies (FDA, NRC). The costs of compliance cannot be solely ascribed to these proposed amendments.

482.22 Deletion of regulations governing autopies
482.22(b) Admitting privileges permitted for dentists and podiatrists
482.23(d) Revision allows more types of personnel to administer drugs, and allows LPN's to accept orders
482.23 Deletion of requirement for meetings of registered professional nurse staff
482.25 Deletion of pharmacy and therapeutics committee requirements
482.27 Deletion of requirement for dietary departmental and interdepartmental conferences
482.28(e) Deletion of routine laboratory tests on admission
482.41(a) Revision permits LPN's and surgical technologists to circulate
482.44 Deletion of requirement for outpatient clinic organization and conferences
482.48 Simplification of social work records and deletion of requirement for ward rounds, conferences, in-service training

Specific Major Changes

Many specific requirements have been added or significantly altered.

1. *Personnel qualifications*—The proposed amendments would revise personnel qualifications in the current regulations, and set forth qualifications for personnel not previously covered in regulations. The qualifications for directors of services would be related directly to the scope and complexity of the services offered. Wherever possible, the regulations would recognize training and experience in lieu of purely academic credentialing, and would require hospitals to be responsible for ensuring that staff demonstrate continuing competence. These revisions are consistent with the Public Health Service Report, "Credentialing Health Manpower" (HEW Publication No. (OS) 77-50057), which sets forth the position of the Department on this subject.

2. *Equal rights*—The proposed amendments would include provisions requiring the governing body of the hospital to ensure that the hospital operates in accordance with Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

3. *Quality assessment and accountability*—The revisions would require the development of a hospital-wide quality assurance program. The chief executive officer and directors of organized services would be required to assess staff performance and report on activities and evaluative findings. The governing body would be responsible for reviewing the program findings and implementing changes in response to them.

4. *Responsibility for contracted services*—The amendments would permit hospitals to contract out certain services but would explicitly require that hospitals remain accountable for the quality of services furnished. This change has been proposed because of the increase in the number of hospitals providing services (e.g., food services and temporary staffing) through contracts with other corporations or with individuals.

5. *Patients' rights*—The regulations would require that hospitals have written policies clearly defining the rights of patients, that they inform the patients or guardians of these policies upon admission, and that staff be informed of these policies and measures be taken to assure their implementation. These policies would have to ensure recognition of each patient's dignity and individuality and that the patient or guardian be informed about consent, billing, medical status, access to records, and so forth. Consumer groups have long advocated establishment of patients' rights by government authority. After review of arguments and cases, HCFA has concluded that some regulation in this area would be beneficial, and consistent with efforts to promote the health and safety of patients.

6. *Medical staff*—The proposed amendments use the term "practitioner" rather than "physcian" in referring to the granting of clinical privileges. At meetings with the American Dental Association and the American Podiatric Association, it was pointed out that the use of the term "physician" in past regulations has been interpreted in such a manner that hospitals, citing Federal requirements, denied clinical privileges to dentists and podiatrists. Although the statute defines the term "physician" to include dentists and podiatrists only when they are performing specified functions, we did not intend to restrict the clinical privileges a hospital could grant to nonphysician practitioners. Thus, the amendments would make clear that the hospital may extend privileges to these professionals if it wishes, without regard to whether they perform services covered under Medicare. Other changes which are proposed for the medical staff requirements include elimination of procedural requirements for granting staff privileges, elimination of all committee and meeting requirements, and the omission of requirements for consultations or autopsies. New provisions would include more specific requirements on the review of clinical privileges, provisions for the medical direction of house staff, and provisions on medical supervision of physician assistants, nurse practitioners, and nurse midwives.

7. *Nursing services*—The requirements would be simplified without major changes, with the exception of the provisions applying to the administration of drugs. These provisions would include more detailed and specific requirements on accountability and safety, and would be more flexible regarding types of personnel permitted to administer drugs, receive verbal drug orders, and give blood or parenterals.

The proposed revision includes a reference to section 1861(e)(5) of the Social Security Act, which provided for waiver of the statutory requirement that hospitals have 24-hour coverage by registered nurses. That section permitted waivers to be granted until January 1, 1979. Legislation is now pending that may extend the waiver authority. If section 1861(e)(5) of the Act is not amended before the proposed regulations are published as a final rule, the reference will be deleted.

8. *Medical records*—The proposed amendments would be generally similar to the current regulations. Some requirements, such as those on indices, would be simplified. The current requirement that original reports be filed in the medical record would be deleted. The requirement that all reports be signed would be modified; the proposed regulation would require instead that all entries be authenticated by the person responsible for the services furnished and by the person making the entry. These changes would be consistent with JCAH requirements and are intended to recognize and permit increased use of computer systems in medical recordkeeping. The amendments would also propose firmer standards on the security of medical records.

9. *Pharmaceutical services*—The proposed amendments would clarify present requirements for pharmaceutical services, whether a hospital has an organized pharmacy service or only a drug room. The requirements would establish clearer standards for accountability and quality control, and would expand basic specific requirements for emergency pharmaceutical services. The revision would delete the requirement that pharmacists have special training in hospital pharmacy, as small, rural hospitals may not have access to personnel with such training. In addition, the amendments would not require a pharmacy and therapeutics committee and would reduce and simplify the standards on recordkeeping.

10. *Radiologic services*—Due to the inherent risks of diagnostic and therapeutic radiology and the danger to patients of unnecessary exposure, the

amendments would place greater emphasis on the qualifications of the director of the service and other personnel. The revision would also provide specific requirements on equipment design and use, operating conditions, radiation protection surveys and personnel monitoring.

11. *Dietetic services*—The proposed revision is similar to the current regulations. However, requirements for departmental and interdepartmental conferences would be eliminated. The role of the director of the service would be clarified, and revised qualifications proposed that would permit new types of qualifying training and experience. The revision would add requirements for menu planning, substitutes for refused meals, bedtime nourishment, and opportunity for patient comment.

The proposed revision would add a new requirement that would allow no more than 15 hours between substantial evening and morning meals. Current regulations for skilled nursing facilities and intermediate care facilities allow only 14 hours between these meals, and we proposed 14 hours in our Notice of Intent. At that time, we received strong comment from 13 groups requesting an extension to 15 hours, which would be consistent with the requirements of the Joint Commission on the Accreditation of Hospitals. We received one comment, from the American Dietetic Association, requesting retention of the 14 hour standard. We particularly invite comment on the impact that this requirement would have on costs and on the health of patients.

12. *Life safety from fire*—The proposed amendments would adopt the 1973 edition of the Life Safety Code of the National Fire Protection Association (NFPA) as the fire safety requirements for hospitals which do not qualify for certain specified exceptions. These exceptions would provide for recognition of hardship situations, for acceptance of State codes in lieu of the Life Safety Code, and for participation of hospitals that continue to meet the requirements of the 1967 edition of the Code if they do so on the effective date of these amendments.

The fire safety requirements for institutional facilities in the 1973 edition place greater reliance on improved systems for detecting and extinguishing fire and less emphasis on building construction. The 1973 edition is required by statute for skilled nursing facilities. We have chosen not to adopt the 1976 edition of the Life Safety Code in order to avoid inconsistency in requirements for facilities which include both a hospital and a SNF. If the statutory requirement for skilled nursing facilities is changed, the Department will propose amending the hospital regulations to maintain consistency.

We also want to call attention to proposed changes in the means by which compliance with the Life Safety Code will be assessed. On June 28, 1979 the Department published a notice for comment on the adoption of the National Bureau of Standards Fire Safety Evaluation Systems (44 FR 37818). A final notice concerning this system is in preparation and will be published soon.

The revised conditions would also incorporate updated NFPA standards on medical gases and respiratory therapy.

13. *Anesthetizing locations*—The requirements for anesthetizing locations in hospitals would be very similar to our current requirements. Isolation transformers are required by the current regulations and by licensure requirements of some States, although the efficacy and cost-effectiveness of these transformers are controversial. Many anesthesiologists and surgeons have recommended strict enforcement of this requirement to ensure adequate protection for the health and safety of patients and staff in operatng rooms. On the other hand, many biomedical engineers oppose the requirement for isolation transformers because, in their opinion, these add little to a safe environment and, therefore, contribute unnecessarily to the rising cost of health care.

Because of this controversy, in October 1978, HEW declared a moratorium on enforcement of its requirement for isolation transformers while the issue was re-evaluated. Hospitals were advised that if they elected not to install isolation transformers and HEW later determined that transformers were required to ensure a safe environment, the hospitals would be required to install them. It has been estimated that at this time there are a significant number of anesthetizing locations not served by an isolation transformer. We particularly request comments and information regarding the efficacy of isolation transformers as used in anesthetizing locations and the costs and benefits of each of the options available. The following alternatives are suggestions for consideration:

a. Retain the present requirement for isolation transformers in anesthetizing locations.

b. Delete the present requirement for isolation transformers.

c. Delete the requirement for an isolation transformer where the grounding system is considered by the authority enforcing the requirement to be adequately maintained, including regular inspection of the grounding system by a qualified person.

d. Modify the present requirement and require transformers to serve all wet locations.

e. Modify the requirement to require isolation transformers in new construction only.

When you comment on the options, please include any cost estimates you may have regarding the option you are recommending.

14. *Infection control*—The amendments would delete the current requirement for an infection control committee, and instead would require monitoring, investigation, and reporting to be performed by one or more infection control officers.

15. *Laboratories*—The existing requirements for laboratories would be recodified without rewriting, and with only minor deletions. Although other revisions are being contemplated, HCFA has agreed to coordinate future regulatory issuances on laboratory personnel, blood banking, and clinical laboratory standards with the Public Health Service, the Food and Drug Administration, and the Center for Disease Control. Because of this agreement, we have not proposed more detailed qualifications for the personnel mentioned in this condition, and these personnel are not included in the proposed § 482.3, referring to personnel qualifications.

The only significant change proposed is the deletion of the requirement of routine urinalysis and hemoglobin or hematocrit on admission of a patient. HCFA has requested Medicare insurance carriers to stop automatic payments for a variety of clinical tests which have sometines been routinely performed on all Medicare admissions. This deletion would ensure that the regulations would be consistent with reimbursement actions. The other deletions from the current regulation are merely editorial and do not have any program impact.

16. *Surgical and anesthesia services*—The proposed revision would expand each of the two standards currently contained in § 405.1031(a) and (b) into a separate Condition of Participation. These would be optional services, and the requirements would apply only to those hospitals which choose to offer surgical and anesthesia services. The amendments would require for the first time that there be a director accountable for each service, and would require the director to be responsible for assignment of duties to personnel. The amendments would permit alternate means of qualifying directors, by Board

certification, education, or experience. We particularly invite comment on the roles and qualifications of directors as a means of assuring quality and establishing accountability. We also invite comment on other consequences of applying these requirements, especially whether hospitals will be able to get qualified directors, and whether the requirements would affect access to services in rural hospitals in remote areas. The revision would also require that surgical privileges and authorizations to administer anesthesia be reviewed annually on the basis of performance.

17. *Surgical circulators*—The current regulations specify that only registered nurses may perform circulating duties in the operating room. The revision would also allow licensed practical (vocational) nurses and surgical technologists (operating room technicians) to perform circulating duties, in accordance with the rules and regulations of the hospital's medical staff. The revision would also require that a registered nurse be immediately available in the operating suite to respond to emergencies. We have already received a great deal of comment on this proposal as contained in the Notice of Intent.

We particularly invite comment on current practices in the assignment of licensed practical (vocational) nurses and surgical technologists to circulating duties, and on the impact of these practices on the health and safety of patients.

18. *Nuclear medicine services*—The amendments would create a new Condition of Participation for nuclear medicine services. These are optional services, and hospitals would only have to meet these proposed requirements if they actually offer these services. These provisions have been proposed because of the growing number of hospitals offering such service, and in recognition of the inherent risks of any medical procedures which expose patients to radiation. The proposed rule would specify minimum requirements for organization of the service, accountability, safety, and records.

19. *Outpatient services*—The proposed revision would simplify the current regulations. It is proposed that if outpatient surgery is offered, the standards applicable to inpatient surgery must be met. The current requirements for clinic organization, conferences, and meeting minutes would be deleted.

20. *Emergency services*—The proposed amendments would require the hospital to evaluate its emergency service capabilities: coordinate planning with an overall community plan, if possible; and inform the community served of the services offered. The amendment would also require that the hospital must not refuse treatment to patients for other than medical reasons. Proposed provisions would permit the initial assessment of a patient's need for treatment to be made by specially trained non-physician personnel, but only in accordance with guidelines approved by the medical staff.

21. *Rehabilitative services*—The current regulations cover these services under Standard (d) of § 405.1031, referring to complementary departments. The proposed revision would expand this standard into a separate Condition of Participation. Rehabilitative services are optional services, and the proposed requirements would be applied only to those hospitals which choose to offer these services. The amendments would apply to physical therapy, occupational therapy, speech-language pathology, and audiology services whether these are organized as a single department or as independent departments. The revision proposes clearer and more specific requirements on direction, accountability, treatment plans, monitoring patient progress, and proper information of the patient, family, or guardian.

22. *Respiratory care services*—The amendments would establish a new Condition of Participation for respiratory care services. These are optional services, and the proposed requirements would be applied only to those hospitals which choose to offer respiratory care services. These provisions have been proposed in response to the growing practice of offering respiratory care through an organized hospital service. The proposed rule would specify minimum requirements for organization, accountability, delivery of services, and records.

23. *Social services*—Like the current regulations, the revision would not require hospitals to have an organized social service. However, if the hospital does have such a service, this Condition of Participation would apply. If the social service needs of the patients are referred to an agency outside the hospital, the amendment would require the hospital to designate an individual on the staff to be responsible for referrals, communications, and follow-up. If there is an organized service, the proposed revision would require the director of the services to have at least a bachelor's degree. The current regulations require the social worker in charge of the social work department to have a master's degree in social work. The amendment would reduce this requirement to a bachelor's degree, and recognize other experience appropriate to the scope and complexity of the services. The amendment would also eliminate current provisions relating to social work assistants.

Current requirements for ward rounds, inservice training, and conferences would be deleted by the proposed revision. The proposed amendments would also delete current detailed requirements on the types of information to be collected by a social work department. The amendment would merely require that records of social information and social services furnished must be incorporated into the patient's unit medical record.

24. *Special care units*—The amendments would establish a new Condition of Participation for special care units. These units offer optional services, and the proposed requirements will be applied only to those hospitals which choose to offer special care unit services. These provisions have been proposed in response to the growing practice of offering special care services (e.g., coronary care, intensive care, burns, etc.) through separate organized units. The proposed rule would specify minimum requirements for organization, accountability, and delivery of services. The amendment will also require special care units in participating hospitals to meet the definition of such units at 42 CFR 405.452(d)(10).

25. *Psychiatric services in general acute care hospitals*—The amendments would establish a new Condition of Participation for psychiatric services which are offered in a general acute care hospital setting. These are optional services, and the proposed requirements would be applied only to those hospitals which choose to offer psychiatric hospital services. The proposed rule would be based on the standards developed for psychiatric hosptials, and would specify minimum requirements for organization, accountability, delivery of services, and records.

26. *Psychiatric hospitals*—The two special Conditions of Participation providing medical record and staff requirements for psychiatric hospitals would be clarified and redesignated with little change. As in other sections, the proposed revision would more clearly specify personnel qualifications and accountability.

27. *Tuberculosis hospitals*—The two special Conditions of Participation providing medical record and staff requirements for tuberculosis hospitals would be clarified and redesignated

without substantive changes. Due to the small number of hospitals to which these conditions apply and the apparent lack of problems with the conditions as they are, we do not propose any further revision.

28. *Additional changes*—Some of the content of the existing Conditions of Participation would be retained in a significantly different form. Section 405.1011 on the provision of emergency services by nonparticipating hospitals would be redesignated under the provisions concerning the scope of the new Part 482. Section 405.1020 on compliance with State and local laws would be embodied in the expanded requirements for governing body and management. The general statement of statutory requirements for psychiatric and tuberculosis hospitals would be redesignated with the same title, but with a greatly simplified text.

29. *Omissions*—Several requirements of the current regulations would be deleted by the proposed amendments. There would be no requirement for a dental staff or department. This was considered analogous to special medical departments (e.g. pediatrics, orthopedics, etc.) for which we do not issue regulations. There would be no provision requiring medical consultation in specific types of cases since this would be duplicative of utilization review and PSRO requirements. The amendments would not require the hospital to have a medicial library. However, these proposed regulations contain minimum standards and are not intended to prohibit hospitals from providing services or facilities which are not required.

30. *Utilization review*—The requirements for utilization review in § 405.1035 are not being recodified as a part of this proposed rule. A forthcoming separate proposed rule will set forth requirements for utilization review as a new Subpart F of Part 482.

31. *Derivation and redesignation tables*—The following tables provide cross references between the current regulations and the proposed rule. The terms in the third column, "Nature of Change", summarize the relationship between the two texts. The terms "new" and "deleted" are self-explanatory. "Similar" means that the language of the current reguations has been revised without substantial change. "Modified" means that the proposed regulations would make a substantial change in policy or practice.

Derivation Table

Proposed new section part 482	Current section part 405	Nature of change
482.1		
(a)–(c)		New.
(d)	405.1011	Similar.
(e)		New.
482.2		New.
482.3	405.1020(b)	Similar.
Anesthesiologist	405.1031(b)(2)(iv)	Modified.
Anesthetist	405.1031(b)(2)(iv)	Modified.
Audiologist		New.
Chief executive officer	405.1021(f)	Similar.
Dietitian	405.1025(a)(1)	Modified.
Director of:		
Anesthesia services		New.
Dietetic services	405.1025(a)(2)	Modified.
Medical record services.	405.1026(c)(1)	Modified.
Medical (tuberculosis) services.	405.1040(a)	Similar.
Nuclear medicine services.		New.
Nursing services	405.1024(b)	Modified.
Psychiatric nursing services.	405.1038(c)(1)	Modified.
Psychiatric services	405.1038(b)(1)	Modified.
Psychological services.	405.1038(e)(1)	Modified.
Radiologic services	405.1029(c)(1)	Modified.
Rehabilitative services.	405.1031(d)(2)	Modified.
Social services	405.1034, (a)(2)	Modified.
Surgical services		New.
Nuclear medicine technologist		New.
Nurse-midwife		New.
Nurse practitioner		New.
Nursing graduate		New.
Occupational therapist	405.1031(d)(4)	Modified.
Occupational therapy assistant.	405.1031(d)(4)	Modified.
Physical therapist	405.1031(d)(3)	Similar.
Physical therapy assistant		New.
Physician assistant		New.
Psychiatric nurse		New.
Radiation physicist or health physicist.	405.1029(b)(2)	Modified.
Radiation therapy technologist.		New.
Radiographer (radiologic technologist).	405.1029(c)(3	Modified.
Radiologist	405.1029(c)(1)	Modified.
Radiotherapist	405.1029(c)(2)	Modified.
Respiratory therapist		New.
Respiratory therapy technican.		New.
Speech-language pathologist.		New.
Surgical technologist circulator	405.1024(c)(2)	Modified.
Thoracic surgeon	405.1040(c)(1)	Similar.
482.21, (a)	405.1021	Similar.
482.21(a)(1)	405.1021(a)(1)–(2).	Similar.
482.21(a)(2)	405.1021(a)(2), (i), (iii), (iv).	Similar.
482.21(a)(3)		New.
482.21(a)(4)	405.1021(d)	Similar.
482.21(a)(5)	405.1021(f)	Similar.
482.21(a)(6)	405.1021(a)(2)	Similar.
482.21(a)(7)		New.
482.21(a)(8)	405.1023(r)(1)	Similar.
482.21(a)(9)	405.1021(a)(2)	Similar.
482.21(a)(10)		New.
482.21(a)(11)	405.1020	Similar.
482.21(a)(12)	405.1021(j)	Similar.
482.21(a)(13) and (14)		New.
482.21(b)	405.1021(g)	Similar.
482.21(c) and (d), (1)–(3)		New.
482.21(d)(4)	405.1030	Modified.
482.21(e)–(j)		New.
482.22	405.1023, (a)	Similar.
482.22(a)	405.1023(f), (h) and (i).	Similar.
482.22(a)(1) and (2)	405.1023(a)(2)	Similar.
482.22(a)(3)	405.1023(f)(3)	Similar.
482.22(a)(4)	405.1021(h)(2)	Similar.
482.22(a)(5)		New.
482.22(a)(6)	405.1021(h)(1)	Modified.
482.22(a)(7)	45.1021(h)	Similar.
482.22(b)	405.1023(e)	Similar.

Derivation Table—Continued

Proposed new section part 482	Current section part 405	Nature of change
482.22(b)(1)	405.1021(e)(1)–(3), and 405.1023(e)(1).	Similar.
482.22(b)(2)	405.1021(e)(4)–(6).	Similar.
	405.1023(d), (1) and (e), (2), (3) and (5).	Similar.
482.22(b)(3)	405.1023(e)(4)	Modified.
482.22(b)(4)	405.1021(e)(7)	Similar.
482.22(b)(5)		New.
482.22(b)(6)	405.1023(d)(2)	Modified.
482.22(c)		New.
482.23	405.1024	Similar.
482.23(a)	405.1024(a)	Similar.
482.23 (a)(1) and (2)	405.1024(e)(2)	Similar.
482.23(a)(3)(i)	405.1024(g)	Similar.
482.23(a)(3)(ii)	405.1024(f)	Similar.
482.23(a)(3)(iii)	405.1024(e)(3) and (6).	Similar.
482.23(a)(3)(iv) and (v)		New.
482.23(b)(1)	405.1024(b)	Similar.
482.23(b)(2)	405.1024(c)	Similar.
482.23(b)(3)	405.1024(e)(1)	Similar.
482.23(b)(4)		New.
482.23(c)	405.1024(g)(1)	Similar.
482.23(c)(1)	405.1024(g)(2)	Similar.
482.23(c)(2)	405.1024(g), (3)	Similar.
482.23(c)(3)		New.
482.23(d)(1)	405.1024(g)(5)	Modified.
482.23(d)(2)	405.1024(g)(6)	Modified.
482.23(d)(3)	405.1024(g)(7)	Modified.
482.23(d)(4)–(9)		New.
482.23(d)(10)	405.1024(g)(8)	Modified.
482.23(d)(11) and (12)		New.
482.24	405.1026	Similar.
482.24(a)(1)–(2)	405.1026(c), (1)–(2).	Similar.
482.24(b)	405.1026(a) and (d)(3).	Similar.
482.24(b)(1)	405.1026(b)	Modified.
482.24(b)(2)		New.
482.24(b)(3)	405.1026(f)	Modified.
482.24(b)(4)	405.1026(a), (1)–(3).	Similar.
482.24(c)	405.1026(g)	Modified.
482.24(c)(1)	405.1026(h) and (i).	Modified.
482.24(c)(2)	405.1026(g)	Similar.
482.24(d)	405.1026(d)(2)	Similar.
482.25, (a)	405.1027, (a)	Similar.
482.25(a)(1)(i)	405.1027(c)(4)	Similar.
482.25(a)(1)(ii)	405.1027(a)(2)	Modified.
482.25(a)(1)(iii)	405.1027(c), (1)–(2).	Similar.
482.25(a)(1)(iv)		New.
482.25(a)(2)	405.1027(a)(3)	Modified.
482.25(a)(3)	405.1027(c)(3)	Modified.
482.25(b)	405.1027(e)	Similar.
482.25(b)(1)		New.
482.25(b)(2)	405.1027(f)(3) and (g)(2).	Similar.
482.25(b)(3)–(11)		New.
482.25(b)(12)	405.1027(d)(4)	Similar.
482.25(c)	405.1027(b)	Similar.
482.25(d)	405.1027(d)	Modified.
482.26	405.1029	Similar.
482.26(a)		New.
482.26(a)(1)	405.1029(c)(1)	Modified.
482.26(a)(2)	405.1029(c)(4)	Modified.
482.26(a)(3)	405.1029(c)	Similar.
482.26(a)(4)	405.1029(c)(3)	Similar.
482.26(b)		New.
482.26(c)	405.1029(b)	Similar.
482.26(c)(1)	405.1029(b)(1) and (3).	Similar.
482.26(c)(2)–(3)	405.1029(b)(2)	Similar.
482.26(d)	405.1029(d)	Similar.
482.27	405.1025	Similar.
482.27(a)	405.1025(a)	Similar.
482.27(a)(1)		New.
482.27(a)(2)	405.1025(a)	Similar.
482.27(a)(3)	405.1025(a)(3)	Modified.
482.27(a)(4)	405.1025(a)(6)	Similar.
482.27(b)	405.1025(a)(1)	Similar.
482.27(b)(1)		New.
482.27(b)(2)	405.1025(b)	Similar.
482.27(b)(3)	405.1025(a)(8)	Similar.
482.27(b)(4)	405.1025(b)(5)	Similar.
482.27(b)(5)	405.1025(b)(10)	Similar.

Derivation Table—Continued

Proposed new section part 482	Current section part 405	Nature of change
482.27(b)(6)		New.
482.27(b)(7)	405.1025(b)	Modified.
482.27(b)(8)		New.
482.27(c)	405.1025(b)	Similar.
482.27(d)	405.1025(c) and (c)(2).	Similar.
482.27(d)(1)	405.1025(c)(3)	Similar.
482.27(d)(2)–(5)		New.
482.28	405.1022	Modified.
482.28(a)	405.1022(b)	Modified.
482.28(b)		New.
482.28(b)(1)	405.1022(b)(3)	Modified.
482.28(b)(2)–(3)	405.1022(b)(4)	Similar.
482.28(b)(4)–(8)		New.
482.28(c)	405.1022(a)(3)(iv)	Modified.
482.28(d)	405.1022(a)(2)	Similar.
482.28(d)(1)	405.1022(a)(3)(iii)	Similar.
482.28(d)(2)	405.1022(a)(3)(i)	Modified.
482.28(d)(3)–(5)		New.
482.28(e)	405.1022(a)(3)–(5) and (b)(5).	Modified.
482.28(f)	405.1022(a)(3) and (8).	Modified.
482.28(g)	405.1022(b)(6)	Modified.
482.29	405.1022(c)	Modified.
482.30	405.1028	Similar.
482.30(a)	405.1028(a)	Similar.
482.30(b)–(c)	405.1028(b)–(c).	Similar.
482.30(d)–(e)	405.1028(d)–(e)	Modified.
482.30(f)–(1)	405.1028(f)–(1)	Similar.
482.41	405.1031(a)	Modified.
482.41(a), (a)(1)		New.
482.41(a)(2)	405.1024(d)(1) and 1031(a)(10).	Similar.
482.41(a)(3)	405.1024(d)	Similar.
482.41(a)(4)	405.1024(d)(2)	Modified.
482.41(b)	405.1031(d)(1)	Similar.
482.41(b)(1)		New.
482.41(b)(2)	405.1031(a)(1) and (4).	Similar.
482.41(b)(3)		New.
482.41(c)		New.
482.41(c)(1)–(2)	405.1031(a)	Similar.
482.41(c)(3)–(4)		New.
482.41(c)(5)	405.1031(a)(14)	Modified.
482.41(c)(6)		New.
482.41(c)(7)	405.1031(a)(9)	Similar.
482.41(d)	405.1031(a)(11)	Modified.
482.41(d)(1)	405.1031(a)(12)	Similar.
482.41(d)(2)	405.1031(a)(13)	Modified.
482.41(d)(3)–(4)		New.
482.41(e)		New.
482.41(e)(1)	405.1031(a)(5)–(6).	Similar.
482.41(e)(2)	405.1031(a)(8)	Similar.
482.42	405.1031(b)	Modified.
482.42(a)	405.1031(b) <(2)(i)–(ii).	Modified.
482.42(a)(1)		New.
482.42(a)(2)	405.1031(b)(2) <(iv).	Modified.
482.42(a)(3)–(4)		New.
482.42(b)		New.
482.42(b)(1)	405.1031(b)(1)	Similar.
482.42(b)(2)	405.1031(b)(1)	Modified.
482.42(b)(3)(i)–(iv)		New.
482.42(b)(3)(v)	405.1031(b)(2)(v)	Modified.
482.42(b)(4)	405.1031(b)(2) <(vii).	Modified.
482.42(c)	405.1031(b)(1) <(ii)–(iii).	Modified.
482.42(d)	405.1031(b)(2) <(vi).	Modified.
482.43		New.
482.44, (a)	405.1032, (a)	Similar.
482.44(a)(1)	405.1032(b)(1)	Similar.
482.44(a)(2)	405.1032(b)(2)	Similar.
482.44(a)(3)	405.1032(b)(3)	Similar.
482.44(b)		New.
482.44(c)	405.1032(c)	Similar.
482.44(d)	405.1032(d)	Similar.
482.45, (a)	405.1033, (a)	Similar.
482.45(a)(1)	405.1033(a)(3)–(4).	Modified.
482.45(a)(2)	405.1033(c)(1)–(2).	Modified.

Derivation Table—Continued

Proposed new section part 482	Current section part 405	Nature of change
482.45(a)(3)	405.1033(a)(3)	Modified.
482.45(a)(4)	405.1033(c) and (c)(4).	Similar.
482.45(b), (1)		New.
482.45(b)(2)	405.1033(a)(1)–(2).	Similar.
482.45(b)(3)	405.1033(c)(3)	Modified.
482.45(b)(4)–(6)		New.
482.45(c)	405.1033(b)	Similar.
482.45(d)	405.1033(d)	Similar.
482.46	405.1031(d)	Modified.
482.46(a)	405.1031(d) and (d)(1).	Similar.
482.46(a)(1)	405.1031(d)(2)	Modified.
482.46(a)(2)	405.1031(d)(4)	Similar.
482.46(a)(3)	405.1031(d)(3)–(4).	Similar.
482.46(b)		New.
482.46(b)(1)	405.1031(d)(6)	Similar.
482.46(b)(2)–(3)		New.
482.46(c)	405.1031(d)(5)	Modified.
482.46(d)	405.1031(d)(7)	Modified.
482.47		New.
482.48	405.1034	Modified.
482.48(a)	405.1034(a)(4)	Similar.
482.48(a)(1)	405.1034(a)(1)	Similar.
482.48(a)(1)(i)	405.1034	Modified.
482.48(a)(1)(ii)	405.1034(a)(3)	Similar.
482.48(a)(2)		New.
482.48(b), (1)	405.1034(b)	Modified.
482.48(b)(2)	405.1034	Similar.
482.48(c)	405.1034(d)	Similar.
482.48(d)	405.1034(c)	Modified.
482.49		New.
482.50, (a) and (a)(1)		New.
482.50(a)(2)	405.1038	Similar.
482.50(a)(3)	405.1038(d)	Modified.
482.50(a)(4)		New.
482.50(b)		New.
482.50(b)(1)	405.1038(a)	Similar.
482.50(b)(2)–(5)		New.
482.50(c)		New.
482.50(d)	405.1037(a)(12)	Similar.
482.50(d)(1)	405.1037(a)	Similar.
482.50(d)(2)–(3)		New.
482.50(d)(4)	405.1037(a)(11)	Similar.
482.60	405.1036	Modified.
482.61	405.1037	Modified.
482.61(a)	405.1037(a)	Similar.
482.61(b)		New.
482.61(c)	405.1037(a)(10)	Similar.
482.61(d)		New.
482.62	405.1038	Similar.
482.62(a)	405.1038(a)	Modified.
482.62(b)	405.1038(b), (b)(1).	Modified.
482.62(c)	405.1038(b)(2)–(3), (c).	Similar.
482.62(d)	405.1038(d)	Similar.
482.62(d)(1)	405.1038(d)(1)	Modified.
482.62(d)(2)–(3)	405.1038(d)(2)	Similar.
482.62(e)	405.1038(e)	Similar.
482.62(f)	405.1038(f)	
482.62(g)		New.
482.62(h)	405.1038(g)	Similar.
482.63	405.1039	Similar.
482.63(a)–(c)	405.1039(a)–(c).	Similar.
482.64	405.1040	Similar.
482.64(a)	405.1040(a)	Modified.
482.64(b)	405.1040(a)	Modified.
482.64(c)	405.1040(b)	Similar.
482.64(d)	405.1040(c)	Similar.
482.64(e)	405.1040(d)	Similar.
482.64(f)	405.1040(e)	Similar.
482.64(g)	405.1040(f)	Similar.
482.64(h)	405.1040(g)	Similar.
482.64(i)	405.1040(h)	Similar.

Redesignation Table

Current section part 405	Proposed new section part 482	Nature of change
405.1011	482.1(d)	Similar.
405.1020, (a), (b), (c)	482.21(a) and (a)(11).	Similar.
405.1021, (a)	482.21 (a)(1)	Similar.
405.1021(a)(1)		Deleted.
405.1021(a)(2), (i)–(iii)	482.21(a)(2)	Similar.

Redesignation Table—Continued

Current section part 405	Proposed new section part 482	Nature of change
405.1021(a)(iv)		Deleted.
405.1021(a)(v)	482.21(a)(9)	Similar.
405.1021(a)(vi)	482.21(a)(6)	Similar.
405.1021(b)		Deleted.
405.1021(c)		Deleted.
405.1021(d)		Deleted.
405.1021(e)	482.21(a)(9)	Similar.
405.1021(e)(1)–(3)	482.22(b)(1)	Similar.
405.1021(e)(4)–(6)	482.22(b)(2)	Similar.
405.1021(e)(7)	482.22(b)(4)	Similar.
405.1021(f)	482.21(a)(5)	Similar.
405.1021(f)(1)	482.3	Similar.
405.1021(f)(2)		Deleted.
405.1021(g)	482.21(b)	Similar.
405.1021(g)(1)–(5)		Deleted.
405.1021(h)	482.22(a)(7)	Similar.
405.1021(h)(1)	482.22(a)(6)	Modified.
405.1021(h)(2)	482.22(a)(4)	Similar.
405.1021(i)		Deleted.
405.1021(i)(1)–(2)		Deleted.
405.1021(j)	482.21(a)(12)	Similar.
405.1021(j)(1)–(4)		Deleted.
405.1022	482.28	Modified.
405.1022(a)		Deleted.
405.1022(a)(1)	482.21(a)(11)	Similar.
405.1022(a)(2)	482.28	Similar.
405.1022(a)(3)(i)	482.28(d)(2)	Similar.
405.1022(a)(3)(ii)	482.28(f), 482.29(b).	Modified.
405.1022(a)(3)(iii)	482.28(d)(1)	Modified.
405.1022(a)(3)(iv)	482.28(c)	Modified.
405.1022(a)(3)(v)	482.28(e)(5)	Modified.
405.1022(a)(4)	482.28(e)(4)	Modified.
405.1022(a)(5)	482.28(e)(2)	Modified.
405.1022(a)(6)		Deleted.
405.1022(a)(7)		Deleted.
405.1022(a)(8)	482.28(f)	Modified.
405.1022(b), (1)–(2)	482.28(a)	Modified.
405.1022(b)(3)	482.28(b)(1)	Modified.
405.1022(b)(4)	482.28(b)(2), (3)	Similar.
405.1022(b)(5)	482.28(e)(2)	Similar.
405.1022(b)(6)	482.28(g)(6), (7)	Modified.
405.1022(c)	482.29	Modified.
405.1022(d)	482.28(d)	Similar.
405.1022(d)(1)–(4)		Deleted.
405.1023	482.22	
405.1023(a)	482.22(a)	
405.1023(a)(1)–(2)		Deleted.
405.1023(b)		Deleted.
405.1023(c)		Deleted.
405.1023(d)	482.22(b)(2)	Similar.
405.1023(d)(1)–(3)		Deleted.
405.1023(e)	482.22(b)	Similar.
405.1023(e)(1)	482.22(b)	Similar.
405.1023(e)(2), (3) and (5).	482.22(b)(1), (2)	Similar.
405.1023(e)(4)		Deleted.
405.1023(f)		Deleted.
405.1023(g)		Deleted.
405.1023(h)	482.22(a)	Similar.
405.1023(h)(1)–(3)		Deleted.
405.1023(i)	482.22, (a)	Similar.
405.1023(i)(1)–(2)		Deleted.
405.1023(j)–(r)		Deleted.
405.1024	482.23, (b)(1)	Modified.
405.1024(a)	482.23(a)	Similar.
405.1024(b)	482.23, (b)	Similar.
405.1024(b)(1)	482.23(b)	Similar.
405.1024(b)(2)–(4)		Deleted.
405.1024(c)	482.23(b)(2)	Similar.
405.1024(d)		Deleted.
405.1024(d)(1)	482.41(a)(2)	Similar.
405.1024(d)(2)	482.41(a)(3)	Modified.
405.1024(e)		Deleted.
405.1024(e)(1)	482.23(b)(3)	Similar.
405.1024(e)(2) director of nursing.	482.23, 482.23(a)(1)–(2).	Modified.
405.1024(e)(2) assistants and supervisors.		Deleted.
405.1024(e)(3)	482.23(a)(2)(iii)	Similar.
405.1024(e)(4)–(5)		Deleted.
405.1024(e)(6)	482.23(a)(2)(iii)	Similar.
405.1024(f), (1)		Deleted.
405.1024(f)(2)	482.23(a)(2)(ii)	Similar.
405.1024(f)(3)		Deleted.
405.1024(g)	482.23(a) and (c).	Similar.
405.1024(g)(1)	482.23(c)	Similar.
405.1024(g)(2)	482.23(c)(1)	Similar.
405.1024(g)(3)	482.23(c)(2)	Similar.

Redesignation Table—Continued

Current section part 405	Proposed new section part 482	Nature of change
405.1024(g)(4)		Deleted.
405.1024(g)(5)	482.23(d)	Modified.
405.1024(g)(6)	482.23(d)(2)	Modified.
405.1024(g)(7)	482.23(d)(3)	Modified.
405.1024(g)(8)	482.23(d)(10)	Modified.
405.1024(h)		Deleted.
405.1025	482.27	Similar.
405.1025(a)	482.27(a)(1)–(2)	Similar.
405.1025(a)(1)	482.27(a)(3)	Modified.
405.1025(a)(2)		Deleted.
405.1025(a)(3)	482.27(a)	Modified.
405.1025(a)(4)–(5)		Deleted.
405.1025(a)(6)	482.27(a)(4)	
405.1025(a)(7)–(8)		Deleted.
405.1025(b)	482.27(b)(2) and (c).	Similar.
405.1025(b)(1)–(11)		Deleted.
405.1025(c)	482.27(d)	Modified.
405.1025(c)(1)		Deleted.
405.1025(c)(2)	482.27(d)	Similar.
405.1025(c)(3)	482.27(d)(1)	Similar.
405.1025(c)(4)		Deleted.
405.1025(d)		Deleted.
405.1026	482.24	Similar.
405.1026(a), (1)	482.24(b), (4)	Similar.
405.1026(a)(2), (3)		Deleted.
405.1026(b)	482.24(b)(1)	Modified.
405.1026(c)	482.24(a), (2)	Similar.
405.1026(c)(1)	482.24(a)(1), 482.3.	Similar.
405.1026(c)(2)	482.24(a)(2)	Similar.
405.1026(d)	482.24(b)	Similar.
405.1026(d)(1)		Deleted.
405.1026(d)(2)	482.24(d)	Similar.
405.1026(d)(3)	482.24(b)	Similar.
405.1026(e), (1)		Deleted.
405.1026(e)(2)	482.24(c)(2)	Modified.
405.1026(f)	482.24(b)(3)	Modified.
405.1026(f)(1)–(5)		Deleted.
405.1026(g)	482.24(c)(2)	Similar.
405.1026(h)–(i)	482.24(c)(1)	Modified.
405.1026(j)		Deleted.
405.1027, (a)	482.25, (a)	Similar.
405.1027(a)(1)		Deleted.
405.1027(a)(2)	482.25(a)(1)(ii)	Modified.
405.1027(a)(3)	482.25(a)(2)	Modified.
405.1027(b)	482.25(c)	Similar.
405.1027(c), (1)–(2)	482.25(a)(1)(iii)	Similar.
405.1027(c)(3)	482.25(a)(3)	Modified.
405.1027(c)(4)	482.25(a)(1)(i)	Similar.
405.1027(d)	482.25(d)	Modified.
405.1027(e)	482.25(b)	Similar.
405.1027(e)(1)–(2)		Deleted.
405.1027(f), (1)–(2)		Deleted.
405.1027(f)(3)	482.25(b)(2)	Similar.
405.1027(f)(4)		Deleted.
405.1027(g), (1)		Deleted.
405.1027(g)(2)	482.25(b)(2)	Similar.
405.1027(g)(3)		Deleted.
405.1028	482.30	
405.1028(a)	482.30(a)	Similar.
405.1028(b)–(c)	482.30(b)–(c)	Similar.
405.1028(d)–(e)	482.30(d)–(e)	Modified.
405.1028(f)–(1)	482.30(f)–(1)	Similar.
405.1029	482.26	Similar.
405.1029(a)		Deleted.
405.1029(b)	482.26(c)	Similar.
405.1029(b)(1)	482.26(c)(1)	Similar.
405.1029(b)(2)	482.26(c)(2)–(3)	Similar.
405.1029(b)(3)	482.26(c)(1)	Similar.
405.1029(b)(4)(5)		Deleted.
405.1029(c)	482.26(a)(3)	Similar.
405.1029(c)(1)	482.26(a)(1)	Modified.
405.1029(c)(2)		Deleted.
405.1029(c)(3)	482.26(a)(4)	Similar.
405.1029(c)(4)	482.26(a)(2)	Modified.
405.1029(d)	482.26(d)	Similar.
405.1030 medical library	482.21(d)(4)	Modified.
405.1031		Deleted.
405.1031(a)	482.41	Modified.
405.1031(a)(1)	482.41(b), (2)	Similar.
405.1031(a)(2)–(3)		Deleted.
405.1031(a)(4)	482.41(b)(2)	Similar.
405.1031(a)(5)–(6)	482.41(e)(1)	Similar.
405.1031(a)(7)		Deleted.
405.1031(a)(8)	482.41(e)(2)	Similar.
405.1031(a)(9)	482.41(c)(6)	Similar.
405.1031(a)(10)	482.41(a)(2)	Similar.
405.1031(a)(11)	482.41(d)	Modified.
405.1031(a)(12)	482.41(d)(1)	Similar.
405.1031(a)(13)	482.41(d)(2)	Modified.
405.1031(a)(14)	482.41(c)(4)	Modified.

Redesignation Table—Continued

Current section part 405	Proposed new section part 482	Nature of change
405.1031(b)	482.42	Modified.
405.1031(b)(1)	482.42(b)(1)–(2)	Modified.
405.1031(b)(1)(i)	482.42(b)(2)	Modified.
405.1031(b)(1)(ii)–(iii)	482.42(c)	Modified.
405.1031(b)(2)(i)–(ii)	482.42(a)	Modified.
405.1031(b)(2)(iii)		Deleted.
405.1031(b)(2)(iv)	482.42(a)(2)	Modified.
405.1031(b)(2)(v)	482.42(b)(3)(v)	Modified.
405.1031(b)(2)(vi)	482.42(d)	Modified.
405.1031(c)		Deleted.
405.1031(d)	482.46, (a)	Modified.
405.1031(d)(1)	482.46(a)	Similar.
405.1031(d)(2)	482.46(a)(1)	Modified.
405.1031(d)(3)	482.46(a)(3)	Similar.
405.1031(d)(3), (i)–(iv)	482.3	Similar.
405.1031(d)(4)	482.46(a)(3) and 482.3.	Modified.
405.1031(d)(5)	482.46(c)	Modified.
405.1031(d)(6)	482.46(b)(1)	Similar.
405.1031(d)(7)	482.46(d)	Modified.
405.1032, (a)	482.44, (a)	Similar.
405.1032(a)(1)–(5)		Deleted.
405.1032(b), (1)–(3)	482.44(a), (1)–(3).	Similar.
405.1032(c)	482.44(c)	Similar.
405.1032(d)	482.44(d)	Similar.
405.1032(e)		Deleted.
405.1033, (a)	482.45, (a)	Similar.
405.1033(a)(1)–(2)	482.45(b)(2)	Similar.
405.1033(a)(3)–(4)	482.45(a)(1), (3)	Modified.
405.1033(b)	482.45(c)	Similar.
405.1033(c)	482.45(a)(4)	Similar.
405.1033(c)(1)–(2)	482.45(a)(2)	Modified.
405.1033(c)(3)	482. (b)(3)	Modified.
405.1033(c)(4)	482.45(a)(4)	Similar.
405.1033(d)	482.45(d)	Similar.
405.1034	482.48	Modified.
405.1034(a), (1)	482.48(a)(1)	Similar.
405.1034(a)(2)		Deleted.
405.1034(a)(3)	482.48(a)(1)(ii)	Similar.
405.1034(a)(4)	482.48(a)	Similar.
405.1034(b)	482.48(b), (1)	Modified.
405.1034(b)(1)–(3)		Deleted.
405.1034(c)	482.48(d)	Modified.
405.1034(d)	482.48(c)	Similar.
405.1035	(1)	(1)
405.1036	482.60	Modified.
405.1037	482.61	Modified.
405.1037(a)	482.61(a)	Similar.
405.1037(a)(1)		Deleted.
405.1037(a)(2)	482.50(d)	Modified.
405.1037(a)(3)		Deleted.
405.1037(a)(4)	482.50(d)(1)	Modified.
405.1037(a)(5)–(9)		Deleted.
405.1037(a)(10)	482.61(c)	Similar.
405.1037(a)(11)		Deleted.
405.1037(a)(12)	482.50(d)	Modified.
405.1038	482.62	Similar.
405.1038(a)	482.62(a)	Modified.
405.1038(b), (1)	482.62(b), 482.3.	Modified.
405.1038(b)(2)–(3)	482.62(c)	Similar.
405.1038(b)(4)		Deleted.
405.1038(c)	482.62(c)	Similar.
405.1038(d)	482.62(d)	Similar.
405.1038(d)(1)	482.3, 482.62(d)(1).	Modified.
405.1038(d)(2)	482.62(d)(2)–(3)	Modified.
405.1038(d)(3)		Deleted.
405.1038(e)	482.62(e)	Simplified
405.1038(f)	482.62(f)	Similar.
405.1038(g)	482.62(h)	Similar.
405.1039	482.63	Similar.
405.1039(a)–(c)	482.63(a)–(c)	Similar.
405.1040	482.64	Similar.
405.1040(a)	482.64(a)–(b), 482.3.	Modified.
405.1040(b)	482.64(c)	Similar.
405.1040(c)	482.64(d), 482.3.	Similar.
405.1040(d)	482.64(e)	Similar.
405.1040(e)	482.64(f)	Similar.
405.1040(f)	482.64(g)	Similar.
405.1040(g)	482.64(h)	Similar.
405.1040(h)	482.64(i)	Similar.

[1] This condition will be redesignated as Subpart F of Part 482 in a forthcoming NPRM.

42 CFR Chapter IV is amended as follows:

1. The table of contents is amended by adding a new Subchapter E, by transferring Part 481 of Subchapter D to Subchapter E, and by adding a new Part 482 to read as follows:

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

* * * * *

SUBCHAPTER D—PROFESSIONAL STANDARDS REVIEW

* * * * *

SUBCHAPTER E—STANDARDS AND CERTIFICATION FOR PARTICIPATION IN MEDICARE AND MEDICAID

PART 481—CERTIFICATION OF CERTAIN HEALTH FACILITIES

PART 482—CONDITIONS OF PARTICIPATION: HOSPITALS

SUBCHAPTER B—MEDICARE PROGRAMS

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

2. Part 405 of Subchapter B is amended by vacating and reserving §§ 405.1011, 405.1020 through 405.1034, and 405.1036 through 405.1040, and by revising their contents and redesignating them under a new Part 482 of Subchapter E, as follows:

§ 405.1011 [Vacated. See Part 482.]

§§ 405.1020–405.1034 [Vacated. See Part 482.]

§§ 405.1036–405.1040 [Vacated. See Part 482.]

SUBCHAPTER D—PROFESSIONAL STANDARDS REVIEW

PART 481—CERTIFICATION OF CERTAIN HEALTH FACILITIES (TRANSFERRED TO SUBCHAPTER E)

3. Subchapter D is amended by transferring Part 481 to Subchapter E.

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

SUBCHAPTER E—STANDARDS AND CERTIFICATION FOR PARTICIPATION IN MEDICARE AND MEDICAID

PART 482—CONDITIONS OF PARTICIPATION: HOSPITALS

Sec.

Subpart A—General Provisions

Subpart B—Basic Hospital Functions

Sec.

Subpart C—Optional Hospital Services

Subpart D—Requirements for Specialty Hospitals

Subparts E through Z [Reserved]

Authority: Secs. 1102, 1861(e), 1861(f), 1861(g), 1864, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395 et seq).

Subpart A—General Provisions

§ 482.1 Scope of this part.

This part states the Federal requirements for hospitals to participate in the Medicare and Medicaid programs.

(a) *Basis in legislation.* Section 1861(e) of the Social Security Act provides that hospitals participating in Medicare must meet certain specified requirements and that 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 the institution. Section 1905(a) of the Act provides that "medical assistance" (Medicaid) payments may be applied to various hospital services. Regulations interpreting these provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (42 CFR 440.10).

(b) *Basis for surveying.* These requirements are Conditions of Participation and will serve as a basis for surveys to determine facilities' eligibility for certification as provided in Sections 1864(a) and (c) of the Act.

(c) *Prerequisite for reimbursement.* In order to be eligible to receive reimbursement under the Medicare and Medicaid programs, a hospital must be certified as being in compliance with these Conditions of Participation.

(d) *Provision of emergency services by nonparticipating hospitals.* A hospital which has not been determined to comply with all of the conditions, or which is not accepted to become a participating hospital, may, nevertheless, be paid under the programs for emergency services furnished if it meets the requirements of section 1861(e) (1), (2), (3), (4), (5), and (7) of the Act.

(e) *Referenced publications.* The following publications are incorporated in this part by reference.

(1) Recommended Dietary Allowances, 8th revised edition, 1974. National Research Council, Food and Nutrition Board. Available from the National Academy of Sciences, 2101 Constitution Avenue, NW., Washington, D.C. 20418.

(2) NFPA Standard No. 101, Life Safety Code, 1973. Available from the National Fire Protection Association, 470 Atlantic Avenue, Boston, Massachusetts 02210.

(3) NFPA Standard No. 56A, Inhalation Anesthetics, 1973. Available from the National Fire Protection Association, 470 Atlantic Avenue, Boston, Massachusetts 02210.

(4) NFPA Standard No. 56B, Respiratory Therapy, 1977. Available from the National Fire Protection Association, 470 Atlantic Avenue, Boston, Massachusetts 02210.

(5) NFPA Standard No. 56F, Nonflammable Medical Gases, 1977. Available from the National Fire Protection Association, 470 Atlantic Avenue, Boston, Massachusetts 02210.

(6) NFPA Standard No. 76A, Essential Electrical Systems for Health Care Facilities, 1977. Available from the National Fire Protection Association, 470 Atlantic Avenue, Boston, Massachusetts 02210.

(7) NCRP Report No. 33, Medical X-ray and Gamma-ray Protection for Energies up to 10 MEV; Equipment Design and Use, 1968. Available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.

(8) NCRP Report No. 49, Structural Shielding Design and Evaluation; Medical Use of X-rays and Gamma-rays for Energies up to 10 MEV, 1976. Available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.

(9) Diagnostic and Statistical Manual of Mental Disorders, second edition, 1968. Available from the American Psychiatric Association, 1700 18th Street, NW., Washington, D.C. 20009.

(10) Diagnostic Standards and Classification of Tuberculosis and Other Mycobacterial Diseases, 13th edition, 1974. Available from the American Lung Association, 1740 Broadway, New York, New York 10019.

§ 482.2 Definitions.

As used in this part:

"Anesthetizing location" means any area of a hospital where inhalation anesthesia agents are administered in the course of examination or treatment, and includes operating rooms, emergency rooms, anesthesia rooms, or delivery rooms.

"Clinical privileges" means permission for practitioners to provide patient care within well-defined limits, based on the applicants' professional licensure, experience, competence ability, and judgment.

"Direction" means a policy or procedural guidance for a function or activity.

"Drug administration" means the act of giving a single dose of a prescribed medication to a patient.

"Drug dispensing" means the issuance from a central source of one or more doses of a prescribed medication for a patient or for a service unit of the facility.

"House staff" means practitioners and graduates from accredited schools of medicine, osteopathy, dentistry, and podiatry who participate in a hospital's organized educational program. The house staff may include graduates of foreign medical schools if approved by the appropriate State agency.

"Medical staff" means a formal organization of physicians, dentists, podiatrists, and other practitioners with clinical privileges with the delegated

responsibility and authority to maintain proper standards of medical care.

"Practitioner" means an appropriately licensed physician (M.D. or D.O.), dentist (O.D.S. or D.M.D.), or podiatrist (D.P.M.) who may be granted clinical privileges in the hospital.

"Supervision" means the onsite monitoring of a function or activity.

"Unit medical record" means a single chronological record including inpatient and outpatient hospital care, and emergency care when it has resulted in subsequent admission.

§ 482.3 Personnel qualifications.

All hospital personnel and consultants must be licensed, registered, or certified as required by Federal, State, or local laws or regulations and must meet any additional educational and experience requirements specified in this section.

An *"anesthesiologist"* is a physician (M.D. or D.O.) who:

(1) Is educated and trained to administer anesthesia; and

(2) Is approved by the director of the anesthesia service or by the medical staff.

An *"anesthetist"* is an individual other than a physician who is educated and trained to administer anesthesia under the supervision of a physician and who:

(1) Is a dentist educated and trained to provide anesthesia; or

(2) Is a registered nurse certified by the Council on Certification of the American Association of Nurse Anesthetists.

An *"audiologist"* is an individual who:

(1) Is eligible to take the examination for a certificate indicating clinical competence in audiology granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification, and has or is in the process of accumulating the supervised clinical experience required for certification.

A *"chief executive officer"* is an individual who:

(1) Is appointed or designated by the governing body to manage the hospital; and

(2) Has education and experience in administration appropriate to the scope and complexity of services offered.

A *"dietitian"* is an individual who:

(1) Is eligible to take the examination required by the American Dietetic Association to become a registered dietitian; and

(2) Has at least one year of supervisory experience in the dietetic service of a health care facility.

A *"director of anesthesia services"* is a physician who has experience appropriate to the scope and complexity of the service, and:

(1) Is either board certified in anesthesiology; or

(2) Has at least 4 years of postgraduate clinical training, including at least 2 years in anesthesiology.

A *"director of dietetic services"* is an individual who has education, training, and experience in food service management appropriate to the scope and complexity of the services, and:

(1) Meets the qualifications of a dietitician as specified in this section; or

(2) Is a graduate of a dietetic technician or dietetic assistant educational program accredited by the American Dietetic Association and who has 6 months of supervisory experience in the dietetic service of a health care facility; or

(3) Is a graduate of a hotel, restaurant management, or State-approved educational program that provides a minimum of 90 classroom hours of instruction in food service management and nutritional care, and who has 6 months of supervisory experience in the dietetic service of a health care facility; or

(4) Is an individual with training and experience in food service management from a military program that is equivalent to the requirements in paragraphs (1) and (2) for a director of dietetic services.

A *"director of medical record services"* is an individual who has experience and demonstrated supervisory competence appropriate to the scope and complexity of the services performed, and:

(1) Is eligible to take the examination required by the American Medical Records Association to be certified as a Registered Record Administrator (ARA) or an Accredited Record Technician (ART); or

(2) Has education, training, and experience in the preparation of medical records, filing and record storage, indexing, coding, statistical reporting, and security and confidentiality of records.

A *"director of medical (tuberculosis) services"* is a physician who has experience appropriate to the scope and complexity of the services, and:

(1) Is either board certified in internal medicine; or

(2) Has at least 3 years of clinical experience with chest diseases.

A *"director of nuclear medicine services"* is a physician who has experience appropriate to the scope and complexity of the services, and:

(1) Is either board certified in nuclear medicine; or

(2) Is board certified in radiology, pathology, or internal medicine, and has clinical training in nuclear medicine and has been approved by the medical staff.

A *"director of nursing services"* is a registered nurse who:

(1) Has supervisory and administrative experience in a hospital; and

(2) Has demonstrated management skills, knowledge, and leadership appropriate to the scope and complexity of the services offered.

A *"director of psychiatric nursing services"* is a psychiatric nurse who:

(1) Has 2 years of psychiatric nursing experience;

(2) Has supervisory and administrative experience in a psychiatric hospital; and

(3) Has demonstrated management skills, knowledge, and leadership appropriate to the scope and complexity of the services offered.

A *"director of psychiatric services"* is a physician who has experience appropriate to the scope and complexity of the services, and:

(1) Is either board certified in psychiatry; or

(2) Has at least 3 years of postgraduate clinical training, including 1 year of psychiatry.

A *"director of psychological services"* is an individual who:

(1) Has experience appropriate to the scope and complexity of the services; and

(2) Is eligible to be considered a professional psychologist according to the American Psychological Association's standards for providers of psychological services.

A *"director of radiologic services"* is a physician who has experience appropriate to the scope and complexity of the services; and

(1) Meets the qualifications of a radiologist or a radiotherapist as specified in this section; or

(2) If only diagnostic services are offered in a geographic area where the services of a radiologist or radiotherapists are not available, is a physician who is approved by the medical staff to practice diagnostic radiology.

A *"director of rehabilitative services"* is an individual who has experience and training appropriate to the scope and complexity of the services, and:

(1) Is either a physician; or

(2) Is a qualified occupational or physical therapist, audiologist or speech pathologist who functions under direction of the medical staff.

A *"director of social services"* is an individual who has experience appropriate to the scope and complexity

of the services, and has at least a bachelor's degree, and:

(1) Has completed the requirements of a social work curriculum accredited by the Council on Social Work Education; or

(2) Has equivalent training and experience.

A *"director of surgical services"* is a physician who has experience appropriate to the scope and complexity of the services, and:

(1) Is either board certified in a surgical specialty; or

(2) Has at least 4 years of postgraduate training in surgery, including at least 2 years of general surgery; or

(3) Has 6 years experience in the practice of general surgery immediately prior to the effective date of these regulations.

A *"nuclear medicine technologist"* is an individual who:

(1) Is eligible to take the examination for registration as a nuclear medicine technologist by the American Registry of Radiologic Technologists, and has 1 year of experience as a nuclear medicine technologist within the last 3 years; or

(2) Is a registered nurse, registered medical technologist, or a college graduate who has a bachelor or science degree with a major in biological or natural science and has successfully completed a 1-year educational program in nuclear medicine technology accredited by the Committee on Allied Health Education and Accreditation (CHAEA) of the American Medical Association in cooperation with the Joint Review Committee on Education in Radiologic Technology; or

(3) Prior to January 1, 1976, met the requirements of this section for radiographer, or is a registered nurse or medical technologist and has successfully completed 2 years of on-the-job training in nuclear medicine technology under the supervision of a physician who meets the requirements for certification in nuclear medicine radiology by the American Board of Pathology, or the American Board of Internal Medicine, or the American Osteopathic Board of Nuclear Medicine, or the American Board of Nuclear Medicine.

A *"nurse-midwife"* is a registered nurse who has successfully completed a formal program of study as a midwife.

A *"nurse practitioner"* is a registered nurse who has successfully completed a formal program of study in the delivery of primary health care.

A *"nursing graduate"* is a graduate of a State-approved or foreign school of nursing who is:

(1) Enrolled for the first time to take the State Board Test Pool Examination (SBTPE) or the State Licensure Examination for Licensure as a Regiistered Nurse or as a Licensed Practical Nurse; or

(2) Has taken the examination and is awaiting the results.

An *"occupational therapist"* is an individual who:

(1) Is eligible to take the examination for certification as an occupational therapist, registered (OTR), by the American Occupational Therapy Association; or

(2) Has equivalent training and experience.

An *"occupational therapy assistant"* is an individual who:

(1) Is eligible for certification as a certified occpational therapy assistant (COTA) by the American Occupational Therapy Association; or

(2) Has equivalent training and experience.

A *"physical therapist"* is an individual who:

(1) Is either a graduate of a program in physical therapy approved by the American Physical Therapy Association or by the Council on Medical Education of the American Medical Association; or

(2) Has 2 years of experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination approved by the Secretary, offered before January 1, 1978; or

(3) Was licensed or registered before January 1, 1966 and had 15 years of full-time experience as a physical therapist before January 1, 1970; or

(4) Was graduated from a State-approved 4-year college program in physical therapy before January 1, 1966.

A *"physical therapy assistant"* is an individual who:

(1) Is a graduate from a 2-year college-level program approved by the American Physical Therapy Association; or

(2) Has equivalent training and experience.

A *"physician assistant"* is an individual who is certified by the National Commission for Certification of Physician Assistants.

A *"psychiatric nurse"* is a registered nurse who:

(1) Has a master's degree in psychiatric or mental health nursing from an educational program accredited by the National League for Nursing; or

(2) Has a bachelor's degree in nursing and has 5 years of experience in a psychiatric hospital with progressive supervisory responsibility; or

(3) Has a diploma in nursing and has 7 years of experience in a psychiatric hospital with progressive supervisory experience.

A *"radiation physicist or health physicist"* is an individual who:

(1) Meets the requirements for certification as a specialist in radiation safety by the American Board of Radiology or the American Association of Physicists in Medicine; or

(2) Has a master's degree with a major in medical radiation physics, health physics, or radiologic health.

A *"radiation therapy technologist"* is an individual who:

(1) Is eligible to take the examination for registration as a radiation therapy technologist by the American Registry of Radiologic Technologists, and has 1 year of experience as a radiation therapy technologist within the 3 years prior to employment; or

(2) Prior to January 1, 1976, had successfully completed 2 years of on-the-job training in radiation therapy technology under the supervision of a physician who meets the requirements for certification in therapeutic radiology by the American Board of Radiology.

A *"radiographer (radiologic technologist)"* is an individual who:

(1) Is eligible to take the examination for registration by the American Registry of Radiologic Technologists or by the American Registry of Clinical Radiography Technologists, and has 1 year of experience as a radiographer (radiologic technologist) within the 3 years prior to employment; or

(2) Has successfully completed an education program in radiography.

A *"radiologist"* is a physician who:

(1) Is board certified in radiology; or

(2) Has at least 4 years of post-graduate clinical training including 3 years in radiology; or

(3) Has 6 years of experience in the provision of radiologic services immediately prior to the effective date of these regulations.

A *"radiotherapist"* is a physician who:

(1) Is board certified in therapeutic radiology; or

(2) Is board certified in radiology.

A *"respiratory therapist"* is an individual who has successfully completed a training program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education, and:

(1) Is eligible to take the regstry examination for respiratory therapists administered by the National Board for Respiratory Therapy, Inc.; or

(2) Has equivalent training and experience.

A *"respiratory therapy technician"* is an individual who has successfully completed a training program accredited by American Medical Association's Committee on Allied Health Education and Accrediation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education, and:

(1) Is eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc.; or

(2) Has equivalent training and experience.

A *"speech-language pathologist"* is an individual who:

(1) Is eligible to take the examination for a certificate indicating clinical competence in speech-language pathology granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification, and has or is in the process of accumulating, the supervised clinical experience required for certification.

A *"surgical technologist circulator"* is an individual who:

(1) Has successfully completed an educational program for surgical technologists (operating room technicians) that is accredited by the Committee on Allied Health Education and Accreditation (CAHEA) of the AMA in cooperation with the Joint Review Committee on Education for Operating Room Technicians, Inc.; and

(2) Is certified by the Association of Surgical Technologists.

A *"thoracic surgeon"* is a physician who is board certified in thoracic surgery.

Subpart B—Basic Hospital Functions

§ 482.21 Condition of participation—governing body and management.

The hospital's governing body and the chief executive officer must exercise authority and responsibility to ensure that quality health care is provided in a safe environment and in response to the needs of the community.

(a) *Standard: Responsibilities of the governing body.* The hospital must have an organized governing body that is responsible for the operation of the hospital, the quality of health services, and compliance with State and local laws. The governing body must:

(1) Adopt bylaws that explain the organizational responsibilities of the governing body and any committees, the objectives of the hospital, and how these objectives are to be met;

(2) Adopt policies and procedures to fulfill its responsibilities, including delegations of authority, election of officers, committee appointments and attendance requirements for meetings;

(3) Establish formal communication with representatives of the community;

(4) Establish formal and regular communication with the medical staff;

(5) Appoint a chief executive officer to act on its behalf;

(6) Approve medical staff bylaws;

(7) Ensure that all services are supervised;

(8) Approve the selection of a chief of the medical staff and of the directors of all organized services;

(9) Appoint all members to the medical staff, and specify their clinical (and surgical) privileges, based upon recommendations from that staff;

(10) Approve and clearly state in writing the functions and responsibilities of house staff;

(11) Ensure that the hospital and staff meet all applicable Federal, State, and local laws and regulations;

(12) Review the hospital's institutional planning activities and ensure that the hospital adheres to the provisions of Section 1861(z) of the Act regarding institutional planning;

(13) Ensure that the hospital operates in accordance with Title VI of the Civil Rights Act of 1964, and the Age Discrimination Act of 1975, and Part 90 of Title 45 of the Code of Federal Regulations;

(14) Ensure that the hospital is accessible to the handicapped, including individuals with ambulatory, sight, hearing, and other impairments, in accordance with Section 504 of the Rehabilitation Act of 1973 and Part 84 of Title 45 of the Code of Federal Regulations.

(b) *Standard: Responsibilities of the chief executive officer.* The chief executive officer must be responsible for administrative and operational activities of the hospital. The chief executive officer must:

(1) Implement policies of the governing body, direct and evaluate services, coordinate medical and administrative activities, and take appropriate action to ensure that patients' needs are met;

(2) Maintain a current organization chart that specifies lines of authority within and between the services of the hospital; and

(3) Ensure that the job performance of all hospital employees is consistent with written position descriptions and policies and procedures.

(c) *Standard: Policies and procedures.* The hospital must maintain written policies and procedures that specify the roles, responsibilities, and interrelationships of employees, services, and contractors. The policies and procedures must be approved by the chief executive officer and must be consistent with general policies of the governing body. The policies and procedures must be available to all staff for reference.

(d) *Standard: Personnel and staff development.* The qualifications of all employees and members of the medical staff must be consistent with assigned responsibilities and must be maintained through training programs.

(1) Current position descriptions must specify the authority and responsibilities of each employee.

(2) The hospital must ensure that all new employees are oriented to the hospital's organization, functions, and services and to the hospital's policies and procedures.

(3) The hospital must ensure that all staff maintain their skills and learn of significant developments in their respective disciplines.

(4) The hospital must provide pertinent current resource materials for use by the staff.

(e) *Standard: Quality assurance.* The governing body must ensure that there is a hospital-wide quality assurance program encompassing medical staff activities and each organized service.

(1) The hospital staff must participate in a utilization review program or a professional standards review when the Professional Standards Review Organization assumes review responsibility in the hospital.

(2) The chief executive officer and the directors of all organized services must conduct a performance evaluation program which provides:

(i) A well-defined method of assessing staff performance; and

(ii) Periodic reporting on the activities and evaluative findings of each organized service.

(3) The governing body must obtain the review of the medical staff and each organized service and use pertinent findings in revision of the hospital's policies, procedures, and staff development programs.

(f) *Standard: Services provided to the hospital under contract.* The governing body must be responsible for services provided by parties under contracts with the hospital, including shared services and joint ventures. The governing body may delegate this responsibility to the chief executive officer.

(1) The scope and nature of the services must be specified in writing.

(2) The services must be provided in accordance with this part and must be consistent with applicable standards of practice.

(3) If the services are performed outside of the hospital, the chief executive officer must ensure that the services are provided in a safe and effective manner.

(g) *Standard: Discharge planning.* The governing body must ensure that the hospital maintains a discharge planning program coordinated with community resources to facilitate the provision of follow-up care. When feasible, the hospital must have a written transfer agreement with one or more skilled nursing facilities, intermediate care facilities, and home health agencies approved for participation under Medicare or Medicaid or both.

(h) *Standard: Patients' rights.* The governing body must establish and implement written policies regarding the rights of patients.

(1) All hospital staff must be informed of these policies, and a staff member must be responsible for assuring their full implementation.

(2) Patients must be treated with consideration, respect, and recognition of their individuality and personal needs, including the need for privacy in treatment.

(3) If a significant number of patients do not speak English, the hospital must provide translators.

(4) Patients or their guardians must be given a written copy of the hospital's patients' rights policies upon admission. This written copy must include the current address of:

(i) The regional office of the Department of Health and Human Services;

(ii) The State survey and certification agency; and

(iii) If the facility is accredited, the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association.

(5) These policies must provide that:

(i) Except in emergencies, the patient or guardian must be informed of charges, billing procedures, diagnosis, plan of treatment, and prognosis.

(ii) Except in emergencies, the patient must give informed consent before treatment is administered.

(iii) Except in emergencies, the patient must not be transferred to another facility without full explanation, provision for continuing care, and acceptance by the receiving institution.

(iv) A patient, guardian, or legal representative must have access to the patient's medical record. If the attending physician determines that direct access would be harmful to the patient, a responsible representative, authorized by the patient, must be given access.

(v) The patient's medical records, including all computerized medical information, must be kept confidential. Only those directly involved in the care of the patient, those with legal access to the record, or those authorized by the patient in writing may have access to the information in a medical record.

(vi) The patient or guardian must be informed of which practitioner is primarily responsible for all medical care given.

(vii) The patient or guardian must be fully informed and give prior consent for participation in any form of research or experimentation.

(viii) The hospital must protect the personal property of the patient against theft or loss.

(ix) The patient or guardian must be informed of the rules under which physical or chemical restraints may be applied to a patient.

(i) *Standard: Disclosure of ownership.* The hospital must comply with the applicable disclosure requirements of Part 420 Subpart C, and Part 455, Subpart B, of this chapter.

§ 482.22 Condition of participation—medical staff.

The hospital must have an organized medical staff that is accountable to the governing body. The medical staff must develop and enforce medical staff bylaws, rules, and regulations governing the ethical and professional practice of its members.

(a) *Standard: Organization and policies.* Subject to the approval of the governing body, the medical staff must adopt bylaws, rules, and regulations that specify the organization, qualifications, and responsibilities of its members, officers, and, if applicable, committees.

(1) The chief of the medical staff is responsible for monitoring and enforcing all bylaws, rules, and regulations.

(2) The chief of the medical staff may delegate responsibilities in accordance with the bylaws.

(3) Medical staff reports and recommendations must be provided to the governing body and to the chief executive officer.

(4) The medical staff must ensure that a physician is on the premises at all times or available within 15 minutes.

(5) In areas of limited physician availability and where geographical barriers prevent 15-minute access, the physician must provide specific instructions to the staff on duty regarding measures to be taken before he or she arrives. There must be approved standing orders to be followed by the staff in different emergency situations.

(6) Every patient must be admitted by and under the care of a member of the medical staff.

(7) All patients must be under the medical supervision of a physician.

(b) *Standard: Membership and clinical privileges.* Members of the medical staff must be legally and professionally qualified to practice in their clinical specialty.

(1) The medical staff must establish and the governing body must approve criteria for evaluating the qualifications of applicants for medical staff membership and for determining clinical privileges.

(2) Based upon the established criteria, the medical staff must make recommendations to the governing body regarding the granting of membership to applicants and the extent of their clinical privileges.

(3) Professionally qualified applicants must not be denied membership on the basis of sex, race, creed, color, national origin, or a handicap which does not directly impair the qualify of professional performance.

(4) A hearing and appeal mechanism must be available for applicants who have been denied membership.

(5) House staff must provide patient care only under the direction of practitioners of the pertinent profession who have clinical privileges in the hospital.

(6) Membership and clinical privileges must be reviewed annually on the basis of performance, training, and ability. Procedures and findings must be coordinated with the utilization review or PSRO programs. The review must evaluate:

(i) Medical histories and admission information;

(ii) Physician entries in the medical record;

(iii) Tissue analyses;

(iv) Hospital acquired infections; and

(v) Unexplained complications and deaths.

(c) *Standard: Physician assistants, nurse practitioners, and nurse midwives.* If physician assistants, nurse practitioners, and nurse midwives work in the hospital, the medical staff must establish written procedures for monitoring, supervising, and assuming responsibility for their clinical activities, in accordance with policies established by the governing body.

§ 482.23 Condition of participation—nursing services.

The hospital must have an organized nursing service that is directed and staffed to ensure that the nursing needs

of all patients are met 24 hours a day, 7 days a week.

(a) *Standard: Organization.* The organization of nursing services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of nursing services who is qualified as specified in § 482.3.

(2) The governing body must clearly specify, in writing, the administrative and patient care responsibilities of the director of nursing services.

(3) The director of nursing services must:

(i) Monitor and evaluate nursing care and initiate corrective actions to ensure effective patient care;

(ii) Participate in hospital planning, policy setting, and decision making that affect nursing services, nursing care, and patient environment;

(iii) Inform all nursing personnel of hospital and nursing service policies and procedures for patient care and of the performance requirements of their jobs;

(iv) With the immediate supervisor, monitor and evaluate the performance of nursing personnel on an ongoing basis; and

(v) Conduct periodic reviews of nursing records.

(b) *Standard: Staffing.* There must be adequate numbers of registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed.

(1) Twenty-four (24) hour nursing service must be rendered or supervised by a registered nurse, with at least one registered nurse on each tour of duty, except for rural hospitals as specified in § 1861(e)(5) of the Social Security Act.

(2) The director of nursing service must be responsible for determining the types and numbers of nursing personnel and staff necessary to provide nursing care.

(3) The director of nursing service must select, promote, discipline, and terminate nursing staff in accordance with the hospital's personnel management policies and procedures.

(4) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing services must ensure that the clinical activities of non-employee nursing personnel are adequately supervised.

(c) *Standard: Delivery of service.* The delivery of service must be consistent with recognized standards of nursing practice.

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

(2) A nursing care plan must be developed for each patient consistent with the patient's medical plan for care. The plan must be initiated when the patient is admitted and reflect the patient's progress.

(3) Physical restraints, forced treatment, or seclusion may be used only on the order of a physician and in circumstances which, under established written policy, warrant such action.

(d) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable patterns of practice.

(1) Drugs must be administered in accordance with applicable State laws by personnel specified in the medical staff rules and regulations.

(2) Verbal orders for drugs and biologicals must be:

(i) Accepted and transcribed by registered nurses or licensed practical (vocational) nurses in accordance with medical staff bylaws;

(ii) Reviewed and countersigned by the prescribing practitioner within 48 hours; and

(iii) Limited to emergencies or unusual circumstances.

(3) Blood, blood-products, and parenteral solutions must be administered only by practitioners, house staff, students in medical schools, registered nurses, or licensed practical (vocational) nurses who have had special training. The patient's medical records must identify the administering personnel.

(4) All parenterals containing admixtures must be prepared and properly labeled according to practitioners' orders.

(5) Current drug references, antidote information, and the telephone number of the regional poison control center must be readily available in each nursing unit.

(6) Clean and sterile equipment must be available for the administration of drugs.

(7) The patient must be identified before drugs are administered.

(8) Drug records must be accurate and signed promptly by the person administering the drug.

(9) The prescribing practitioner must be notified of any automatic stop orders before the administration of the last ordered drug dose.

(10) Adverse drug reactions must be reported immediately upon discovery to the attending practitioner and documented in the patient's medical record.

(11) Self-administration of drugs is permitted only upon the written order of the prescribing practitioner and in accordance with hospital policy.

(12) Drugs for outpatient use may be released to patients upon discharge only on written authorization by the attending practitioner.

§ 482.24 Condition of participation—medical record services.

The hospital must provide medical record services to meet the needs of patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the medical record service must be appropriate to the scope and complexity of the services performed.

(1) There must be a director of medical record services, qualified as specified in § 482.3 who is responsible for the medical record service.

(2) Adequate qualified personnel must be employed to ensure prompt completion, filing, and retrieval of records.

(b) *Standard: Form and retention of record.* The hospital must maintain a unit 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 authentication and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form:

(i) In accordance with applicable statutes or for a period of 6 years, whichever is longer; or

(ii) In the case of a minor, for at least 3 years after the patient becomes of age under State law.

(2) The medical staff must approve a list of all acceptable and current forms and abbreviations which may be used in the medical record.

(3) The director of the medical record service must establish a consistent system of coding and indexing medical records. The system must allow for immediate retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(4) Records must be kept confidential and released only to authorized individuals. The hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.

(c) *Standard: Content of record.* The medical record must contain information to justify admission and continued hospitalization, to support the diagnosis, and to 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 discipline) who is responsible for ordering, providing, or evaluating the service furnished. The author of each entry must be identified and must authenticate the entry. Identification may include signatures, written initials, or computer entry.

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

(i) Evidence of a physical examination, including a health history, performed within 48 hours after admission or no more than 7 days before 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 drug reactions and anesthesia or other incidents;

(v) Properly executed informed consent forms;

(vi) All physicians' 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 prognosis, disposition of case and provisions for follow-up care; and

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

(d) *Standard: Facilities.* There must be adequate space, equipment, and supplies to permit the systematic maintenance of medical records.

§ 482.25 condition of participation—pharmaceutical services.

The hospital must provide routine and emergency drugs and biologicals in a safe and accurate manner to meet the needs of its patients, through either an organized pharmacy service or maintenance of a drug room.

(a) *Standard: Organization and staffing.* The organization of the pharmaceutical service must be appropriate to the scope and complexity of the services offered.

(1) If there is an organized pharmacy service:

(i) The service must be directed by a pharmacist who is qualified as specified in § 482.3;

(ii) The director must be responsible for establishing policies, procedures, rules, and regulations governing the service and its activities, and instituting controls for the receipt, storage, distribution, and administration of drugs and biologicals;

(iii) An adequate number of pharmicists and other personnel must be employed as required by the activities and services; and

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

(2) If the hospital maintains only a drug room for the storage of drugs:

(i) A pharmacist must provide regular consultation to ensure that the drug room is operated in accordance with acceptable principles and practices;

(ii) A licensed nurse whose duties are determined by the medical staff must be designated in writing to supervise the drug room under the direction of the consulting pharmacist;

(iii) Prescription drugs must be dispensed from a pharmacy outside the hospital.

(3) Emergency pharmaceutical services must be provided, including:

(i) A "crash cart," with a tamperproof lock or seal, for use in acute emergencies; and

(ii) A procedure for obtaining drugs for inpatients when the pharmacy is closed and pharmacist is not available.

(b) *Standard: Delivery of service.* All drugs and biologicals must be controlled and an account made of their use.

(1) In accordance with medical staff rules and regulations, the hospital must adopt and enforce standards for the prescription of drugs consistent with recognized professional references and sources. To provide safety for patients and prevent abuse, these standards must include:

(i) Circumstances for which particular drugs are recommended;

(ii) Suggested dosages and routes of administration; and

(iii) Suggested intervals and duration of use.

(2) A current formulary or list of acceptable drugs must be maintained for use by the hospital.

(3) The pharmacist must review original drug orders either before a drug is dispensed or as soon as possible afterwards.

(4) The pharmacist must immediately report drug irregularities, incompatibilities, abuses, and misuses to the practitioner, and to the nursing service and the chief executive officer if appropriate.

(5) Compounding drugs, preparing intravenous admixtures, dispensing, administering, and recalling of drugs, biologicals and radiopharmaceuticals must be accomplished in accordance with written procedures.

(6) Drugs, biologicals, and diagnostic agents must be issued in accordance with practitioner orders.

(7) All drugs must be distributed in accordance with procedures that ensure correct usage and drug administration. Drug administration errors must be reported to the hospital-wide quality assurance program.

(8) Persons permitted access to drug storage and preparation areas must be identified by title or position in the written policies.

(9) The hospital must ensure that current information on drugs and drug interactions is available to physicians, nurses, and other designated health care staff. Staff or consulting pharmacists must select and recommend recently published findings for distribution. The system for communication of drug information must be appropriate to the scope and complexity of hospital services.

(10) Loss of controlled drugs and the facts surrounding their loss must be immediately reported to the chief executive officer and other appropriate individuals.

(11) Discontinued, outdated, and deteriorated drugs and containers with worn, illegible, or missing labels must be returned to the pharmacist for disposition.

(12) Drugs for outpatient use must be in containers that are correctly labeled with the patient's name, the contents, instructions, and all other vital information needed for correct usage and drug administration.

(c) *Standard: Facilities.* Appropriate facilities and equipment must be provided for the preparation, storage, and dispensing of drugs and biologicals.

(1) Controlled substances, ethanol, and prescription drugs must be kept in a locked storage space in compliance with Federal and State requirements.

(2) All floor stock must be properly controlled.

(3) The drug preparation areas must be clean, well lighted, and of sufficient size to ensure the safe preparation of drugs for administration.

(4) The drug storage area must be properly ventilated, equipped with humidity and temperature controls, and monitored regularly by the pharmacist.

(d) *Standard: Records.* Current and accurate records must be kept of the receipt and disposition of all drugs.

§ 482.26 Condition of participation—radiologic services.

The hospital must maintain or arrange for diagnostic radiologic services. If therapeutic radiologic services are provided, they, as well as diagnostic services, must be provided in

accordance with acceptable standards of practice to meet the needs of patients as determined by the medical staff.

(a) *Standard: Organization and staffing.* The organization of the radiologic service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of radiologic services, qualified as specified in § 482.3, who is responsible for the radiologic services.

(2) The qualifications, training, functions, and responsibilities of radiologic professional and technical personnel must be specified by the service director and approved by the medical staff.

(3) If the service director is not a radiologist or radiotherapist, the hospital must obtain regular and frequent consultation from a radiologist or radiotherapist to evaluate the quality of services.

(4) Adequate professional and technical personnel must be assigned to provide radiologic services appropriate to patient needs.

(b) *Standard: Delivery of service.* Diagnostic or therapeutic radiology must be performed only on the order of a practitioner with clinical privileges. Procedures for patient preparation, examinations, and administration of diagnostic agents must be specified by the service director and include precautions for the safety of patients and radiology personnel.

(1) Diagnostic X-ray equipment must be operated by radiologists and radiographers. Students in an approved radiologic technology program may operate X-ray equipment under the supervision of a radiologist or radiographer.

(2) Radiologic services must be provided in accordance with applicable Federal and State regulations and recommendations (see U.S. Department of Health, Education, and Welfare, Food and Drug Administration recommendations contained in 21 CFR 1000, Subpart C—"Radiation Protection Recommendations"). For conditions not subject to such regulations, radiation safety precautions must be established in accordance with the applicable recommendations of NCRP Reports No. 33 and 49 of the National Council on Radiation Protection and Measurements.

(3) Therapeutic radiologic services must be performed by a radiologist or radiotherapist. Radiation therapy technologists may assist in radiation therapy under the supervision of a radiologist or radiotherapist.

(c) *Standard: Facilities.* Equipment and supplies must be appropriate to the types of radiologic services offered and must be maintained for safe and efficient performance.

(1) Radiologic services must be provided in a safe, appropriately equipped area of the hospital that is adequately shielded. Occupationally exposed personnel must be monitored regularly, and the cumulative radiation exposure of each individual must be recorded at least monthly.

(2) X-ray equipment must meet applicable Federal and State standards and requirements (21 CFR 1020.30, Performance Standards for Diagnostic X-ray Systems).

(3) Radiation equipment must be routinely tested to ensure consistent performance. All equipment must be inspected, tested, and calibrated at least annually by a radiation physicist or health physicist.

(d) *Standard: Records.* Authenticated and dated reports of radiology interpretations and consultation, therapy, and radiotherapy must be incorporated in the patient's medical record. Copies of these reports, films, the patient log, documentation of instrument performance and equipment calibration, and records of inspections and consultations must be retained in the radiologic service.

§ 482.27 Condition of participation—dietetic services.

The hospital must provide or arrange for hygienic food services that meet the daily nutritional and therapeutic dietary needs of patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the dietetic service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of dietetic services, qualified as specified in § 482.3, who is responsible for the dietetic services.

(2) A qualified dietitian must be regularly available to ensure an optimal level of quality of the food service.

(3) A director of dietetic services who is not qualified as a dietitian must participate at least annually in continuing dietetic education or other comparable training.

(4) If meals are prepared on the premises, there must be adequate numbers of cooks and support personnel.

(b) *Standard: Delivery of service.* Acceptable standards of practice must be used in operating the service, planning menus, and purchasing and preparing food.

(1) Food must be procured from sources that comply with applicable laws and regulations.

(2) Food must be stored, prepared, and distributed under sanitary conditions.

(3) Food handling techniques must be routinely checked to ensure that they meet hygienic standards.

(4) In order to detect communicable diseases, employees must have routine health examinations which meet local, State, and Federal codes for food service personnel. Action must be undertaken to prevent spread of infection.

(5) Proper cleaning techniques must be used to ensure sanitized serviceware and to prevent recontamination.

(6) Safety practices must be used by employees operating appliances, equipment, and machinery.

(7) Provision must be made for special diets which are ordered by the practitioner based on medical necessity or patient request.

(8) Training must be available to patients who need a special diet after discharge. Training should be coordinated with the nursing service and may be given by licensed nursing staff.

(c) *Standard: Facilities.* The kitchen and dietetic service areas must be well ventilated and properly equipped and maintained.

(d) *Standard: Menus and nutritional adequacy.* Menus must be planned at least 1 week in advance in accordance with Recommended Dietary Allowances (8th revised edition, 1974), Food and Nutrition Board of the National Research Council, National Academy of Sciences.

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

(2) At least three palatable meals must be served daily at regular hours, with no more than 15 hours between the substantial evening meal and the first substantial meal on the following day.

(3) Patients who refuse the food served must be offered appropriate substitutes of similar nutritive value.

(4) Bedtime nourishment must be available upon request unless medically contraindicated.

(5) The director must ensure that patients have opportunities to comment on the quality and palatability of food. Patient comments and refusals must be considered in menu revision.

§ 482.28 Condition of participation—environmental health and safety.

The hospital must provide a safe and sanitary environment.

(a) *Standard: Life safety from fire.* The hospital must meet the applicable provisions of the National Fire

Protection Association (NFPA) Standard No. 101, Life Safety Code (1973), except that:

(1) The Secretary may waive provisions of the Code which would result in unreasonable hardship to the hospital, if the waiver will not adversely affect the health and safety of the patients; or

(2) The hospital will be considered to meet this standard if:

(i) The hospital complied, prior to the effective date of these regulations, and maintains compliance with the applicable provisions of the NFPA Standard No. 101 (1967), with or without waivers of specific provisions; or

(ii) The hospital meets the requirements of a State fire and safety code which the Secretary finds adequately protects hospital patients.

(b) *Standard: Life safety from electric shock and explosion.* The electrical systems, electrical equipment, and specialized electronic and mechanical equipment in the hospital must be designed, installed, operated, and maintained to prevent electric shock and explosion.

(1) Each anesthetizing location in the hospital must meet the provisions of NFPA Standard No. 56A, Inhalation Anesthetics (1973), with the exception of sections 335 and 3421. In addition:

(i) The grounding system and isolation transformer must be adequate to minimize the difference in potential which can occur between any conductive surface that the patient, or a person touching the patient, can contact. The difference in electrical potential between either isolated conductor and the ground must be less than five (5) millivolts.

(ii) In locations where nonflammable anesthetics are used, receptacles and attachments must be listed by a nationally recognized testing laboratory (e.g., UL or Factory Mutual) for hospital use.

(2) Facilities and equipment in the hospital used for inhalation therapy must comply with applicable provisions of NFPA Standard No. 56B, Respiratory Therapy (1977).

(3) Nonflammable medical gas systems installed in the hospital must comply with the applicable provisions of NFPA Standard No. 56F, Nonflammable Medical Gas Systems (1977).

(4) Electrical instruments, electrical installations, and electrical appliances must be regularly tested for current leakage and proper grounding. If the hospital permits patients to bring in personal appliances, they must be tested prior to use.

(5) Special, precautions, including a periodic maintenance program, must be established and observed in the use of biomedical devices and electrical equipment.

(6) The hospital must maintain written records of all electrical and electronic inspections. The records must note actions taken or recommended in accordance with the periodic preventive maintenance schedule.

(c) *Standard: Emergency electrical power.* The hospital must have and periodically test an emergency electrical power system which is designed, installed, and maintained to ensure continuity of electrical power in accordance with NFPA Standard No. 76A, Essential Electrical Systems for Health Care Facilities (1977).

(d) *Standard: Nursing units and other service areas.* Physical facilities must be designed, equipped, and used to permit effective treatment, care, comfort, safety, and privacy of patients.

(1) Single patient rooms must provide at least 100 square feet of floor area and multipatient rooms must provide a minimum of 80 square feet per bed.

(2) The hospital must provide single rooms for isolation of patients, as necessary. These rooms must be identified with precautionary signs, appropriately ventilated, and have private toilet and handwashing facilities.

(3) Patients' rooms must be equipped with a signal system to contact nursing staff.

(4) Bedside rails and visual privacy measures must be available.

(5) The hot water temperature at shower, bathing, and handwashing facilities must not exceed 120° F (48.8° C).

(e) *Standard: Sanitary environment.* The hospital must maintain a sanitary environment to minimize health hazards. The hospital must provide for:

(1) the control of pests:

(2) the sanitary disposal of infectious and other wastes;

(3) monthly testing of water, if not from a public water supply, and treatment to ensure potability, if indicated;

(4) the regular inspection and maintenance of air handling systems in anesthetizing locations, isolation rooms, special care units, and other "high risk" areas; and

(5) water during emergencies.

(f) *Standard: Other facilities and services.* Housekeeping, laundry, central service and maintenance services must be organized and maintained for proper patient care and comfort and for the safety of patients and personnel, whether the services are provided directly or under arrangement.

(g) *Standard: Disaster preparedness.* The hospital must have a written disaster plan that:

(1) Is rehearsed frequently enough to ensure that the staff is familiar with it;

(2) Specifies the procedures to be followed in case of disasters;

(3) Specifies the care of casualties arising from disaster;

(4) Describes how the hospital will coordinate with other emergency and community resources;

(5) Describes procedures for transfer of casualties and records;

(6) Instructs personnel in the use of fire alarm systems, signals, and fire fighting equipment; and

(7) Specifies evacuation routes and methods of containing fires.

§ 482.29 Condition of Participation-Infection control.

The hospital must have an active program for the prevention, control, and investigation of infection and communicable diseases.

(a) *Standard: Organization.* A person (or persons) must be designated as infection control officer(s) to develop and implement written policies governing asepsis and infection control.

(1) The infection control officer(s) must develop a system for identifying reporting, investigating, and controlling infection of patients and personnel who come in contact with patients, their food, or their laundry.

(2) The infection control officer(s) must monitor the hospital's aseptic and isolation techniques, use of antibiotics, and procedures for culturing to ensure acceptable staff performance.

(3) The infection control officer(s) must report findings and any recommendations to the medical staff, the chief executive officer, and the director of the nursing services.

(4) The chief executive officer, the medical staff, and the director of nursing service must ensure that the hospital-wide quality assurance program and training program address problems identified by the infection control officer(s).

(b) *Standard: Equipment and supplies.* Processing, handling, cleaning, and storage of supplies and equipment must be in accordance with standards of practice and must ensure an acceptable level of asepsis throughout the hospital.

§ 482.30 Conditions of participation—laboratories.

The hospital has a well organized, adequately supervised clinical laboratory with the necessary space, facilities and equipment to perform those services commensurate with the hospital's needs for its patients.

Anatomical pathology services and blood bank services are available either in the hospital or by arrangement with other facilities.

(a) *Standard; adequacy of laboratory services.* Clinical laboratory services adequate for the individual hospital are maintained in the hospital. The factors explaining the standard are as follows:

(1) The extent and complexity of service are commensurate with the size, scope, and nature of the hospital, and the demands of the medical staff upon the laboratory.

(2) Basic laboratory services necessary for routine examinations are available regardless of the size, scope, and nature of the hospital.

(3) Necessary space, facilities and equipment to perform both the basic minimum and all other services are provided by the hospital.

(b) *Standard; clinical laboratory examinations.* Provision is made to carry out adequate clinical laboratory examinations including chemistry, microbiology, hematology, serology, and clinical microscopy. The factors explaining the standard are as follows:

(1) Some or all of these services may be provided under arrangements by the hospital with a laboratory which is:

(i) Part of a hospital approved for participation in the Health Insurance for the Aged program; or

(ii) Approved to provide these services as an independent laboratory under the Supplementary Medical Insurance for the Aged program.

(2) In the case of work performed by an outside laboratory, the original report from this laboratory is contained in the medical record.

(c) *Standard; availability of facilities and services.* Facilities and services are available at all times. The factors explaining the standard are as follows:

(1) Adequate provision is made for assuring the availability of laboratory services, either in the hospital or under arrangements with a laboratory which meets one or more of the alternatives listed under paragraph (b)(1) of this section. Such services are available 24 hours a day, 7 days a week, including holidays.

(2) Where services are provided by an outside laboratory, the conditions, procedures, and availability of work done are in writing and available in the hospital.

(d) *Standard; personnel.* Personnel adequate to supervise and conduct the services are provided. The factors explaining the standard are as follows:

(1) Services are udner the supervision of a physician with training and experience in clinical laboratory services or a laboratory specialist qualified by a doctoral degree.

(2) The laboratory does not perform procedures and tests which are outside the scope of training of the laboratory personnel.

(3) There is a sufficient number of clinical laboratory technologists to promptly and proficiently perform the tests requested of the laboratory.

(e) *Standard; routine examinations.* Routine examinations required on admissions are determined by the medical staff. The factors explaining the standard are as follows:

(1) Required tests upon admission, as approved by the medical staff, are consistent with the scope and nature of the hospital.

(2) The required list of tests is in written form and available to all members of the medical staff.

(f) *Standard; laboratory report.* Signed reports are filed with the patient's medical record and duplicate copies kept in the department. The factors explaining the standard are as follows:

(1) The laboratory director is responsible for the laboratory report.

(2) There is a procedure for assuring that all tests are ordered by a physician.

(g) *Standard; pathologist services.* Services of a pathologist are provided as indicated by the needs of the hospital. The factors explaining the standard are as follows:

(1) Services are under the direct supervision of a pathologist on a full-time, regular part-time or regular consultative basis. If the latter pertains, the hospital provides for, at a minimum, monthly consultative visits by a pathologist.

(2) The pathologist participates in staff, departmental and clinicopathologic conferences.

(3) The pathologist is responsible for the qualifications of his staff and their inservice training.

(h) *Standard; tissue examination.* All tissues removed at operation are sent for examination. The extent of examination is determined by the pathology department. The factors explaining the standard are as follows:

(1) All tissues removed from patients at surgery are macroscopically, and if necessary, microscopically examined by the pathologist.

(2) The pathologist or designated physician, in his absence, is responsible for verifying the receipt of tissues for examinations.

(3) A list of tissues which routinely require microscopic examination is developed in writing by the pathologist or designated physician with the approval of the medical staff.

(4) A tissue file is maintained in the hospital.

(5) In the absence of a pathologist or suitable physician substitute, there is an established plan for sending to a pathologist outside the hospital all tissues requiring examination.

(i) *Standard; reports of tissue examination.* Signed reports of tissue examinations are filed with the patient's medical record and duplicate copies kept in the department. The factors explaining the standard are as follows:

(1) All reports of macro and microscopic examinations performed are signed by the pathologist or designated physician.

(2) Provision is made for the prompt filing of examination results in the patient's medical record and notification of the physician requesting the examination.

(3) Duplicate copies of the examination reports are filed in the laboratory in a manner which permits ready identification and accessibility.

(j) *Standard; blood and blood products.* Facilities for procurement, safekeeping and transfusion of blood and blood products are provided or readily available. The factors explaining the standard are as follows:

(1) The hospital maintains, as a minimum, proper blood storage facilities under adequate control and supervision of the pathologist or other authorized physician.

(2) For emergency situations the hospital maintains at least a minimum blood supply in the hospital at all times, can obtain blood quickly from community blood banks or institutions, or has an up-to-date list of donors and equipment necessary to bleed them.

(3) Where the hospital depends on outside blood banks, there is an agreement, governing the procurement, transfer and availability of blood which is reviewed and approved by the medical staff, administration and governing body.

(4) There is provision for prompt blood typing and cross-matching, 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 physician.

(5) Blood storage facilities in the hospital have an adequate alarm system, which is regularly inspected and is otherwise safe and adequate.

(6) Records are kept on file indicating the receipt and disposition of all blood provided to patients in the hospital.

(7) Samples of each unit of blood used at the hospital are retained according to the instructions of the committee indicated in paragraph (j)(8) of this

section for further testing in the event of reactions. Blood not so retained which has exceeded its expiration date is disposed of promptly.

(8) A committee of the medical staff or its equivalent reviews all transfusions of blood or blood derivatives and makes recommendations concerning policies governing such practices.

(9) The review committee investigates all transfusion reactions occurring in the hospital and makes recommendations to the medical staff regarding improvements in transfusion procedures.

(k) *Standard: Proficiency Testing.* The laboratory meets the proficiency testing provisions of § 405.1314(a). The definition of "proficiency testing program", as stated in § 405.1310(c), is also applicable. Hospitals which are accredited by the American Osteopathic Association (AOA) are not deemed to meet the requirements of this paragraph.

(l) *Standard: Quality Control.* The laboratory meets the quality control provisions of § 405.1317. Hospitals which are accredited by the American Osteopathic Association (AOA) are not deemed to meet the requirements of this paragraph.

Subpart C—Optional Hospital Services

§ 482.41 Condition of participation—surgical services.

If the hospital provides surgical services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the surgical service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of surgical services who is a medical staff physician qualified as specified in § 482.3, and who is responsible for the surgical services.

(2) The operating room service must be supervised by a registered nurse with training, experience, and competence in the management of surgical services.

(3) Adequate numbers of personnel must be assigned to provide care as needed. The qualifications, roles, and responsibilities of all personnel who assist in surgical procedures must be specified in the medical staff bylaws. The qualifications of the staff must be consistent with the types of surgical procedures performed.

(4) Registered nurses, licensed practical (vocational) nurses, and surgical technologist circulators who are educated and trained in surgical (operating room) technology may be permitted to perform circulating duties if so specified in the medical staff bylaws. The circulator must have demonstrated supervisory capability and the knowledge and skills needed to ensure continuity of care and maintenance of a safe and therapeutic environment for the patient. In all cases a registered nurse must be immediately available in the operating suite to respond to emergencies.

(b) *Standard: Surgical privileges.* The hospital must ensure that surgical privileges for practitioners are granted in accordance with each practitioner's qualifications and competencies.

(1) The director of the surgical service must evaluate the qualifications and competence of each practitioner who seeks appointment to the surgical staff.

(i) These evaluations must include consideration of a practitioner's training and of the frequency and difficulty of surgical procedures he or she has performed.

(ii) Surgical privileges must be reviewed annually on the basis of each practitioner's performance.

(2) A current roster of the surgical privileges of each practitioner must be maintained in the surgical suite.

(3) The director of the surgical service must regularly monitor adherence to the provisions of these privileges.

(c) *Standard: Delivery of service.*— Surgical services must be consistent with needs and resources. Policies and procedures must ensure a high standard of patient care and safety.

(1) The medical staff must approve, annually review, and enforce the policies and procedures developed by the director of the service.

(2) Written procedures and instructions must specify all operating room responsibilities and activities, including scrub techniques.

(3) Standing orders must be comprehensive.

(4) Physician orders prescribing postoperative care, including the need for patient observation or tests, must be promptly specified in writing.

(5) Specific rules for safety, sanitation, and housekeeping must be established.

(6) Equipment, materials, and trained personnel must be available to provide emergency and shock therapy.

(7) All postoperative infections must be reported to the infection control officer(s).

(d) *Standard: Facilities.* The operating room, suite, equipment, and supplies must be appropriate to the types of services offered. The operating room supervisor must implement a preventive maintenance program for equipment.

(1) Each operating room must be located to control traffic and prevent through traffic.

(2) Air handling systems, electrical systems, and equipment must be installed and maintained in accordance with governing codes (see § 482.28(a)(b) and (c) concerning environmental health and safety).

(3) Ceiling, wall, and floor finishes must be washable and moisture resistant.

(4) Emergency oxygen must be readily available.

(e) *Standard: Records.* Reports of all surgical consultations, procedures, and complications must be verified, signed, dated and included in the patient's medical record within 96 hours after surgery. The reports must include at least the following:

(1) A complete history and physical examination report, diagnostic reports, provisional diagnosis, evidence of patient consent, and preoperative notes, all of which must have been recorded before surgery is performed.

(2) A signed surgical report describing techniques, findings, and the tissues removed or altered.

§ 482.42 Condition of participation—anesthesia services.

If the hospital provides anesthesia services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and Staffing.* The organization of the anesthesia service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of anesthesia services who is qualified as specified in § 482.3, and who is responsible for the anesthesia services.

(2) The qualifications, responsibilities, and required supervision of all persons who administer anesthesia must be specified in the hospital policies and approved by the medical staff.

(3) A roster of persons authorized to administer anesthetics must be maintained in the surgical area. Authorizations must be reviewed annually on the basis of performance.

(4) Sufficient numbers of appropriately trained anesthesiologists and anesthetists must be employed as required by the scope of services.

(b) *Standard: Delivery of service.* Anesthesia services must be consistent with needs and resources. Policies and procedures must ensure a high standard of patient care and safety.

(1) The medical staff must approve, annually review, and enforce the policies and procedures developed by the director of the service.

(2) The preanesthesia evaluation and preparation of the patient must include:

(i) Medical, anesthetic, drug, and allergy history;

(ii) Appropriate laboratory tests; and

(iii) Identification of potential anesthetic problems.

(3) The anesthesiologist or anesthetist must:

(i) Reevaluate the patient prior to induction of anesthesia;

(ii) Prepare equipment, drugs, fluids, and gas supplies;

(iii) Administer all general anesthesia;

(iv) Use monitoring equipment to ensure the safety of the patient during the anesthetic period;

(v) Make at least one visit to the patient during the early postanesthetic period and make appropriate notes on the patient's chart; and

(vi) Write a postoperative report within 48 hours of the operation, and note the presence of any abnormalities or complications.

(4) The service must provide for safe postoperative care.

(i) There must be adequate nursing personnel and equipment.

(ii) The discharge of a patient from any postoperative care unit must be made by a physician or an anesthetist.

(c) *Standard: Records.* The anesthesiologist of anesthetist must note all appropriate findings and occurrences in the patient's unit medical record, including at least:

(1) The report of the preanesthesia evaluation of the patient, noting history, tests, medications, and problems;

(2) The report of all events during surgery, including dosage of all drugs and agents employed, type and amount of all fluids administered, and a description of anesthetic techniques employed; and

(3) The postoperative follow-up report.

(d) *Standard: Safe use of anesthetic agents.* The medical and administrative staff must ensure that anesthetic agents are used in a manner to prevent hazards.

(1) The medical staff must establish written safety measures and standards of safe operation in accordance with NFPA Standard No. 56A, Standard For the Use of Inhalation Anesthetics (1973).

(2) All anesthesia service staff must be trained to observe standards of safe operation.

(3) The director of anesthesia services must ensure that the anesthesiologist of anesthetist inspects and tests all equipment prior to the administration of anesthetics.

§ 482.43 Condition of participation—nuclear medicine services.

If nuclear medicine services are provided, they 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 of nuclear medicine services, qualified as specified in § 482.3, who is responsible for the nuclear medicine services.

(2) The qualifications, training, functions, and legal responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(3) Adequate personnel must be assigned to provide nuclear medicine services.

(b) *Standard: Delivery of service.* Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with applicable rules and regulations of the United States Nuclear Regulatory Commission and of State regulatory bodies.

(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.

(1) Nuclear medicine services must be provided in an area of the hospital that is adequately shielded.

(2) All equipment must be maintained in safe operating condition and inspected, tested, and calibrated at least annually by qualified personnel.

(D) *Standard: Records.* Signed and dated reports of nuclear medicine interpretations, consultations, and therapy must be incorporated in the patient's medical record. Copies must be retained in the nuclear medicine service.

(1) Patient records must indicate the amount of radiopharmaceutical administered, the supplier lot number, and the date of the therapy.

(2) Service personnel must be monitored and the cumulative radiation exposure for each individual must be recorded at least monthly.

(3) Records of the receipt and disposition of radiopharmaceuticals must be maintained. Documentation of instrument performance and records of inspections must be retained in the service.

§ 482.44 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 and staffing.* The organization of the outpatient service must be appropriate to the scope and complexity of the services offered.

(1) The governing body must specify in writing the qualifications and responsibilities of the service director.

(2) A registered nurse must be responsible for the nursing care provided in the service.

(3) Outpatient services must be adequately staffed by personnel qualified by training and experience to provide the services offered.

(b) *Standard: Delivery of service.* Outpatient services must be consistent in quality with inpatient care and in accordance with resources available.

(1) Written policies and procedures must specify the services furnished, the methods of providing those services, and the procedures for transferring patients to the inpatient facility or to other community resources.

(2) If outpatient surgery is performed, the standards governing inpatient surgery (§ 482.41) must be met.

(3) The attending physician must determine the methods of evaluation and treatment furnished to each outpatient.

(c) *Standard: Facilities.* There must be adequate and accessible space, equipment, and supplies to ensure safe and effective patient care. Consultation, examination, and treatment rooms must provide privacy.

(d) *Standard: Records.* Records of outpatient services must be maintained in accordance with accepted professional standards.

(1) All outpatient care and treatment must be accurately recorded.

(2) The outpatient medical records must be promptly incorporated into the patient's unit medical record.

§ 482.45 Condition of participation—emergency services.

The hospital must have at least a procedure for appraisal, advice, referral, or initial treatment for emergency cases. If the hospital regularly provides emergency services, they must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the emergency service must be appropriate to the scope and complexity of the services offered.

(1) The emergency services must be under the direction of a member or committee of the medical staff.

(2) A physician must be on duty at all times or available within 15 minutes. If unable to reach the patient within 15 minutes, the physician must provide specific instructions to the emergency staff on duty regarding emergency measures to be taken before he or she arrives. There must be approved standing orders to be followed by the

emergency staff on duty for different emergency situations.

(3) A registered nurse with special training in emergency care must be available and responsible for the emergency nursing care provided.

(4) The emergency service must be adequately staffed by personnel qualified by training and experience to provide the services offered.

(b) *Standard: Delivery of service.* Emergency services must be consistent in quality with inpatient care and in accordance with resources available.

(1) The hospital must evaluate its capabilities to provide emergency medical services and develop an emergency service plan that is coordinated, when possible, with the overall community-based emergency plan.

(2) Written policies and procedures that specify the services offered and the methods of providing those services must be enforced.

(3) Specially trained personnel must assess the condition of all individuals who present themselves for treatment. The hospital may not refuse treatment for other than medical reasons.

(4) Assessment of the patient's condition, if performed by non-physician personnel, must be in accordance with guidelines approved by the medical staff.

(5) A physician must determine the methods of evaluation and treatment furnished to each patient.

(6) The hospital must inform the community of the emergency services provided and the hours of operation.

(c) *Standard: Facilities.* There must be adequate and accessible space. Equipment and supplies must be maintained to ensure safe and effective patient care. Consultation, examination, and treatment rooms must be designed to provide privacy.

(d) *Standard: Records.* Records of emergency services furnished must be maintained in accordance with accepted professional standards and practice. All care and treatment provided by emergency service personnel must be accurately recorded.

(1) Emergency medical records must be promptly incorporated into the patient's unit medical record if the patient is subsequently admitted.

(2) The hospital must designate a person to regularly review emergency medical records for legibility and completeness. The record for each patient treated must contain at least the following:

(i) Patient identification;

(ii) History of the disease or injury;

(iii) Physical findings;

(iv) Laboratory and X-ray reports, if any;

(v) Record of treatment;

(vi) Disposition of the case; and

(vii) The attending physician's authentication.

§ 482.46 Condition of participation—rehabilitative services.

If the hospital provides rehabilitative services (e.g. occupational therapy, physical therapy, speech pathology, audiology, and speech therapy), the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of a rehabilitative service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of rehabilitative services who is qualified as specified in § 482.3, and who is responsible for the rehabilitative services.

(2) The service must be appropriately staffed to meet patient needs with qualified occupational and physical therapists and assistants, speech-language pathologists, and audiologists.

(3) The director must ensure that all occupational or physical therapy assistants are under the supervision of an appropriately qualified therapist.

(b) *Standard: Delivery of services.* Services must be furnished in accordance with a written plan of treatment that includes treatment objectives, rehabilitation potential, discharge planning, contraindications, if any, and type, amount, frequency, and duration of treatment procedures.

(1) Services must be provided only upon written prescription of a practitioner.

(2) The progress of each patient must be monitored and evaluated at appropriate intervals during the course of treatment. The patient's progress must be reviewed with personnel involved in the care of the patient.

(3) The patient, family, or guardian must be informed of the patient's plan of treatment.

(c) *Standard: Facilities.* The hospital must provide adequate space, equipment, and supplies for the rehabilitation of patients. Rehabilitative personnel must be trained to recognize hazards inherent in the use of equipment.

(d) *Standard: Records.* Records of evaluations, referrals, diagnoses, plans of care, treatment objectives, responses to treatment, and other information must be included in the patient's medical record. Records of equipment performance and inspections must be retained in the service.

§ 482.47 Condition of participation—respiratory care services.

If the hospital provides respiratory care through an organized service depatment, it must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the respiratory care service 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 physican with experience in respiratory care, and who is responsible for respiratory care services.

(2) There must be adequate numbers of qualified respiratory therapists, respiratory therapy technicians, registered nurses, and licensed practical (vocational) nurses who are trained in respiratory care.

(b) *Standard: Delivery of service.* Services must be provided in accordance with the written policies and procedures which are approved by the medical staff.

(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 are tested in the respiratory care unit, the unit must meet the requirements for clinical laboratories with respect to technical supervision, preventive maintenance of equipment, and quality controls (42 CFR 405.1317).

(3) Equipment must be maintained and used to avoid cross-infection or transmission of infectious organisms.

(4) Equipment and materials must be inspected to safeguard against hazards.

(5) The director of respiratory care must establish criteria to identify side effects that may occur to patients.

(6) There must be procedures for handling and reporting adverse treatment reactions that require cardiopulmonary resuscitation.

(c) *Standard: Physicians' orders.* A physician's order for respiratory care must specify the type, frequency and duration of treatment, the type and dose of medication, including dilution ratio and precautions to be taken.

(d) *Standard: Facilities.* The hospital must provide adquate and accessible space, equipment, and supplies to ensure the safe provision of respiratory care services.

(1) Nonflammable medical gases, vapors, and aerosols, and the equipment used in their administration must be

used in conformance with National Fire Protection Association (NFPA) Standard No. 56B, Respiratory Therapy (1977). (See § 482.28(b), Life safety from electic shock and explosion.)

(2) Gases used for therapeutic purposes must be stored in accordance with written procedures.

(e) *Standard: Records.* Records of equipment performance and inspections must be retained in the service. Respiratory care must be recorded in the patient's unit medical record by the person rendering the service. The record must include:

(1) Practitioner orders;
(2) The type of therapy;
(3) Date and time of administration;
(4) Therapeutic or adverse reactions;
(5) Periodic evaluations; and
(6) Follow-up by the practitioner.

§ 482.48 Condition of participation—social services.

The hospital must meet the social serivices needs of patients and their families either directly or by referral to an outside resource.

(a) *Standard: Organization and staffing.* The hospital must evaluate its capabilities to provide social services and develop a comprehensive plan to meet the medically related social service needs of patients.

(1) If the hospital provides social services through an organized service, the organization must be appropriate to the scope and complexity of the services offered.

(i) There must be a director of social services qualified as specified in § 482.3, who is responsible for the social services.

(ii) The social service must be adequately staffed by personnel qualified by education and experience to ensure professional practice consistent with recognized standards.

(2) If social services are provided by ourside resources, an individual on the hospital staff must be designated to be responsible for arranging referrals, communicating to patients how social services may be received, and initiating appropriate follow-up measures.

(b) *Standard: Delivery of service.* Social services must be provided in accordance with acceptable standards of practice.

(1) Services must be coordinated with other hospital services and community health and social service agencies.

(2) Written social service policies and procedures must be approved by the governing body.

(c) *Standard: Facilities.* Facilities for social services must be accessible and ensure privacy for interviews and counseling.

(d) *Standard: Records.* Social information and social services furnished must be recorded and incorporated into the patient's unit medical record.

(1) Records must include any medicosocial and home environment studies, social therapy and rehabilitation, services received from community agencies, social service summaries, and follow-up reports on discharged patients.

(2) Social service records must be periodically reviewed by the service director.

§ 482.49 Condition of participation—special care units.

If the hospital maintains special care units (e.g., coronary care, intensive care, burn, etc.), each unit must provide services to meet the needs of patients in accordance with acceptable standards of practice. To be considered as a special care unit, the unit must meet the requirements of § 405.452(d)(10) of this chapter.

(a) *Standard: Organization and staffing.* Each special care unit must be directed by a qualified physician and must be staffed by sufficient personnel to provide effective patient care.

(1) Registered nurses must be on duty during all shifts in each special care unit to supervise the services and provide nursing care.

(2) The number of registered nurses required to carry out patient care responsibilities in each unit must be appropriate to the number, type, and condition of patients in the unit.

(b) *Standard: Delivery of service.* Written administrative and patient care policies and procedures must be established by the medical staff in accordance with the extent and scope of care required in each unit.

(1) Responsibilities for professional and support staff assigned to each unit must be specified.

(2) Specific admission and discharge criteria appropriate to the unit must be established.

(3) Measures to prevent cross-contamination must be established.

(4) Equipment, drugs, and biologicals must be available as needed.

(5) The activities of the unit must be coordinated with other services.

(c) *Standard: Facilities and supplies.* Each special care unit must have space, equipment, and supplies necessary for the safe and effective care of its patients.

(1) All equipment must be inspected and tested at least annually.

(2) Traffic and access to each unit must be controlled to ensure patient privacy and infection control.

(d) *Standard: Records.* Records of instrument performance, equipment calibration, and inspections must be retained in the service.

§ 482.50 Condition of participation—psychiatric services.

If the hospital provides psychiatric services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the psychiatric service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of psychiatric services, qualified as specified in § 482.3, who is responsible for the psychiatric services.

(2) There must be adequate numbers of qualified personnel to implement an active treatment program for each psychiatric inpatient.

(3) A psychiatric nurse must supervise the nursing care in the psychiatric service.

(4) Psychiatric service staff must work with medical, nursing, and other professional personnel in patient care planning and must provide consultation on the psychiatric problems of patients, as requested by the staff of other services.

(b) *Standard: Delivery of care.* An active treatment program must be developed for each patient. The program must be supervised and evaluated by a physician and revised as necessary. The program must be provided under an individual treatment plan that is developed by a physician-directed multi-disciplinary team.

(1) The individual treatment plan must designate the persons responsible for each component of care and must:

(i) Be reasonably expected to improve the patient's condition;

(ii) Be specific and appropriate to individual problems and take into consideration the patient's strengths as well as disabilities; and

(iii) Be reviewed, evaluated, and updated at regularly scheduled intervals by all professional personnel involved in the patient's care.

(2) Policies of the service must be developed in conjunction with other hospital services. They must specify the responsibilities and functions of professional and support staff and provide for evaluation of staff performance and the quality of care.

(3) Results of examinations to assess the patient's mental status must be recorded within 48 hours of admission. The record must include a description of the patient's physical and emotional state and intellectual functioning.

(4) Each patient must be allowed to communicate with persons outside the facility, except where communication is excluded or limited in accordance with the treatment plan.

(5) Each patient's active treatment program must include aftercare and follow-up services by designated staff members.

(c) *Standard: Facilities.* The psychiatric service must have space, equipment, and supplies sufficient to permit prompt diagnosis and treatment, safe and efffective patient care, and privacy for each patient.

(d) *Standard: Records.* Comprehensive records of assessment, evaluation, and treatment must be maintained. Admitting and subsequent psychiatric diagnoses must be recorded in the terminology of the American Psychiatric Association's Diagnostic and Statistical Manual, second edition, 1968.

(1) The record of the patient's psychiatric history and social evaluation must contain:

(i) Information on the patient's background;

(ii) Information on the onset and development of the illness;

(iii) Factors and precipitating circumstances that led to the patient's admission; and

(iv) Data useful for patient care and discharge planning.

(2) A properly executed consent form must be obtained and incorporated into the record if a treatment modality involves significant risks. The form must show that the patient, family, or legally responsible person is informed of the proposed treatment and of available alternative treatments.

(3) There must be safeguards to protect the confidentiality of the patient-therapist relationship and to prevent disclosure of information that would be harmful or embarrassing to the patient, family, or others.

(4) The record must show that planning for aftercare and follow-up services are coordinated with the patient, family, or others in the social environment.

Subpart D—Requirements for Specialty Hospitals

§ 482.60 Special rules and exceptions applying to psychiatric and tuberculosis hospitals.

Psychiatric and tuberculosis hospitals must provide active treatment programs. To assure that these hospitals do provide active treatment, these hospitals must meet the following requirements:

(a) *JCAH accredited hospitals.* A psychiatric or tuberculosis hospital that is accredited by the JCAH may qualify for participation in its entirety, or a portion of the institution that has been designated as providing an active treatment program may qualify as a "distinct part". An accredited hospital is deemed to meet, by virtue of its accreditation, the Conditions of Participation for Hospitals as specified in §§ 482.1 through 482.50. In addition, the hospital or "distinct part" of a hospital must meet the special conditions on clinical records and staffing, as applicable, specified in §§ 482.61 through 482.64.

(b) *Nonaccredited hospitals.* A nonaccredited psychiatric or tuberculosis hospital which provides an active treatment program may qualify for participation in its entirety, or a portion of the institution that has been designated as providing an active treatment program may qualify as a "distinct part." The hospital or "distinct part" must meet all Conditions of Participation for Hospitals as specified in §§ 482.1 through 482.50. In addition, the hospital or "distinct part" must meet the special conditions on clinical records and staffing, as applicable, specified in §§ 482.61 through 482.64.

§ 482.61 Condition of participation—special medical record requirements for psychiatric hospitals.

A psychiatric hospital (or a distinct part of a hospital) must maintain records that specify procedures, types, and intensity of treatment provided, and must meet the requirements of § 482.24, relating to medical records, and § 482.50, relating to psychiatric service records. The records must be readily available to staff involved in patient care.

(a) *Standard: Record of diagnostic information.* The medical record must contain information necessary for psychiatric evaluation, diagnosis, development of treatment objectives, and treatment.

(b) *Standard: Record of treatment plan and procedures.* All active treatment related to short term and long term goals, including discharge planning, must be recorded.

(c) *Standard: Record of progress.* Care provided in accordance with the active treatment program is recorded at least weekly for the first 2 months after admission and at least monthly thereafter. The record must also note changes in treatment and in the patient's condition.

(d) *Standard: Confidentialty of records.* There must be safeguards to protect the confidentiality of the patient-therapist relationship and to prevent disclosure of information that would be harmful or embarrassing to the patient, the patient's family, or others.

§ 482.62 Condition of participation—special staff requirements for psychiatric hospitals.

An inpatient psychiatric facility (psychiatric hospital, distinct part of a psychiatric hospital, or inpatient component of a community mental health center) must provide technical and professional personnel to implement an active treatment program to meet the needs of psychiatric inpatients.

(a) *Standard: Active treatment.* The hospital must be staffed with sufficient numbers of qualified personnel to implement an active treatment program for each patient. This active treatment program must be provided under an individual treatment plan that is developed by a physician-directed multi-disciplinary team. The plan must be reasonably expected to improve the patient's condition. The program must be supervised and evaluated by a physician and revised as necessary.

(b) *Standard: Psychiatric services.* There must be a director of psychiatric services who is qualified as specified in § 482.3. The director of psychiatric services must monitor and evaluate the quality and appropriateness of all psychiatric services furnished.

(c) *Standard: Physician services.* Physicians must be available at all times to provide medical and surgical diagnosis and treatment.

(d) *Standard: Nursing service.* There must be a director of psychiatric nursing services who is qualified as specified in § 482.3. There must be an adequate number of registered nurses, licensed practical (vocational) nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing service must monitor and evaluate nursing care furnished.

(2) A registered nurse must plan, supervise, and evaluate the care of each patient.

(3) In addition to the director of psychiatric nursing service, there must be an adequate number of registered nurses on duty 24 hours a day, 7 days a week.

(e) *Standard: Psychological services.* The hospital must provide or arrange for psychological services to meet the needs of the patients. If there is an organized psychological service, there must be a director of psychological services who is qualified as specified in § 482.3. The director must monitor psychological services and evaluate their quality and appropriateness. The services must be furnished in accordance with acceptable

standards of practice, service objectives, and established policies and procedures.

(f) *Standard: Social services.* There must be a director of social services qualified as specified in § 482.3, who monitors social services and evaluates their quality and appropriateness. The services must be furnished in accordance with acceptable standards of practice, and established policies and procedures.

(g) *Standard: Discharge planning.* The hospital must have an individualized written plan for aftercare services for each patient. The plan must take into account placement alternatives and available community resources. Provision must be made for exchange of appropriate information with outside resources.

(h) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program which is appropriate to the needs and interests of patients and is directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(1) 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.

(2) If occupational therapy services are furnished, they must be provided under the supervision of an occupational therapist.

(3) Therapeutic recreational activities must be under the supervision of a designated staff member who has competence in therapeutic recreational activities.

(4) The support staff for occupational and recreational therapy activities must be provided inservice training necessary for performance of their assigned functions.

(5) If physical therapy services are offered, the director of the service must be a physical therapist who monitors the quality and appropriateness of services.

(6) If volunteers are used in the therapeutic activities program, they must receive appropriate orientation, training, and supervision.

§ 482.63 Condition of participation—special medical record requirements for tuberculosis hospitals.

A tuberculosis hospital (or a distinct part of a hospital) must maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Reports on laboratory procedures.* The record must contain reports on laboratory procedures undertaken to:

(1) Identify and characterize organisms;

(2) Identify their drug susceptibility;

(3) Protect the patient against potential drug toxicity; and

(4) Measure pulmonary function.

(b) *Standard: Records of case review conferences.* The medical staff must record summaries of all case review conferences and the major medical decisions that are made on each patient's program of treatment.

(1) Case reviews must be performed:

(i) On initiation of therapy;

(ii) Within 8 weeks after therapy is begun;

(iii) At least 3 months after therapy is begun; and

(iv) Before discharge.

(2) The records of case review conferences must include summaries of:

(i) Current diagnosis according to the American Lung Association's Diagnostic Standards and Classification of Tuberculosis and Other Mycobacterial Diseases, 13th edition, 1974;

(ii) Treatment;

(iii) Response to treatment;

(iv) X-ray and bacteriological findings;

(v) Special consultations, if applicable;

(vi) Recommendations for future therapy; and

(vii) Prognosis.

(3) The records of case review conferences before each patient's discharge must include:

(i) A review of hospitalization history;

(ii) A listing of all drugs used and the reasons for discontinuing each;

(iii) The current diagnosis;

(iv) Assessment of medical status; and

(v) Recommendations for post-hospitalization follow-up, including kind and duration of chemotherapy.

(c) *Standard: Progress notes.* Progress notes must be entered in the record and must indicate response to therapy. Progress notes must include:

(1) Monthly notes, signed by a physician, on the status of the patient's condition.

(2) Any charges in treatment plan.

§ 482.64 Condition of participation—special staff requirements for tuberculosis hospitals.

A tuberculosis hospital (or a distinct part of a hospital) must have an adequate number of qualified staff to provide an active treatment program to meet the needs of patients.

(a) *Standard: Director of medical (tuberculosis) services.* There must be a director of medical (tuberculosis) services who is qualified as specified in § 482.3.

(1) The director must supervise the medical care provided in the hospital.

(2) If the director treats patients in addition to supervising medical care activities, this must not interfere with supervisory duties.

(b) *Standard: Administrator or business manager.* There must be an administrator or business manager other than the director of medical services to direct administrative activities of the hospital.

(c) *Standard: Staff physicians.* There must be a sufficient number of qualified physicians on the medical staff to provide active treatment for each tuberculosis patient.

(1) One or more physicians must be on duty at all times.

(2) If full-time staff cannot be obtained:

(i) The services of regularly scheduled part-time physicians may be used in order to provide needed services; and

(ii) The hospital must continue efforts to obtain sufficient full-time staff.

(3) Active treatment must include:

(i) Initial evaluation at a staff case review conference;

(ii) A planned regimen of specific antituberculous measures, including chemotherapy; and

(iii) Periodic assessment of progress at case review conferences.

(4) Antituberculous measures must be designed to:

(i) Render the disease noncommunicable; and

(ii) Improve the patient's condition so that he or she safely return to the community for continued supervision and treatment.

(d) *Standard: Thoracic surgeon.* The services of a thoracic surgeon, as a member of the medical team responsible for treatment of the tuberculosis patient, must be available on a regularly scheduled basis and for emergencies. The thoracic surgeon must:

(1) Either be on the full-time hospital staff or be available under arrangements with the hospital to provide specified consultative and surgical services. Surgical procedures may be performed in another hospital.

(2) Regularly visit the hospital to examine selected patients; and

(3) Attend case review conferences on these selected patients as a member of the medical team responsible for the care of the tuberculosis patient.

(e) *Standard: Consultative services.* Consultative services in other medical and surgical specialties must be available to meet the total medical needs of the patients.

(1) Specialists in urology and orthopedic surgery must be available to consult with the staff and, if necessary, to provide service.

(2) Specialists in other fields must be available to assist in the treatment of additional medical disorders of the patients.

(f) *Standard: Mental health.* Qualified mental health personnel must be available to provide consultation and guidance to the staff and to provide care to the patients as needed.

(1) If the hospital does not provide mental health services directly, arrangements must be made for these services with outside agencies or institutions.

(2) Mental health consultation and guidance must be provided to the staff by qualified mental health personnel such as psychiatrists and/or psychologists.

(g) *Standard: Social service.* The hospital must provide social services to meet the needs of patients in accordance with § 482.48.

(h) *Standard: Diversionary and recreational services.* A staff member must be responsible for arranging diversionary and recreational activities for patients as an important adjunct to the active treatment program.

(1) These activities must be under the supervision of an occupational therapist.

(2) Assistants, aides, or volunteers providing these services must be provided on the job training and be supervised by the responsible staff member.

(i) *Standard: Liaison:* A designated person must be responsible for liaison between the hospital and the official health agency that controls tuberculosis in the community in which the patient is to be supervised and any other agencies or individuals who will be involved in the patient's treatment and follow-up.

(1) This individual must:

(i) Be either an employee of the hospital or of an outside health agency; or

(ii) Be responsible for the administration of a written policy establishing lines of communication between the hospital and the official health agency and other agencies or individuals.

(2) There must be a written liaison policy that includes procedures for:

(i) Informing the official health agency of the admission of the patient to the hospital and of the anticipated return of the patient to the community either on discharge or on leave from the hospital;

(ii) assisting the local health agency in obtaining information from the patient on sources of infection and contacts that may have public health significance; and

(iii) Transferring to the official health agency, and any other agencies or individuals, medical and related information as needed to ensure continuity and effectiveness of medical care.

Subparts E through Z [Reserved]

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program and No. 13.773, Medicare-Hospital Insurance)

Dated: December 19, 1979.

Leonard D. Schaeffer,

Administrator, Health Care Financing Administration.

Approved: May 27, 1980.

Patricia Roberts Harris,

Secretary.

[FR Doc. 80-17412 Field 6-19-80; 8:45 am]

BILLING CODE 4110-35-M